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CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1107

CPSC Docket No. CPSC-2011-0082

Testing and Labeling Pertaining to Product Certification Regarding Representative Samples for Periodic Testing of Children's Products

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: The Consumer Product Safety Commission (CPSC, Commission, or we) is issuing a final rule to amend its regulations on testing and labeling pertaining to product certification. Pursuant to section 14(i)(2)(B)(ii) of the Consumer Product Safety Act (CPSA), the final rule requires the testing of representative samples to ensure continued compliance of children's products with all applicable children's product safety rules. The final rule also establishes a recordkeeping requirement associated with the testing of representative samples.

DATES: To coincide with the effective date of 16 CFR part 1107, the final rule is effective on February 8, 2013, and it applies to products manufactured after that date.[1]

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SUPPLEMENTARY INFORMATION:

I. Introduction

[1] The Commission voted 2-1 to publish this final rule in the Federal Register. Chairman Inez M. Tenenbaum and Commissioner Robert S. Adler voted to publish the final rule. Commissioner Nancy A. Nord voted against publication of the final rule.

A. What is the purpose of the final rule?

The final rule amends 16 CFR §§ 1107.21 and 1107.26 of the Commission's regulation on testing and labeling pertaining to product certification in order to implement the statutory requirement in section 14(i)(2)(B) of the CPSA for the periodic testing of representative samples of children's products, as well as associated recordkeeping.

B. What does the law require?

Section 14(a)(2) of the CPSA, 15 U.S.C. 2063(a)(2), requires manufacturers, including importers, and private labelers of any children's product that is subject to a children's product safety rule, to submit sufficient samples of the product, or samples that are identical in all material respects to the product, to a third party conformity assessment body whose accreditation has been accepted by the CPSC, to be tested for compliance with such children's product safety rule. Based on that testing, the manufacturer or private labeler must issue a certificate, which certifies that such children's product complies with the children's product safety rule. 15 U.S.C. 2063(a)(2)(B). A children's product certifier must issue a separate certificate for each applicable children's product safety rule, or a combined certificate that certifies compliance with all applicable children's product safety rules, and specifies each rule. This certificate is called a Children's Product Certificate (CPC).

Section 14(i)(2)(B) of the CPSA, 15 U.S.C. 2063(i)(2)(B), as originally provided in section 102 of the Consumer Product Safety Improvement Act of 2008 (CPSIA) prior to amendment, requires, in relevant part, that we establish protocols and standards for "ensuring that a children's product tested for compliance with a children's product safety rule is subject to testing periodically and when there has been a material change in the product's design or

manufacturing process, including the sourcing of component parts," and the "testing of random samples to ensure continued compliance."

In the **Federal Register** of May 20, 2010 (75 FR 28336), we published a proposed rule on "Testing and Labeling Pertaining to Product Certification." The proposed rule was intended to implement parts of what was then known as section 14(d)(2)(B) of the CPSA (now renumbered section 14(i)(2)(B)) and to implement parts of section 14(a) of the CPSA. Proposed § 1107.22, "Random Samples," would have implemented the testing of random samples' requirement in the CPSA, by requiring each manufacturer of a children's product to select samples for periodic testing by using a process that assigns each sample in the production population an equal probability of being selected (75 FR at 28349 through 28350, 28365).

On August 12, 2011, the President signed into law Public Law 112-28. Among other things, Public Law 112-28 changed the obligation for the testing of "random samples" to the testing of "representative samples." Additionally, Public Law 112-28 corrected an editorial error in section 14 of the CPSA, by renumbering section 14(d) of the CPSA, "Additional Regulations for Third Party Testing," as section 14(i) of the CPSA.

On November 8, 2011, we published a final rule in the **Federal Register** (76 FR 69482) for the testing and labeling rule, 16 CFR part 1107, on those aspects of the rule left unchanged by Public Law 112-28. However, because Public Law 112-28 amended section 14(i)(2(B)(ii) of the CPSA to require the testing of "representative samples," the Commission deleted § 1107.22 from the final rule on testing and labeling, and it issued a proposed rule (76 FR 69586), also on November 8, to implement the new statutory requirement for the testing of representative samples.

The Commission is now issuing a final rule amending 16 CFR §§ 1107.21(f) and 1107.26(a)(4) to implement the requirement to test "representative samples," pursuant to section 14(i)(2)(B)(ii) of the CPSA, as well as our implementing authority under section 3 of the CPSIA.

C. How does the final rule implement the law?

The final rule amends § 1107.21(f) to require a manufacturer to select representative product samples to be submitted to a third party conformity assessment body for periodic testing. The procedure used to select representative product samples for periodic testing must provide a basis for inferring compliance about the population of untested products produced during the applicable periodic testing interval. The number of samples selected for the sampling procedure must be sufficient to ensure continuing compliance with all applicable children's product safety rules. Moreover, a manufacturer must document the procedure used to select representative product samples for periodic testing and the basis for inferring the compliance of the product manufactured during the periodic testing interval from the results of the tested samples.

The final rule also amends § 1107.26(a)(4) to require a manufacturer of a children's product subject to an applicable children's product safety rule to maintain records documenting the testing of representative samples, including the number of representative samples selected and the procedure used to select representative samples. Records also must include the basis for inferring compliance of the product manufactured during the periodic testing interval from the results of the tested samples. Existing § 1107.26(b) requires that records be maintained for five years.

D. How do I comply with the requirement to periodically test representative samples?

1. Selecting Representative Samples

Under the final rule, various methods can be used to determine that the selected samples are representative, depending upon on the rule, ban, standard, or regulation being evaluated. For example, for the chemical tests, a sample selected from a homogeneous material, such as a well-mixed container of paint, could be considered representative of the entire container. For discretely produced products, information indicating uniform materials and dimensional control could be used to indicate that a sample is representative of the product for mechanical tests. For example, if a bicycle handlebar sample is manufactured from the same grade of steel and with the same dimensions (*e.g.*, wall thickness, length, shape, placement of holes for attaching brake levers) as other handlebars produced, then that handlebar sample can be considered representative of the population of handlebars for the purpose of complying with the handlebar stem test in 16 CFR 1512.18(g).

Other methods may be used to establish that samples selected for periodic testing are representative—with respect to compliance—of the population of products manufactured since the last periodic test. Examples of such methods include: inspecting incoming raw materials or component parts; generating process control data during product manufacture; and using manufacturing techniques with intrinsic manufacturing uniformity, such as die casting.

Random sampling is another way of selecting representative samples that provides a basis for inferring the compliance of untested product units from the tested product units. The conditions that allow for the inference of compliance concerning untested units versus tested units may be met by a range of probability-based sampling designs, including, but not limited to, simple random sampling, cluster sampling, systematic sampling, stratified sampling, and

multistage sampling. These methods allow the manufacturer the flexibility to select a random sampling procedure that is most appropriate for the manufacturer's product production setting but still allow for the inference about the compliance of the population of product units. For example, alternative sampling procedures—like systematic sampling (where a starting unit is randomly selected and then every k^{th} unit after that is selected) or multistage sampling (where units are grouped in clusters, such as pallets, the clusters are randomly selected, and then units within the selected clusters are randomly drawn)—can be employed for products for which such sampling procedures would be beneficial. Even though every unit produced does not have the same probability of selection for testing in these examples, these techniques can be used to infer the compliance of the untested units. It should be noted, however, that just because random sampling can be used as one method of conducting representative testing, it is by no means the only method to meet the new broader "representative" sampling requirement in Public Law 112-28.

With evidence that the samples submitted to a third party conformity assessment body are representative of the children's product produced since the last periodic test (or since product certification for the first periodic test interval), the manufacturer can infer the compliance of the untested units.

2. Determining Continued Compliance

For the purposes of periodic testing, passing test results means the samples tested are in compliance with the applicable children's product safety rule. Most children's product safety rules require each product sample submitted to pass the prescribed tests. For example, each pacifier subjected to the guard and shield testing specified in 16 CFR § 1511.3 must pass the test.

In a similar manner, each infant walker submitted for testing must pass the tests prescribed in 16 CFR part 1216.

However, for some children's product standards, compliance with the standard can include individual test results that exceed a specified maximum. For example, for children's products tested for compliance to 16 CFR part 1611, *Standard for the flammability of vinyl plastic film*, the burn rate of 10 samples is averaged to determine if the average exceeds the maximum burn rate of 1.2 inches per second, as specified in 16 CFR 1611.3. Because the maximum burn rate requirement in part 1611 applies to the average burn rate of the 10 samples tested, it is possible for one or more of the tested samples to exceed the maxiumum burn rate when tested. In this example, if the average burn rate does not exceed 1.2 inches per second, the samples are considered to be in conformance with the standard and have passed the test.

As another example, small carpets and rugs that are children's products are subject to the requirements for periodic testing. For small carpets and rugs, at least seven of the eight samples tested for compliance to 16 CFR part 1631, *Standard for the surface flammability of small carpets and rugs (FF 2-70)*, must meet the test criterion specified in § 1631.3(b). Alternatively, a small carpet or rug that does not meet the test criterion must be permanently labeled prior to its introduction into commerce. Small carpets and rugs that meet either condition would be considered to be in compliance with 16 CFR part 1631 and deemed to have passed the periodic tests.

3. Creating and Maintaining Required Records

Manufacturers must document periodic testing of representative samples. Documentation must include the number of representative samples selected, how the samples were selected, and

the manufacturer's basis for inferring compliance of the untested units during the testing interval, based on testing of the sampled units. Such documentation must be maintained for five years.

II. Comments on the Proposed Rule and CPSC's Responses

A. How many comments were received about the proposed rule?

The comment period for the proposed rule closed on January 23, 2012. Eight commenters responded. A summary of these comments and the Commission's responses are set forth below in section II.B of this preamble. Additionally, on November 8, 2011, a request for comments titled, *Application of Third Party Testing Requirements; Reducing Third Party Testing Burdens*, Docket CPSC-2011-0081, was published in the **Federal Register** (76 FR 69596). Some of the comments received in that docket also address the testing of representative samples. We summarize and respond to those comments in section II.B, as well, to ensure that all comments on representative samples were considered as part of this rulemaking, in addition to any suggestions for amending the final rule. After consideration of all the comments, however, no changes were made to the final rule.

B. What comments did the Commission receive?

A summary of the commenters' topics is presented below, followed by staff's responses. For ease of reading, each comment will be prefaced with a numbered "Comment"; and each response will be prefaced by a numbered "Response." The numbering is for identification purposes only and does not imply the importance of the comment or the order in which it was received.

1. General Comments and Comments on Definitions

(Comment 1) – A commenter welcomes the change from random sampling (in the 16 CFR part 1107 NPR) to representative sampling in the proposed rule because the proposed rule includes a variety of methods to assure compliance.

(Response 1) – As long as the test results from the representative samples can infer compliance of the untested units of the children's product, a variety of means can be employed, at the manufacturer's discretion, to select samples for testing under the final rule.

(Comment 2) – A commenter asserts that:

> There is no definition of "representative"' in 16 CFR Part 1107.26 (sic) of the notified draft Regulation, so it would likely lead to a misunderstanding in the implementation of the regulation. It is suggested that a clear definition of "representative samples" should be given so that the representative samples can be selected in a convenient and applicable way. Only in this way can the implementation of the regulation be more effective.

(Response 2) – We agree with the commenter that a clear understanding of "representative samples" will help to implement the required periodic testing of such samples effectively. For this reason, we define a "representative sample" in proposed § 1107.21(f) as one that provides the manufacturer with a basis for inferring the compliance of the untested units of the product population from the tested units. In other words, the manufacturer must have a basis for thinking that the units making up the sample to be tested (or the representative sample) are like the untested units of the children's product with respect to compliance to the applicable children's product safety rule. The final rule maintains this definition, which places responsibility on the manufacturer to choose representative samples in a manner that provides a basis for inferring the compliance of the untested product units.

(Comment 3) – A commenter opines that the proposed rule defines "representative" in a rigid way, and thereby re-creates the effect of "random" as in the original wording of the CPSIA. The commenter asserts that the word "representative" does not require any clarification. The

commenter suggests that the common meaning of the word "representative" is that the sample stands for the body of product being tested, and further suggests the following as an alternate definition of "representative":

> a sample is "representative" when it is
>
> (a) produced in a manufacturing lot not known to be produced in a materially different manner than other production lots of the same item,
>
> (b) produced according to the usual, typical manufacturing procedures,
>
> (c) selected without attempting to "game" the testing protocol, and
>
> (d) is not otherwise known by the manufacturer to be unrepresentative in any material way which might result in misleading testing results.

(Response 3) – No change to the final rule was made based on this comment. The commenter's proposed definition characterizes "representative" samples as those units that are "not known to be different" from the untested units, as opposed to the Commission's characterization, which is that "representative" samples are those units that are "known to be like" the untested samples on the basis provided by the manufacturer. The Commission considered the commenter's alternative definition but regards this definition of "representative sampling" as an attempt to prove a negative, which cannot be done. A "not known to be different" form of representative sampling does not provide a basis for knowing that the samples tested are similar to the untested units of the product. Without that basis, the testing results can indicate only the compliance of the samples actually tested and not the compliance of the untested product units. Without a means to infer compliance of the untested product units, the testing of "not known to be different" representative samples cannot ensure continued compliance, as required by section 14(i)(2)(B)(ii) of the CPSA.

To ensure continued compliance, the Commission's approach is to require a manufacturer to have knowledge of the similarity of the tested samples to the untested units because the absence of knowledge of their differences is not sufficient to ensure continued compliance.

Knowledge of the similarity of tested samples may come from prior testing, the manufacturer's knowledge of its product, production processes, quality control procedures, a production testing program, the materials used in the product, and/or the design of the product. So long as the manufacturer has a rational basis for inferring the similarity of the untested product to the tested samples, and documents this rationale, the manufacturer has met the requirements in the final rule.

(Comment 4) – A commenter suggests that the CPSC define "representative samples" based on what they are not. The commenter states that as long as a sample is not a "golden sample," meaning that it was not manufactured to be different in any way from the rest of the produced samples, then it should be considered to be representative.

The commenter reasons that noncompliant outliers may exist even in the most homogenous of manufacturing practices, and manufacturers may not be able to prove why a single test result was an outlier. However, the commenter adds that it is much easier to prove that the manufacturer performed the due diligence necessary to ensure they did everything possible to prevent the outlier from being created.

The commenter opines that this clarification would in no way change the CPSC's definition of a "representative sample." According to the commenter, all manufacturers would still have to be able to prove that a test result is representative of their entire product line. Moreover, adds the commenter, such a clarification will give manufacturers the assurance needed to rely on their individual remedial action plans if a failure occurs due to an outlier that does not represent the entire product line. The commenter predicts that this interpretation will protect manufacturers from having to destroy many more products that may still be compliant, should testing reveal a noncompliance.

(Response 4) – The Commission considered this alternative definition but regards this definition of "representative sampling" as an attempt to prove a negative, which cannot be done. A "not a golden sample" form of representative sampling does not provide a basis for knowing that the samples tested are similar to the untested units of the product. Without that basis, the testing results can indicate the compliance only of the samples actually tested and not the compliance of the untested product units. Without a means to infer compliance of the untested product units, the testing of "not a golden sample" representative samples cannot ensure continued compliance, as required by section 14(i)(2)(B)(ii) of the CPSA.

The term "golden sample" would seem to suggest a sample that is: (1) not known to be similar to the population of units produced, and (2) would have a greater likelihood of passing the required tests. However, the absence of those two traits does not make a sample representative based on the definition in the final rule. For example, if a sample was taken of the first 400 items from a production run of 100,000, the sample selector may have no greater confidence before the test that these items would pass the test than items selected from later in the run or throughout the run. The first 400 items may be representative samples, however, if the manufacturer has a basis for inferring that the units are representative of the remaining 99,600 units. Absent some independent basis for knowing that the remaining 99,600 units are similar to the first 400 units of product from the run, this could be a sampling approach that could fail to be representative.

A single test failure in a number of samples tested does not automatically mean that the production lot from which the samples were selected is not compliant, and therefore, must be reworked or destroyed. A failing test result means that the manufacturer does not have a high degree of assurance that all of the units from the production lot from which the sample was taken

are compliant with the applicable children's product safety rule. Further investigation is needed for the manufacturer to determine whether the manufacturer can still have a high degree of assurance that the untested units are compliant. This investigation might include examining the testing procedures, calibrating the test instrumentation, testing additional samples, or other actions.

(Comment 5) – A commenter states that the CPSC interprets the need to "ensure" compliance to mean that no exercise of judgment or good faith is allowed and that regulated companies must always be able to prove compliance. The commenter adds that the proposed rule rules out reliance on "process," or even the absence of contrary indicators, to support a conclusion that samples are "representative."

(Response 5) – No changes to the final rule were made based on this comment because the final rule does indeed allow and require manufacturers to exercise judgment and good faith in selecting representative samples. In fact, the entire third party testing regime set forth in 16 CFR parts 1107 and 1109 depends upon the exercise of "due care" by all certifiers. "Due care" is a flexible concept, defined as "the degree of care that a prudent and competent person engaged in the same line of business or endeavor would exercise under similar circumstances. Due care does not permit willful ignorance." 16 CFR 1107.2 & 1109.4(g).

Because of the multitude of different industries and children's products, the Commission adopted a flexible performance standard in implementing third party testing requirements. Determining what constitutes "a high degree of assurance," and "the exercise of due care," requires the exercise of business judgment in all aspects of testing. The Commission stated numerous times throughout the final testing rule that manufacturers are required to know about their products and they must implement a testing program accordingly. Sections 1107.20(b) and

(d), 1107.21(b)(2), 1107.21 (c)(1), and 1107.23(a) of 16 CFR part 1107, all refer to the manufacturer's knowledge of the product and its fabrication in implementing sampling and testing plans, as well as other manufacturer actions intended to provide a high degree of assurance of compliance to the applicable children's product safety rules.

The final rule requires regulated companies to be able to provide a basis for inferring the compliance of the untested production units from the tested samples. Without such a basis, the testing would serve no purpose other than to demonstrate the compliance of the tested units. However, the final rule does not rule out the use of "process." In fact, "process" can show that the samples selected for testing are like the untested units. For example, a process that manages the lots or batches of constituent materials of a children's product can be used as a basis for inferring homogeneity of the products with respect to the chemical tests for lead and phthalates. As another example, a process that creates uniformly spaced holes in the crib rails for the uniformly constructed crib slats can be used as a basis for inferring the homogeneity of that portion of the product when conducting the component spacing test of ASTM F1169-10.

Standing alone, the absence of contrary indicators is not sufficient to infer compliance of the untested production units from the tested samples because this could include willful ignorance of the potential differences between the untested units and the tested samples. Such an approach would not likely meet minimum due care requirements.

2. Selecting Representative Samples

(Comment 6) – A commenter desires that the CPSC continue to consider random sampling to be a subset of representative sampling. The commenter asserts that including random sampling methods allows the manufacturer the flexibility to select a random sampling procedure that is most appropriate for the manufacturer's product production setting but still

allows for the inference about the compliance of the population of product units. The commenter further states that many companies proactively implemented random testing programs when the CPSC first proposed and supported such programs in December 2008, and the commenter wants the CPSC to continue to recognize this as an acceptable means of representative sampling.

(Response 6) – No change to the final rule arises out of this comment because the final rule allows random sampling as a means to ensure representative sampling. The Commission agrees that random samples are a form of representative sampling because the test results of the tested units can be used to infer the compliance of the untested units of the children's product. The preamble to the proposed rule specifically states:

> Random sampling is another means of selecting representative samples that provide a basis for inferring the compliance of untested product units from the tested product units. The conditions that allow for the inference of compliance concerning untested units versus tested units may be met by a range of probability-based sampling designs, including, but not limited to, simple random sampling, cluster sampling, systematic sampling, stratified sampling, and multistage sampling. These methods allow the manufacturer the flexibility to select a random sampling procedure that is most appropriate for the manufacturer's product production setting but still allow for the inference about the compliance of the population of product units.

76 FR 69586, 69587 (Nov. 8, 2011).

(Comment 7) – One commenter is having difficulty understanding how to select a representative sample for periodic testing. The commenter's products consist of sets of component parts, each produced on a different date. Some of the finished products contain component parts that were manufactured more than a year ago. The commenter adds that their finished products consist of multiple variations of component parts from many production lots, resulting in no more than a few with the same set of component parts.

(Response 7) – The purpose of periodic testing is to ensure compliance with all the applicable children's product safety rules for continued production of a children's product.

Previously tested lots or batches of component parts do not require periodic testing. If a lot or batch of component parts was sampled and tested for certification purposes, those test reports remain valid for the remainder of the particular lot or batch. Continued production or importation of newly produced component parts (assuming no material changes) are subject to periodic testing. If a manufacturer or importer conducted certification testing on each new lot or batch of component parts, that testing would constitute, in essence, recertification of the finished product, based on tests of each batch or lot of the components, and therefore, periodic testing requirements might not apply.

Continuing production of the component parts can have representative samples selected for periodic testing purposes. For example, if a component part continues to be produced or imported, and it is included in a children's product, representative samples of the component part could be tested to comply with the periodic testing requirements. Alternatively, representative samples of continued production of the finished product could be selected for periodic testing purposes.

If the source of component parts changes (either a new supplier of a currently used component part or a component part that had not been used before), that would be a material change, necessitating certification testing to the children's product safety rules that could be affected by the material change.

Another method of conducting periodic testing could involve random sampling and testing of the continued production of component parts or of the finished product. Random sampling is an acceptable means of selecting a representative sample.

If varying combinations of component parts can affect the compliance of the finished product, then those combinations of component parts represent a material change that requires certification testing for each combination that is materially different.

(Comment 8) – This comment was received in Docket CPSC-2011-0081. A commenter believes that knowledge from first party testing and/or second party testing can be used to develop sampling plans for third party testing that reduce the overall test burden, while still allowing the compliance of untested products to be inferred from the products tested by the third party conformity assessment body.

(Response 8) – We interpret "first party testing" as testing conducted by the manufacturer and "second party testing" as testing conducted by a retailer to whom a manufacturer sells children's products. We agree with the commenter that the manufacturer's knowledge of a product, the applicable children's product safety rules, and the manufacturing process, combined with first or second party testing, can be used to determine the procedure for selecting representative samples. The combination of the factors listed above can be used to infer the compliance of the untested production units from the samples tested by a third party conformity assessment body.

3. Imported Products

(Comment 9) – A commenter states that if the manufacturing process of a children's product is "managed properly," then the first customs clearance article should be regarded as a representative sample.

(Response 9) – We are not sure what the commenter means by "first customs clearance article," but we will assume, for the purposes of this answer, that it means the first article manufactured outside of the United States that is cleared for entry and consumption by U.S.

Customs and Border Patrol. If the article is a finished children's product subject to a children's product safety rule, it must be accompanied by a Children's Product Certificate based on testing by a CPSC-accepted third party conformity assessment body.

If, by "managed properly," the commenter means that the imported products are homogeneous with respect to compliance, then the first customs clearance article, assuming that it was tested by a CPSC-accepted third party conformity assessment body, can be regarded as a representative sample. Under the final rule, the manufacturer or importer must be able to provide a basis for why it believes its products are homogeneous. A demonstration of homogeneity with respect to compliance would serve as a basis to show that the representative samples chosen for testing are like the untested production units.

For example, if a manufacturer injection molded an item using plastic pellets from the same lot or batch, the manufacturer would be assured that, with respect to the chemical tests, the plastic items were homogeneous. As another example, if a manufacturer produced small balls, and the production process included an automatic test to reject balls small enough to pose a small parts hazard (perhaps by falling through a hole into a reject bin), then the manufacturer would have demonstrated homogeneity with respect to the small balls requirement. Because an imported children's product must comply with all of the applicable children's product safety rules, an importer, wishing to use the first customs clearance article as a representative sample, must also show how that sample is representative for all of the applicable tests, including those for which the finished product is required to assess compliance.

(Comment 10) – This comment was received in Docket CPSC-2011-0081. Two commenters state that the CPSC should clarify that importers are not required to determine "representative sampling" procedures. One commenter recommends that the CPSC look at the

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

(Response 10) – If the importer is the party that issues the Children's Product Certificate for a product, it is that importer's responsibility to ensure that periodic testing is performed on the children's products they import that are subject to an applicable children's product safety rule. Under the component part testing rule, 16 CFR part 1109, an importer can rely on test reports or certificates from another party as long as they (the importer) exercise due care.

If an importer relies on certificates for component parts or finished products that are supplied by another party, such as a foreign manufacturer or a supplier, then it is the voluntary certifier of the component part or finished product who is responsible for periodic testing of representative samples for the component parts or finished products they certify, and not the

importer. The importer must exercise due care to ensure that applicable testing is completed in an appropriate manner. However, if the importer arranges for periodic testing itself, the importer retains the responsibility for selecting and testing representative samples periodically to ensure continued compliance. Periodic testing, including representative sample selection, may be contracted to another party. If so contracted, the other party, called the "testing party" in the component part testing rule, 16 CFR part 1109 (*e.g.*, a foreign manufacturer or distributor) must provide the basis that the samples selected for testing are representative.

A manufacturer or importer issuing the Children's Product Certificate must still exercise due care in relying on another party's test reports or certifications.

The Commission reminds the commenter that representative samples are selected for periodic testing, which is testing conducted on continuing production of a previously certified children's product. If each imported lot or batch of a children's product is third party tested and certified, then the periodic testing requirements might not apply. Lots or batches that are tested and certified would not represent continued production, even if the name or model number of the children's product did not change.

4. Periodic Testing of Component Parts

(Comment 11) – A commenter suggests that the frequency of testing component parts needs to be considered with respect to the level of control exerted over product safety from other regulations with stricter limits on lead and heavy metals, and with respect to the business relationships they have with their suppliers. For example, the commenter considers it sufficient to test for conformity to ASTM F963, "Standard Consumer Safety Specification for Toy Safety," and total lead once every 2 years as a consequence of the strict specification on the raw materials used in their component parts.

(Response 11) – If the commenter's phrase "strict specification on the raw materials used in their component parts" means a production testing plan as described in 16 CFR 1107.21(c)(2), then submitting representative samples to a third party conformity assessment body for periodic testing every 2 years is allowable, as long as it provides a high degree of assurance of compliance with all applicable children's product safety rules. Unless the manufacturer implements and documents a production testing plan (or uses an ISO/IEC 17025:2005-accredited first party testing laboratory for testing to ensure continued compliance), the maximum testing interval for periodic tests is one year. These periods are the maximum allowed interval. Periodic testing should be conducted at a frequency which, when combined with the manufacturer's other efforts at assuring continued compliance, gives the manufacturer a high degree of assurance of continued compliance.

(Comment 12) – This comment was received in Docket CPSC-2011-0081. A commenter states that the manufacturer, working together with the factory, should determine representative sampling of products with a substantial number of different components, based on knowledge of the products, the applicable product safety standard, and the manufacturing processes that go into making the products.

(Response 12) – We agree that the above-mentioned factors should be taken into account when selecting a representative sample for periodic testing purposes. The method used for selecting representative samples must be one that provides a basis for inferring the compliance of the untested production units from the test results of the tested samples. The manufacturer or importer of a children's product subject to a children's product safety rule retains the responsibility to ensure that periodic tests are conducted on representative samples. Representative sample selection and testing may be contracted to another party. If so contracted,

the other party (*e.g.*, a foreign manufacturer or distributor) must provide the basis for inferring the compliance of the untested production units based on testing of the selected representative samples. The manufacturer or importer issuing the Children's Product Certificate must still exercise due care in relying on another party's test reports or certifications.

(Comment 13) – A commenter who manufactures multiple products from a set of common component parts states that the proposal for testing representative samples has an advantage for this product type. The representative sample can be assembled from common components across the product lines and each component tested according to the relevant safety concerns under the CPSIA.

(Response 13) – This practice is acceptable under the final rule for tests that do not require the finished product for testing. For example, determining compliance to the use and abuse testing of toys described in §§ 1500.50, 1500.51, 1500.52, and 1500.53 on representative samples of common component parts is likely to be unacceptable to determine compliance of a finished product to that standard. For the use and abuse tests, a finished product is necessary to conduct the tests.

However, component part testing of representative samples for compliance to all children's product safety rules that do not require the finished product to assess compliance (such as the chemical tests) can be conducted. The passing test results for those component parts may be used to support children's product certification for finished products employing those component parts.

(Comment 14) – A commenter recommends that 16 CFR 1107.21(c)(1) be amended to include explicit language allowing the use of component part testing for periodic testing purposes. The commenter states that specific regulatory language needs to be inserted into the

text, or the commenter's customers may not include component part testing in their contractual relationships with the commenter.

(Response 14) – Section 16 CFR 1107.21(a) states: "Component part testing pursuant to 16 CFR part 1109 may be used to support the periodic testing requirements of this section." Because the use of component part testing is allowed explicitly in § 1107.21(a), repetition of this in § 1107.21(c)(1) is unnecessary.

(Comment 15) – The following comments on using component parts as representative samples were received in Docket CPSC-2011-0081. One commenter suggests that if a product can be proven to be composed of the same material throughout the end product, then a component could be submitted as a representative sample. The commenter adds that traceability would be important as there are ways that raw materials could be contaminated in the assembly.

A second commenter provides an example of a representative sample with sampling from a construction set of 50 different physical component configurations injection molded with four different colors of polyvinyl chloride resin. The commenter states that a sample could be considered representative as long as all four colors of material were sampled and compliance with the lead substrate or phthalate limits could be established.

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

(Response 15) – The commenters are describing forms of component part testing used to meet the requirements of periodic testing. These practices are allowed by 16 CFR part 1109. For the chemical content tests, component part testing can be used for periodic test purposes. If the raw materials are tested for lead (and phthalates, if appropriate), then any products made from those raw materials can use the raw material test reports to support the products' Children's Product Certificates. Component part testing is not allowed for tests that require a finished product, such as use and abuse testing of toys described in §§ 1500.50, 1500.51, 1500.52, and 1500.53.

5. Testing Costs

(Comment 16) – This comment was received in Docket CPSC-2011-0081. One commenter states that changing the "random" sampling requirement to "representative" sampling will reduce the testing burden because, for some manufacturers, particularly suppliers of raw materials or components, or manufacturers of simple products, substantially similar products may be representative of the whole body of product to be certified.

(Response 16) – The Commission agrees that changing "random" sampling to "representative" sampling has the potential to reduce the testing burden for manufacturers because more techniques for sample selection are available that can leverage the manufacturer's knowledge of the product and its production processes. Component part testing of raw materials for periodic testing purposes is one means by which a representative sample can be selected. For example, if the same lots or batches of raw materials were used to create several children's products, the results of the chemical tests for one of the products could be used to support the certification requirements of the other products.

(Comment 17) – A commenter states that implementation of the new rules will impose a significant compliance cost on his company. The commenter asserts that the additional costs will not result in increased safety of his company's products and states that "they were already safe." The commenter's additional compliance cost concerns pertain to rules promulgated since the CPSIA, in particular, 16 CFR part 1107, on testing and labeling pertaining to children's product certification, and not specifically to the proposed rule regarding the use of representative samples for periodic testing.

(Response 17) – No change to the final rule was made based on this comment. Congress provided the CPSC with a third party testing regime to improve the safety of children's products. The final rule implements part of this testing regime. The Commission acknowledges that the cost of the testing required by 16 CFR part 1107 can be significant for some companies. The Commission also is considering other means to reduce third party testing burdens pursuant to section 14(i)(3) of the CPSA, which requires the Commission to seek and consider comments on opportunities to reduce third party testing burdens consistent with assuring compliance.

(Comment 18) – A commenter states that the CPSC's rules for testing children's products are too complicated and costly, and that compliance with the rules is practically impossible. The commenter fears that "[t]he power of the agency to use violations of its rules to levy excessive fines and even attack via injunction ensures that it can dictate any outcome it wants."

(Response 18) – This rulemaking is limited to the use of representative samples for periodic testing of children's products covered by an applicable children's product safety rule. The final rule is intended to aid industry and the regulated community in understanding what is expected for the periodic testing of children's products.

6. Recordkeeping Requirements

(Comment 19) – A commenter opines that the recordkeeping requirements of the proposed rule are excessive, uneconomical, and unreasonable. The commenter asserts: "There is absolutely no safety benefit to this recordkeeping, nor will the records maintain (sic) help the agency figure out if there is a safety issue with the affected product."

(Response 19) – The Commission disagrees with the assertion that no safety benefit comes from recordkeeping. Because failure in the certification system of children's products could occur in many ways, recordkeeping can provide data to help identify the source of the failure. A safety benefit of the recordkeeping requirement is that, if noncompliant products are found in the marketplace, information is readily available that might help the manufacturer and the CPSC determine how such noncompliance occurred and its extent. Requiring manufacturers to provide a rationale for why their samples were chosen for periodic testing may help determine whether that rationale could have been a contributing factor in the incidence of noncompliant children's products being introduced into commerce.

(Comment 20) – A commenter suggests that the Commission prove that:

> (a) Congress wanted all manufacturers to ESTABLISH that each and every sample was 'representative,'
> (b) the required recordkeeping for proof that each testing sample is "representative" bears a rational relationship to the agency's mandate to keep the citizenry safe,
> (c) the devotion of resources to the activities described in the rule actually makes anyone safer, and
> (d) the benefits of the new rule outweigh its costs.

(Response 20) – Section 2(a)(1) of Public Law 112-28 amended section 14(i)(2)(B)(ii) of the CPSA to state that the Commission shall, by regulation, establish protocols and standards "for the testing of representative samples to ensure continued compliance." Because the text of the CPSA in this section explicitly calls for regulations to establish standards, we interpret that phrase to include establishing standards for representative samples.

With regard to the commenter's suggestion regarding the relationship between recordkeeping and "keeping the citizenry safe," the safety benefits of the recordkeeping requirement are described in the response to Comment 19 above. The recordkeeping requirements are intended to help prevent children's products from creating an unreasonable risk of death or injury for consumers.

By enacting section 14(i)(2)(B)(ii) of the CPSA, Congress determined that establishing protocols and standards for periodic testing of representative samples of children's products are worthy of resources and they strengthen the safety of children's products.

The Commission has provided an assessment of the impact of the rule on small businesses under the Regulatory Flexibility Act, but it is not required to conduct a cost-benefit analysis.

7. Comments Considered Outside the Scope of the Rulemaking

(Comment 21) – A commenter proposes that they provide a Certificate of Conformity to the CPSC for each finished product distributed to the U.S. market that requires certification under the CPSIA. The commenter wants the CPSC to determine whether the commenter acted with due diligence with respect to product safety. The certificate would include references to component part tests.

(Response 21) – The final rule is limited to the testing of representative samples for periodic testing of children's products. A request for the CPSC to evaluate certificates of conformity regarding due diligence is beyond the scope of this proposal.

(Comment 22) – A commenter recommends that the Commission have a series of public meetings to review the concept of representative samples because of the enormous range of children's products subject to the rule. The commenter predicts that Commission guidance on an

industry basis, over the range of products, would materially assist its member companies to comply.

(Response 22) – This rulemaking is limited to the use of representative samples for periodic testing of children's products covered by an applicable children's product safety rule. However, the Commission will consider the request for public meetings or other guidance regarding the implementation of 16 CFR part 1107, as necessary, beyond the efforts taken, to date.

III. Environmental Considerations

Generally, the Commission's regulations are considered to have little or no potential for affecting the human environment, and environmental assessments and impact statements are not usually required. *See* 16 CFR 1021.5(a). The final rule sets forth the Commission's regulation for meeting the requirement in section 14(i)(2)(B)(ii) of the CPSA to test "representative samples." As such, the final rule is not expected to have an adverse impact on the environment. The rule falls within the categorical exclusion in 16 CFR 1021.5(c)(2). Accordingly, no environmental assessment or environmental impact statement is required.

IV. Regulatory Flexibility Analysis

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601–612, generally requires that agencies review proposed rules for their potential economic impact on small entities, including small businesses. The RFA calls for agencies to prepare and make available for public comment, an initial regulatory flexibility analysis describing the impact of the proposed rule on small entities and identifying impact-reducing alternatives. 5 U.S.C. 603. The RFA further requires agencies to consider comments they receive on the initial regulatory flexibility analysis and prepare a final regulatory flexibility analysis describing the impact of the final rule on small

entities and identifying alternatives that could reduce that impact. *Id*. 604. This section summarizes the Commission's final regulatory flexibility analysis for the final rule on representative samples for periodic testing of children's products.

A. Objective of the Final Rule

The objective of the final rule is to reduce the risk of injury from consumer products, especially from products intended for children age 12 years and younger. The final rule will accomplish this objective by requiring manufacturers (including private labelers and importers of products manufactured by foreign manufacturers) to select the samples of children's products for periodic testing (which is be required by 16 CFR 1107.21), using a procedure that provides a basis for inferring that if the selected samples comply with the applicable children's product safety rules, then the units not selected will also comply. In order to ensure compliance of all units produced, one must be able to infer the compliance of the untested units of a product from tests performed on the sampled units.

B. Comments on the Initial Regulatory Flexibility Act

We received several comments regarding the initial regulatory flexibility analysis (IRFA), which we respond to below.

(Comment 23) – One commenter states that the initial regulatory flexibility analysis was a "[s]ham." The commenter argues that the "regulatory cost analysis is a whitewash, not a true arm's length analysis" and that "no company will be able to keep up with these rules, big or small." The commenter further states: "[t]he new rules cannot be afforded by any but the biggest companies—and yet, it's the big companies that have caused the most notorious and dangerous recalls of Children's Products." The commenter opines that it is the small companies that will be impacted most adversely by the new rule. The commenter finally argues: "[h]aving devoted

pages to toting up how many companies would be affected by the rule and meaningless and inaccurate data on revenues of those companies, the authors then punt on the impact of the law."

(Response 23) – The Commission disagrees with the assertion that the IRFA for the proposed rule, which would establish requirements for the selection of representative samples, is a sham. As the commenter noted, the IRFA described the number and types of small entities that could be impacted by the proposed rule, the requirements that the rule would impose on small entities, and the types of costs small businesses might incur in meeting the requirements. However, the proposed rule did not specify the procedure that firms must use for selecting representative samples: it only required firms to use a procedure that would provide a basis for inferring compliance about the population of products manufactured during that period. Because the Commission did not know what procedures firms would use to meet the requirements of the proposed rule, or know to what extent the procedures used would differ from the procedures that firms would have used to select samples for periodic testing in the absence of the proposed rule, we were not able to quantify further the costs that the rule would have on small businesses. The IRFA specifically requested comments on this issue.

The only revenue data that was included in the IRFA was the average revenue reported by the U.S. Bureau of the Census for the very small, nonemployer businesses that could be impacted by the proposed rule. It is not known to what the commenter is referring when the commenter states that the IRFA contained meaningless and inaccurate data on the revenues of the affected companies. We agree that the proposed rule could have a disproportionate impact on small businesses. However, the commenter seems to be discussing the impacts of the general rule on testing and labeling pertaining to product certification, which was published in the **Federal Register** on November 8, 2011. The current rulemaking pertains only to the selection

of samples for periodic testing and not to the requirements for testing and certification, in general.

(Comment 24) – One commenter notes that two industries were omitted from the list of industries that could be impacted by the proposed rule in the IRFA. The two omitted industries were "screen printing" (NAICS code 323113) and "digital printing" (NAICS code 323115).

(Response 24) – We agree that some manufacturers in the two industries referred to by the commenter could be impacted by the final rule. These industries have been added to the relevant table in the final regulatory flexibility analysis. Additionally, the tables have been updated to reflect the most current available data.

(Comment 25) – One commenter states that the rule will have a tremendous negative economic impact on a substantial number of small entities, and that generally, when agencies request information regarding economic impact on small entities, cost and time estimates are provided. The commenter "believe[s] that these costs will outweigh the paperwork and necessity of testing products that are well within the limits based on component part testing." The commenter further provides: "the Commission needs to consider alternative testing strategies that allow the small business to incorporate and use current testing protocols that meet the same end goal: ensuring that all products meet both the lead and phthalate content limits, as applicable."

(Response 25) – We agree that the final rule could have a negative economic impact on some small entities. The IRFA described the requirements of the proposed rule and the types of costs that firms subject to the rule might incur. However, because the proposed rule did not specify the procedure that firms must use for selecting representative samples, and because we did not know what procedures firms would use to meet the requirements of the proposed rule or

to what extent the procedures used would differ from the procedures that firms would have used to select samples for periodic testing in the absence of the proposed rule, we were not able to quantify further the costs that the rule would have on small businesses. The notice of proposed rulemaking also contained an additional discussion of the potential costs associated with the recordkeeping requirements of the proposed rule.

Although alternatives for reducing the costs associated with third party testing are not being addressed in this rulemaking, the Commission is examining alternatives for further reducing the costs associated with third party testing. Any alternatives that are identified may be addressed in future rulemakings, as needed.

C. Description of the Number of Small Entities to Which the Final Rule Will Apply

By regulation (16 CFR part 1110), the Commission has determined that the domestic manufacturer or importer is responsible for ensuring that a consumer product is properly tested, and, based on the testing results, certifying that it conforms to all applicable consumer product safety rules. Therefore, it is the domestic manufacturer or importer who will be responsible for ensuring that representative samples of children's products that are subject to one or more children's product safety rules are tested to ensure continued compliance. The definition of a children's product is broad and includes bicycles, furniture, apparel, jewelry, televisions, electronic games, toys, and so on, if designed or intended primarily for a child 12 years of age or younger. Virtually all children's products are subject to one or more children's product safety rules. A full list of the children's product safety rules for which third party testing and certification will be required is provided in Table 1.

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

16 CFR Part # (or Test Method or Standard)	Description
1420	All-Terrain Vehicles

1203	Bicycle Helmets
1512	Bicycles
1513	Bunk Beds
1500.86(a)(5)	Clacker Balls
1500.86(a)(7) and (8)	Dive Sticks and Other Similar Articles
1505	Electrically Operated Toys or Articles
1615	Flammability of Children's Sleepwear, Sizes 0 through 6X
1616	Flammability of Children's Sleepwear, Sizes 7 through 14
1610	Flammability of Clothing Textiles
1632	Flammability of Mattresses and Mattress Pads
1633	Flammability (Open-Flame) of Mattress Sets
1611	Flammability of Vinyl Plastic Film
1219	Full-Size Cribs
1215	Infant Bath Seats
1216	Infant Walkers
Sec. 101 of CPSIA (Test Method CPSC-CH-E1001-08, CPSC-CH-E1001-08.1 or 2005 CPSC Laboratory SOP)	Lead Content in Children's Metal Jewelry
Sec. 101 of CPSIA (Test Method CPSC-CH-E1001-08 or CPSC-CH-E1001-08.1)	Lead Content in Children's Metal Products
Sec. 101 of CPSIA (Test Method CPSC-CH-E1002-08 and/or CPSC-CH-E1002-08.1)	Lead Content in Children's Non-Metal Products
1303	Lead Paint
1220	Non-Full-Size Cribs
1511	Pacifiers
Sec. 108 of CPSIA (Test Method CPSC-CH-C1001-09.3)	Phthalate Content of Children's Toys and Child Care Articles
1510	Rattles
1224	Portable Bed Rails
1501	Small Parts Rule
1630	Surface Flammability of Carpets and Rugs
1631	Surface Flammability of Small Carpets and Rugs
1217	Toddler Beds
(ASTM F963)	Toys

The number of firms that could be impacted was estimated by reviewing every industry in the North American Industrial Classification System (NAICS) and selecting industries with

firms that could manufacture or sell any children's product that could be covered by a consumer product safety rule. Firms are classified in the NAICS category that describes their primary activity. Therefore, firms that might manufacture or import consumer products covered by a safety rule as a secondary or tertiary activity may not have been counted. There is no separate NAICS category for importers. Firms that import products might be classified as manufacturers, wholesalers, or retailers.

1. Manufacturers

According to the criteria established by the U.S. Small Business Administration (SBA), manufacturers are generally considered to be small entities if they have fewer than 500 employees. Table 2 shows the number of manufacturing firms by the NAICS categories that cover most children's products subject to a children's product safety rule. Although there are more than 26,000 manufacturers that would be considered small in these categories, not all of these firms are engaged in manufacturing children's products subject to a children's 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, the category Surgical Appliance and Supplies Manufacturing includes crash helmets, but most of the other products in this category are not under the CPSC's jurisdiction.

Table 2. Number of Manufacturing Firms in Selected Product Categories

NAICS Code	Description	Small Firms	Total Firms
31411	Carpet and Rug Mills	241	258
315	Apparel Manufacturing	7,508	7,565
316211	Rubber and Plastic Footwear Manufacturing	38	40
316212	House Slipper Manufacturing	2	2
316219	Other Footwear Manufacturing	45	46
323113	Commercial Screen Printing	4,464	4,488
323115	Digital Printing	2,326	2,357
326299	All Other Rubber Product Manufacturing	583	626
336991	Motorcycle, Bicycle, and Parts Manufacturing	417	422

33712	Household and Institutional Furniture Manufacturing	5,145	5,227
33791	Mattress Manufacturing	398	410
339113	Surgical Appliance and Supplies Manufacturing	1,772	1,866
33991	Jewelry and Silverware Manufacturing	2,369	2,382
33992	Sporting and Athletic Goods Manufacturing	1,619	1,652
33993	Doll, Toy and Game Manufacturing	649	660
339942	Lead Pencil and Art Good Manufacturing	123	129
339999	All Other Miscellaneous Manufacturing	3,798	3,841
	Total Manufacturers	31,497	31,971

Source: U.S. Department of Commerce, Bureau of the Census, 2009 County Business Patterns, Number of Firms, Number of Establishments, Employment, and Annual Payroll by Enterprise Employment Size for the United States, All Industries: 2009. (available at http://www2.census.gov/econ/susb/data/2009/us_6digitnaics_2009.xls. Last accessed on 28 February 2012.)

In addition to the manufacturers in Table 2, there were 25,184 nonemployer businesses classified in NAICS 315 (Apparel Manufacturing), 27,645 classified in NAICS 3231 (Printing and Related Support Activities), and 61,180 classified in NAICS 3399 (Other Miscellaneous Manufacturers) in 2008. Nonemployer businesses are generally very small businesses with no employees. They are generally sole proprietorships and may or may not be the owner's principal source of income. The average receipts for the nonemployer businesses classified in apparel manufacturing were about $31,000; for those classified in printing and related support activities, the average revenue was $49,424; and the average receipts for the nonemployer businesses classified other miscellaneous manufacturers were about $41,000.[2] There is no information regarding the number of nonemployer businesses that actually manufacture children's products.

2. Wholesalers

Wholesalers would be impacted by the final rule if they import any children's product that is subject to a children's product safety rule. Wholesalers who obtain their products strictly from domestic manufacturers or from other wholesalers would not be impacted by the final rule

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

because the manufacturer or importer would be responsible for certifying the products. Table 3 shows the number of wholesalers by NAICS code that would cover most children's products that are subject to a children's 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 78,000 wholesalers that would be considered small in these categories, not all of these firms are engaged in importing children's products that are subject to a children's product safety rule. A significant proportion of the firms classified as Toy and Hobby Goods and Supplies Merchant Wholesalers probably import at least some children's products. However, the only firms classified as Motor Vehicle and Motor Vehicle Parts and Suppliers that would be impacted by the final rule are those that import all-terrain vehicles that are intended for children 12 year old or younger.

Table 3. Number of Wholesalers in Selected Product Categories

NAICS Code	Description	Small Firms	Total Firms
4231	Motor Vehicle and Motor Vehicle Parts and Suppliers	16,815	17,776
4232	Furniture and Home Furnishing Merchant Wholesalers	10,574	10,974
42362	Electrical and Electronic Appliance, Television, and Radio Set Merchant Wholesalers	2,368	2,512
42391	Sporting and Recreational Goods and Supplies Merchant Wholesalers	4,693	4,845
42392	Toy and Hobby Goods and Supplies Merchant Wholesalers	2,068	2,138
42394	Jewelry, Watch, Precious Stone, and Precious Metal Merchant Wholesalers	7,162	7,234
42399	Other Miscellaneous Durable Goods Merchant Wholesalers	8,816	9,054
42432	Men's and Boy's Clothing and Furnishings Merchant Wholesalers	3,375	3,515
42433	Women's, Children's, and Infant's Clothing, and Accessories Merchant Wholesalers	6,655	6,859
42434	Footwear Merchant Wholesalers	1,435	1,498
42499	Other Miscellaneous Nondurable Goods Merchant Wholesalers	10,812	11,058
	Total Wholesalers	74,773	77,463

Source: U.S. Department of Commerce, Bureau of the Census, 2009 County Business Patterns, Number of

Firms, Number of Establishments, Employment, and Annual Payroll by Enterprise Employment Size for the United States, All Industries: 2009. (available at http://www2.census.gov/econ/susb/data/2009/us_6digitnaics_2009.xls. Last accessed on 28 February 2012.)

In addition to the wholesalers tabulated in Table 3, the U.S. Census Bureau estimated that there were 206,072 nonemployer businesses classified in NAICS categories that could include wholesalers of children's products. As noted above, nonemployer businesses are generally very small sole proprietorships. The average receipts for the nonemployer business wholesalers were about $86,000.[3] An unknown number of nonemployer wholesalers could import children's products.

3. Retailers

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

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

obtain all of their products from domestic wholesalers or manufacturers and would not be directly impacted by the final rule.

Table 4. Number of Retailers for Selected Product Categories

NAICS Code	Description	SBA Size Standard (millions of dollars of annual sales)	Criteria Used for Estimate of Small Firms (millions of dollars of annual sales)	Small Firms	Total Firms
441221	Motorcycle, ATV, and Personal Watercraft Dealers	<30	<25	4,794	4,879
4421	Furniture Stores	<19	<10	16,033	16,611
44813	Children's and Infant's Clothing Stores	<30	<25	2,057	2,074
44814	Family Clothing Stores	<25.5	<25	6,588	6,684
44815	Clothing Accessories Stores	<14	<10	2,757	2,774
44819	Other Clothing Stores	<19	<10	6,331	6,393
4482103	Children's & Juveniles' Shoe Stores	<25.5	<25	227	230
4482104	Family Shoe Stores	<25.5	<25	2,905	2,941
45111	Sporting Goods Stores	<14	<10	14,388	14,545
45112	Hobby, Toy, & Game Stores	<25.5	<25	4,612	4,629
452	General Merchandise Stores	<30	<25	6,873	6,971
45322	Gift, Novelty, and Souvenir Stores	<30	<25	19,297	19,339
454111	Electronic Shopping	<30	<25	11,374	11,646
454113	Mail Order Houses	<35.5	<25	5,281	5,645
4542	Vending Machine Operators	<10	<10	3,796	3,887
	Total Retailers			107.313	124,700

Source: U.S. Census Bureau, 2007 Economic Census, Retail Trade, Summary Statistics by Sales Size of Firms for the United States, Release date 11/02/2010.

In addition to the retailers tabulated in Table 4, the U.S. Census Bureau estimated that there were 324,918 nonemployer businesses classified in NAICS categories that could include

retailers of children's products. As noted above, nonemployer businesses are generally very small sole proprietorships. The average receipts for the nonemployer business retailers were about $40,000.[4] An unknown number of nonemployer retailers could import children's products.

D. Compliance, Reporting, and Recordkeeping Requirements

The final rule requires that children's product manufacturers select samples required for third party periodic testing (required by 16 CFR 1107.21) using a procedure that provides a basis for inferring compliance about the population of untested products produced during the applicable periodic testing interval. The final rule requires further that the number of samples selected must be sufficient to ensure continuing compliance with all of the applicable children's product safety rules.

In order to be able to infer the compliance of the untested products, the samples selected must be representative of the untested or unselected units in the population of products produced during the periodic testing interval. In other words, children's product manufacturers must have a basis for believing that if the samples selected for periodic testing show compliance with the applicable children's product safety rules, then one can infer the compliance of the untested units in the population. In many cases, a manufacturer's knowledge of the manufacturing processes or materials used may provide such information. For example, if the manufacturer knows that a product or component is manufactured using the same grade of material as all of the other units, and the production processes are controlled such that all of the dimensions are the same as all other units, then that product or component could be considered representative of all other units produced during the interval. Information that can be used to establish that a sample is representative can come from a variety of sources, including inspection of, or tests on, incoming

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

materials or components and inspection, tests, and process-control data generated during production.

Other methods of selecting representative samples include various probability-based sampling methods. These methods include simple random sampling, cluster sampling, systematic sampling, stratified sampling, and multistage sampling. Probability-based sampling methods allow statistical inferences to be made about the population of the products, based upon results of tests on the selected samples.

The final rule requires that manufacturers document the procedures used to select the product samples for periodic testing and note the basis for their belief that the samples are representative of the untested product produced during the periodic testing interval. The records must be maintained for five years. The records can be maintained electronically or in hardcopy. The manufacturer must make the records available for inspection by the CPSC, upon request. The records may be maintained in languages other than English, if they can be provided immediately to the CPSC, upon request, and as long as the manufacturer can translate the records into English accurately within 48 hours of a request to do so by the CPSC, or any longer period negotiated with CPSC staff.

There will be some costs associated with developing and implementing sampling procedures that will result in the selection of representative samples. Some knowledge of subjects, such as statistics and quality control techniques, may be necessary to develop the procedure. Some manufacturers may have these skills in-house; others may need to hire consultants with these skills. There also may be some ongoing costs associated with selecting the representative samples once the procedures have been developed. There will also be some costs associated with documenting the procedure and maintaining the records that are required

by the final rule. However, because there are potentially a wide range of methods for selecting representative samples, and we do not know which methods will be used by firms, the magnitude of the costs cannot be estimated.

E. Federal Rules that May Duplicate, Overlap, or Conflict with the Final Rule

The final rule establishes requirements that must be met in selecting the samples of children's products for the periodic testing required by 16 CFR 1107.21. It does not duplicate, overlap, or conflict with other federal rules.

F. Steps Taken to Minimize the Adverse Economic Impact on Small Businesses

The final rule establishes a performance standard rather than mandates a specific procedure for selecting samples for periodic testing that all manufacturers must use. Manufacturers may use any procedure they choose for selecting samples for periodic testing as long as the procedure provides a basis for inferring compliance about the entire population of products manufactured during the applicable interval. Manufacturers are also free to change the procedures that they use to select samples, if they determine that a procedure different from the one they are using would be less costly, provided that the new procedure provides a basis for inferring compliance about the population of untested products produced during the applicable period.

As discussed in the initial regulatory flexibility analysis, we considered less stringent alternatives for selecting representative samples, such as allowing manufacturers to select the samples using any procedure, provided that the procedure used would not purposively lead to the selection of samples that the manufacturer knows are more likely to comply with a standard or requirement than other samples (often referred to as "golden samples"). We reexamined these alternatives during review of the public comments submitted in response to the notice of

proposed rulemaking. Such alternatives were not adopted because we generally believe that it is necessary for manufacturers to have a positive basis for believing that the samples selected for periodic testing are, in fact, representative of the entire population of units produced during the applicable periodic testing interval. Using a "not a golden sample" form of representative sampling would require manufacturers to prove a negative, which cannot be implemented or enforced. The approach does not provide a basis for knowing that the samples tested are similar to the untested units of the product. Without that basis, the testing results can indicate the compliance only of the samples actually tested and not the compliance of the untested product units. Without a means to infer compliance of the untested product units, the testing of "not a golden sample" representative samples cannot ensure continued compliance, as required by section 14(i)(2)(B)(ii) of the CPSA.

V. Paperwork Reduction Act

The final rule contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). In a November 8, 2011, **Federal Register** notice regarding the proposed rule (76 FR 69586, 69592-93), we described the information collection and the annual reporting burden. Our estimate includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

We invited comment on: (1) whether the collection of information is necessary for the proper performance of the CPSC's functions, including whether the information will have practical utility; (2) the accuracy of the CPSC's estimate of the burden of the proposed collection of information, including the validity of the method and assumptions used; (3) ways to enhance

the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

We received one comment on the burden estimates contained in the proposed rule.

(Comment 26) – One commenter agrees with our estimate that it might take 4 hours per product or group of products to prepare the records required by the rule to document the procedures used to select representative samples and the basis for inferring the compliance of the untested products manufactured during the period. However, the commenter states that the estimated hourly cost of $50.08 was probably low and that a more accurate estimate was $75 per hour, given the likely involvement of lawyers and other professionals. The commenter also questions the assumption that manufacturers would use the same sampling plan for similar or closely related products or product lines. The commenter states that they thought it would be much more likely that a plan would be developed and documented for each item. The commenter also states that another 4 hours would be required for each test sample selected.

(Response 26) – The hourly cost estimate of $50.08 in the proposed rule was based upon the average hourly cost for total employee compensation for all management, professional, and related workers in private industry, as reported by the Bureau of Labor Statistics as part of the "Employer Costs for Employee Compensation data series. Therefore, the cost estimate we used assumed appropriately that the work would be done by management and professional employees. Of course, the costs for any particular businesses may be higher or lower than the average. We do not believe that the commenter provided sufficient information to change our approach for estimating the hourly cost of producing the records for documenting the selection of representative samples. However, the hourly cost estimate is being updated to reflect the most

recent estimate reported by the Bureau of Labor Statistics, which is $50.41, as of September 2011.

We agree with the commenter that some manufacturers may determine that they need to develop a separate sampling procedure for each children's product that they manufacture. The discussion in the notice of proposed rulemaking allowed for this possibility when it stated that in some cases, "a manufacturer might have only one product in a particular product line." 76 FR 69592. However, we believe that other manufacturers may have multiple products in their product lines and determine that the same sampling procedure may be used for groups of similar or closely related products or product lines. As stated in the notice of proposed rulemaking, we do "not have information on the number of closely related products or product lines that manufacturers offer or the average number of individual models within each set of closely related products or product lines." *Id*. Therefore, a range of possible values was used in estimating the recordkeeping burden, and the notice of proposed rulemaking invited comments from manufacturers and others to gain better insight on the potential recordkeeping burden of the proposed rule. This comment was the only one that addressed this issue. However, it did not provide sufficient information to change the assumptions we used in the notice of proposed rulemaking for estimating the recordkeeping burden.

The commenter's statement that an additional 4 hours would be required for each test sample selected appears to be a reference to the amount of time associated with the other recordkeeping requirements of the final rule on testing and labeling pertaining to product certification (16 CFR part 1107), which was published in the **Federal Register** on November 8, 2011. Those recordkeeping costs were discussed in the **Federal Register** notice associated with that rulemaking (76 FR 69537 -40) and are not related to the current final rule on selecting

representative samples.

The information collection requirement associated with the final rule is summarized below.

Title: Amendment to Regulation on Testing and Labeling Pertaining to Product Certification Regarding Representative Samples for Periodic Testing of Children's Products

Description of Respondents: Manufacturers of children's products.

Description: The final rule would require records that describe how the samples for periodic testing are selected, the number of samples that will be selected, and an explanation of why the procedure described will result in the selection of representative samples, such that one can infer that the untested units produced during the periodic testing interval comply with the applicable children's product safety rules if the samples selected comply.

We estimate the burden of this collection of information as follows: Although it might take a manufacturer several hours, perhaps several days to analyze its products and manufacturing processes to determine its options for selecting representative samples (and some might need to hire consultants for this purpose), the actual documentation of the procedure and basis for inferring compliance will probably take less time.

On the assumption that because this document is required by regulation, manufacturers will make sure that the document is reviewed and edited properly, it could take an average of 4 hours to prepare this document, once the procedure that will be used is decided and the number of samples has been determined. Developing the sampling procedure and documenting it are managerial or professional functions. According to the Bureau of Labor Statistics, as of September 2011, total compensation for management, professional, and related occupations for all workers in private industry was $50.41 an hour. Therefore, the cost of creating the record

documenting a procedure for selecting representative samples could be estimated to be about $202 ($50.41 x 4 hours).[5]

In developing the estimates of the recordkeeping burden associated with the testing and labeling pertaining to the certification of a children's products rule, we estimated that there were about 1.6 million children's products. However, manufacturers probably will not need to develop and document a separate sampling procedure for each product. It might be more reasonable to believe that manufacturers will be able to use the same sampling plan for similar or closely related products or product lines. Therefore, manufacturers may need to develop and document separate sampling procedures for each set of closely related children's products or children's product lines rather than each individual product. For example, a manufacturer of die-cast toy cars might offer 50 different models, but if each one is manufactured using the same manufacturing processes and the same materials, one sampling plan for all die-cast cars by this manufacturer might be sufficient. We do not have information on the number of closely related products or product lines that manufacturers offer or the average number of individual models within each set of closely related products or product lines. In some cases, a manufacturer might have only one product in a particular product line. Some large manufacturers may offer several hundred models or styles within some product lines.

A starting point to estimate the recordkeeping burden of the final rule is to assume that each product line averages 10 to 50 individual product models or styles. If each product line averages 50 individual models or styles, then a total of 32,000 individual sampling plans (1.6 million children's products ÷ 50 models or styles) would need to be developed and documented. This would require 128,000 hours (32,000 plans x 4 hours per plan) at a total cost of

[5] Bureau of Labor Statistics, Employer Costs for Employee Compensation, Table 9 (September 2011). Available at: http://www.bls.gov/news.release/archives/ecec_12072011.htm.

approximately $6.5 million (128,000 hours x $50.41 per hour). If each product line averages 10 individual models or styles, then a total of 160,000 different sampling plans (1.6 million children's products ÷ 10 models or styles) would need to be documented. This would require 640,000 hours (160,000 plans x 4 hours per plan), at a total cost of approximately $32.3 million (640,000 hours x $50.41 per hour).

Once a sampling plan is developed and documented, manufacturers will probably not incur the full cost of documenting their sampling plans in subsequent years because the same plan and documentation should be valid. However, each year, it is expected that manufacturers will retire some product lines and introduce new ones. Moreover, some manufacturers will leave the market, and other manufacturers will enter the market. Therefore, there will be some ongoing costs associated with documenting sampling plans.

We do not have data on the number of new product lines introduced annually, whether from existing manufacturers or from new manufacturers entering a market. For purposes of this analysis, we will assume that about 20 percent of the children's product lines are new each year, either because an existing manufacturer has changed an existing product line to the extent that a new sampling plan is required, introduced a new product line, or because a new manufacturer has entered the market. If this is the case, then the ongoing recordkeeping costs associated with the final rule would be 25,600 hours (128,000 hours x 0.2) to 128,000 hours (640,000 hours x 0.2) annually or approximately $1.3 million (25,600 hours x $50.41 per hour) to approximately $6.5 million (128,000 hours x $50.41 per hour) annually.

Another potential ongoing recordkeeping cost might result if manufacturers make adjustments or revisions to their sampling plans or procedures for their existing product lines. This might occur if manufacturers find that their initial procedures are difficult to implement or

if they come up with more efficient methods of selecting representative samples. We do not have any information that could be used to estimate how often manufacturers will revise these plans. For purposes of this analysis, we will assume that this, too, would amount to about 20 percent of the burden estimated for the initial year, or approximately $1.3 million to $6.5 million annually.

VI. Executive Order 12988 (Preemption)

Executive Order 12988 (February 5, 1996), requires agencies to state in clear language the preemptive effect, if any, of new regulations. The final rule would be issued under the authority of the CPSA and the CPSIA. The CPSA provision on preemption appears at section 26 of the CPSA. The CPSIA provision on preemption appears at section 231 of the CPSIA. The preemptive effect of this rule would be determined in an appropriate proceeding by a court of competent jurisdiction.

VII. Effective Date

The Administrative Procedure Act (APA) generally requires that the effective date of a rule be at least 30 days after publication of a final rule. 5 U.S.C. 553(d). The Commission stated in the proposed rule, at 76 FR 69593, that a final rule would become effective on the same date as the rule on "Testing and Labeling Pertaining to Certification" because §§ 1107.21(f) and 1107.26(a)(4) on representative sampling are an amendment to that rule. Accordingly, the effective date of the final rule is February 8, 2013, and it applies to products manufactured after this date, to coincide with the effective date of 16 CFR part 1107.

List of Subjects in 16 CFR Part 1107

Business and industry, Children, Consumer protection, Imports, Product testing and certification, Records, Record retention, Toys.

Accordingly, the Commission amends 16 CFR part 1107 as follows:

Part 1107—Testing and Labeling Pertaining to Product Certification

1. The authority citation for part 1107 continues to read as follows:

AUTHORITY: 15 U.S.C. 2063, Sec. 3, 102 Pub. L. 110-314, 122 Stat. 3016, 3017, 3022.

Subpart C – Certification of Children's Products

2. Add paragraph (f) to § 1107.21 to read as follows:

§ 1107.21 Periodic testing.

*** * * * ***

(f) A manufacturer must select representative product samples to be submitted to the third party conformity assessment body for periodic testing. The procedure used to select representative product samples for periodic testing must provide a basis for inferring compliance about the population of untested products produced during the applicable periodic testing interval. The number of samples selected for the sampling procedure must be sufficient to ensure continuing compliance with all applicable children's product safety rules. The manufacturer must document the procedure used to select the product samples for periodic testing and the basis for inferring the compliance of the product manufactured during the periodic testing interval from the results of the tested samples.

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3. Add paragraph (a)(4) to § 1107.26 to read as follows:

§ 1107.26 Recordkeeping.

(a) * * *

(4) Records documenting the testing of representative samples, as set forth in § 1107.21(f), including the number of representative samples selected and the procedure used to select representative samples. Records also must include the basis for inferring compliance of the product manufactured during the periodic testing interval from the results of the tested samples;

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Dated November 29, 2012

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Todd A. Stevenson,
Secretary, Consumer Product Safety Commission.

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