



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

This document has been electronically approved and signed.

THIS MATTER IS NOT SCHEDULED FOR A BALLOT VOTE.

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

DATE: September 21, 2011

TO: The Commission
Todd A. Stevenson, Secretary

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

FROM: Philip L. Chao, Assistant General Counsel
Mary A. House, Attorney, OGC

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

On August 12, 2011, the President signed H.R. 2715 into law. Among other things, H.R. 2715 replaced the requirement for the testing of "random samples" in section 14(i)(2)(B) of the Consumer Product Safety Act ("CPSA") with a requirement for the testing of "representative samples." The draft proposed rule, "Amendment to Regulation on Testing and Labeling Pertaining to Product Certification Regarding Representative Samples for Periodic Testing of Children's Products," attached to staff's briefing package at Tab B, would implement the requirement to test "representative samples," including a recordkeeping requirement.

Please indicate your vote on the following options:

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

(Signature)

(Date)

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

(Signature)

(Date)

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

(Signature)

(Date)

IV. Take other action. (Please specify.)

(Signature)

(Date)



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

Memorandum

This document has been electronically
approved and signed.

Date: September 20, 2011

TO : The Commission
Todd A. Stevenson, Secretary

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

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

Randy Butturini
Project Manager
Office of Hazard Identification and Reduction

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

1 Introduction

On August 14, 2008, the Consumer Product Safety Improvement Act ("Act" or the "CPSIA") was signed into law [Public Law 110-314]. Section 102 of the CPSIA established requirements for third party testing of children's products that are subject to a product safety rule, by amending section 14 of the Consumer Product Safety Act (CPSA). Section 14(a)(2) of the CPSA requires manufacturers and private labelers of children's products subject to a children's product safety rule to submit samples of their children's product (or samples that are identical to the product in all material respects) to a third party conformity assessment body. Based upon such testing, the manufacturer or private labeler must issue a certificate of conformity, called a Children's Product Certificate, which certifies that the product complies with all the applicable children's product safety rules.

The Commission published a final rule, 16 CFR part 1110, limiting the persons required to comply with the certification requirements of section 14(a) of the CPSA to the importer and the domestic manufacturer. In this memorandum, an importer or domestic manufacturer that is required to certify children's products is referred to as a "manufacturer." Staff's proposed final rule on component part testing (16 CFR part 1109) contains a section 1109.5(h)(2), which notes that a party that is not required to certify a children's product, but chooses to do so voluntarily, assumes the responsibilities of a manufacturer, including ensuring continuing compliance.

Section 14(d)(2) of the CPSA, as amended by the CPSIA, further establishes requirements for additional regulations for third party testing by stating:

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

- ...
- (B) establish protocols and standards--
 - (i) for ensuring that a children's product tested for compliance with an applicable children's product safety rule is subject to testing periodically and when there has been a material change in the product's design or manufacturing process, including the sourcing of component parts;
 - (ii) for the testing of random samples to ensure continued compliance;
 - (iii) for verifying that a children's product tested by a conformity assessment body complies with applicable children's product safety rules; and
 - (iv) for safeguarding against the exercise of undue influence on a third party conformity assessment body by a manufacturer or private labeler."

This became section 14(d)(2)(B)(i) – (iv) of the CPSA.

The Commission issued a Notice of Proposed Rulemaking (NPR) on May 20, 2010, to implement the above legal requirements, with the exception of (iii) (*75 Federal Register*, 28336).

On August 12, 2011, before a final rule was issued, the President signed into law H.R. 2715, which amended section 14(d) of the CPSA in two areas:

1. The second paragraph numbered as paragraph (d) in section 14 of the CPSA was renumbered as section 14(i) of the CPSA¹; and
2. In (newly renumbered) section 14(i)(d)(2)(B)(ii) of the CPSA, "random" was replaced with "representative."²

Section 14(i)(2)(B)(ii) of the CPSA now reads: "for the testing of representative samples to ensure continued compliance."

This memorandum presents CPSC staff's recommendation for implementing section 14(i)(2)(B)(ii) of the CPSA. The implementation would amend 16 CFR part 1107, by creating §

¹ Section 10(a) of H.R. 2715.

² Section 2(a)(1) of H.R. 2715.

1107.21(f) in the section on periodic testing and replacing the text in § 1107.25(a)(4) in the section on recordkeeping.

2 Testing Representative Samples to Ensure Continued Compliance

Proposed § 1107.21(f) would implement the testing of the representative samples mandated in section 14(i)(2)(B)(ii) of the CPSA, by requiring each manufacturer of a children's product to select product samples for periodic testing that are known to be representative of the population of products manufactured since the last periodic test (or since certification for the first periodic test). Samples for periodic testing are to be submitted to a CPSC-accepted third party conformity assessment body whose scope includes the required test(s). To ensure continued compliance, the test results of the submitted samples must infer the compliance of the untested population of the children's product.

In order to infer continued compliance of a children's product through testing representative samples, two conditions must be met. First, the samples tested must be representative of the population of the children's product manufactured. Demonstrating that the samples selected are representative of the unselected units in the product population establishes a basis for inferring the compliance of the untested units from the tested samples. Haphazard or nonpurposive methods of sample selection are unable to provide such a basis without additional information indicating that the samples are indeed representative. Second, the samples must demonstrate compliance with the applicable children's product safety rules. Usually, this means passing the prescribed tests in the applicable children's product safety rules. Each of these conditions is discussed below.

2.1 Representative Samples

Representative samples of a children's product selected for testing are comparable to the unselected portion of the children's product population with respect to compliance to the applicable children's product safety rule(s). To be representative, the manufacturer must have knowledge that, had other samples been chosen for testing, the test results from those samples would have indicated the same compliance or noncompliance to the applicable children's product safety rule as the representative samples.

Determining that the selected samples are representative may be achieved in many ways, 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, 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: incoming inspection of raw materials or component parts, using process control data generated during product manufacture, and employing manufacturing techniques with intrinsic manufacturing uniformity, such as die casting.

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 about untested units from the 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 its product production setting but still allow the inference of compliance of the entire population of product units. For example, alternative sampling procedures, such as 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 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 in H.R. 2715.

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.

2.2 Testing to Ensure Compliance

For the purposes of periodic testing, “passing test results” means that 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*, 10 samples are averaged to determine if the maximum burn rate exceeds 1.2 inches per second, as

specified in 16 CFR § 1611.3. Because the maximum burn rate applies to the average, it is possible for one or more of the tested samples to exceed that burn rate when tested. In this circumstance, the samples are considered to be in conformance with the standard and deemed to 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 Recordkeeping Requirements

The proposal would require the manufacturer to document the procedure used to select representative samples for periodic testing; explain the basis upon which the samples are representative; and establish whose testing results can be used to infer compliance of the untested units of the children's product population.

4 Initial Regulatory Flexibility Analysis

As required by the Regulatory Flexibility Act, staff prepared an initial regulatory flexibility analysis, which describes the impact that the draft final rule will have on small businesses. This analysis can be found in Tab A.

5 Notice of Proposed Rulemaking

Tab B contains a draft *Federal Register* Notice of Proposed Rulemaking for a proposed rule titled, *Amendment to Regulation on Testing and Labeling Pertaining to Product Certification Regarding Representative Samples for Periodic Testing of Children's Products*.

6 Commission Options

The following options are available for Commission consideration:

- (1) Publish the Notice of Proposed Rulemaking, as drafted by the Office of the General Counsel;
- (2) Publish the Notice of Proposed Rulemaking, with changes, as directed by the Commission; or
- (3) Consider other options, as directed by the Commission.

7 Staff Recommendation

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

TAB A:

**Initial Regulatory Flexibility Analysis for Proposed 16 CFR § 1107.21(f),
Testing of Representative Samples to Ensure Continued Compliance**



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

Memorandum

Date: 7 September 2011

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

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

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

FROM : Robert Franklin
Economist
Directorate for Economic Analysis

SUBJECT : Regulatory Flexibility Analysis for the Draft Proposed Rule Providing for the
Testing of Representative Samples to Ensure Continued Compliance

Attached is a draft regulatory flexibility analysis for the draft proposed rule that would provide for the testing of representative samples to ensure continuing compliance of children's products with all applicable children's product safety rules.

**Initial Regulatory Flexibility Analysis for a Draft Proposed Rule, Amendment
to Regulation on Testing and Labeling Pertaining to Product Certification
Regarding Representative Samples for Periodic Testing of Children's
Products**



**Robert Franklin
Directorate for Economic Analysis
7 September 2011**

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Initial Regulatory Flexibility Analysis for a Draft Proposed Rule, Amendment to Regulation on Testing and Labeling Pertaining to Product Certification Regarding Representative Samples for Periodic Testing of Children’s Products

1 Introduction

This report provides an analysis of the impact on small businesses and other entities of a draft proposed rule that would implement section 14(i)(2)(B)(ii) of the Consumer Product Safety Act (CPSA), as amended by the Consumer Product Safety Improvement Act of 2008 (CPSIA) and H.R. 2715. This provision of the CPSA requires the U.S. Consumer Product Safety Commission (“CPSC” or “Commission”) to establish protocols and standards for the testing of representative samples to ensure the continued compliance of children’s products with all applicable children’s product safety rules. The other provisions of section 14(i)(2)(B) of the CPSA are being addressed in a separate rulemaking.

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

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

An IRFA must also contain a description of any significant alternatives that would accomplish the stated objectives of the applicable statutes and that would minimize any significant economic impact of the proposed rule on small entities. Alternatives could include: (1) the establishment of differing compliance or reporting requirements that take into account the resources available to small businesses; (2) the clarification, consolidation, or simplification of compliance and reporting requirements for small entities; (3) the use of performance rather than design standards; and (4) an exemption from coverage of the rule, or any part of the rule thereof, for small entities.

2 Reason for Agency Action

The Commission is proposing this rule in order to implement section 14(i)(2)(B)(ii) of the CPSA. This provision was added to the CPSA by the CPSIA in 2008, and requires the Commission to promulgate a regulation to establish protocols and standards for the testing of “random samples” to ensure that children’s products continued to comply with all applicable children’s product safety rules. H.R. 2715, which was enacted in August 2011, amended the provision by substituting the term “representative” for the term “random” in describing the samples that must be tested.

3 Objectives of, and Legal Basis for, the Rule

The objective of the rule is to require that manufacturers³ select the samples of children’s products for periodic testing (which will be required by 16 CFR § 1107.21) using a procedure that results in the selection of samples from a population that is representative of the unselected products and 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. Being able to infer the compliance of the untested units is how the continued compliance of the product is ensured.

The legal basis for the rule is section 14(i)(2)(B)(ii) of the CPSA, as amended by H.R. 2715.

4 Small Entities to Which the Rule Will Apply

By regulation (16 CFR part 1110), the Commission has determined that the domestic manufacturer or importer is responsible for ensuring that a consumer product is tested properly, and, based upon the testing results, certifying that the product 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 rule. A full list of the children’s product safety rules for which third party testing and certification will be required is given in Table 1.

³ The term “manufacturer,” when used in this report, includes private labelers and importers of products manufactured by foreign manufacturers.

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

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

1501	Small Parts Rule
1630	Surface Flammability of Carpets and Rugs
1631	Surface Flammability of Small Carpets and Rugs
1217	Toddler Beds
(ASTM F963)	Toys

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 describing 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.

4.1 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 that are subject to a product safety rule. Although there are more than 26,000 manufacturers that would be considered small in these categories, not all of these firms are engaged in manufacturing children’s products that are subject to a 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 *Surgical Appliance and Supplies Manufacturing* category includes crash helmets, but most of the other products in this category are not under CPSC’s jurisdiction.

Table 2. Manufacturers

NAICS Code	Description	Small Firms	Total Firms
31411	Carpet and Rug Mills	244	262
315	Apparel Manufacturing	7,126	7,195
316211	Rubber and Plastic Footwear Manufacturing	43	45
316212	House Slipper Manufacturing	1	1
316219	Other Footwear Manufacturing	53	54
326299	All Other Rubber Product Manufacturing	622	666
336991	Motorcycle, Bicycle, and Parts Manufacturing	447	452
33712	Household and Institutional Furniture Manufacturing	6,058	6,154
33791	Mattress Manufacturing	427	441
339113	Surgical Appliance and Supplies Manufacturing	1,817	1,916
33991	Jewelry and Silverware Manufacturing	2,470	2,484
33992	Sporting and Athletic Goods Manufacturing	1,707	1,748
33993	Doll, Toy and Game Manufacturing	694	705
339942	Lead Pencil and Art Good Manufacturing	124	129
339999	All Other Miscellaneous Manufacturing	4,646	4,695
	Total Manufacturers	26,479	26,947

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

In addition to the manufacturers in Table 3, there were 25,184 nonemployer businesses classified in NAICS 315 (Apparel Manufacturing) and 61,180 classified in NAICS 3399 (Other Miscellaneous Manufacturers) in 2008. Nonemployer businesses are generally very small businesses with no employees. They are typically sole proprietorships and may or may not be the owner's principal source of income. The average receipts for the nonemployer businesses classified in *Apparel Manufacturing* were about \$31,000, and the average receipts for the nonemployer businesses classified as "*Other Miscellaneous Manufacturers*," were about \$41,000.⁴

4.2 Wholesalers

Wholesalers would be impacted by the 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 rule because the manufacturer or importer would be responsible for certifying the products. Table 3 shows the number of wholesalers by NAICS code that would cover most children's products that are

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).

subject to a product safety rule. According to the SBA criteria, wholesalers are generally considered to be small entities if they have fewer than 100 employees. Although there are more than 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 draft final rule are those that import all-terrain vehicles that are intended for children 12 years old or younger.

Table 3. Wholesalers

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

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

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

about \$86,000.⁵ An unknown number of nonemployer wholesalers could import children's products.

4.3 Retailers

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

Table 4. Retailers

NAICS Code	Description	SBA Size Standard (millions of dollars of annual sales)	Criteria Used for Estimate of Small Firms (millions of dollars of annual sales)	Small Firms	Total Firms
441221	Motorcycle, ATV, and Personal Watercraft Dealers	<30	<25	4,794	4,879
4421	Furniture Stores	<19	<10	16,033	16,611
44813	Children's and Infant's Clothing Stores	<30	<25	2,057	2,074
44814	Family Clothing Stores	<25.5	<25	6,588	6,684
44815	Clothing Accessories Stores	<14	<10	2,757	2,774
44819	Other Clothing Stores	<19	<10	6,331	6,393

⁵ 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).

4482103	Children's & Juveniles' Shoe Stores	<25.5	<25	227	230
4482104	Family Shoe Stores	<25.5	<25	2,905	2,941
45111	Sporting goods stores	<14	<10	14,388	14,545
45112	Hobby, toy, & game stores	<25.5	<25	4,612	4,629
452	General Merchandise Stores	<30	<25	6,873	6,971
45322	Gift, Novelty, and Souvenir Store	<30	<25	19,297	19,339
454111	Electronic Shopping	<30	<25	11,374	11,646
454113	Mail Order Houses	<35.5	<25	5,281	5,645
4542	Vending machine operators	<10	<10	3,796	3,887
	Total Retailers			107,313	124,700

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

In addition to the retailers tabulated in Table 4, the U.S. Census Bureau estimated that there were 324,918 nonemployer businesses classified in NAICS categories that could include retailers of children's products. As noted above, nonemployer businesses are generally very small sole proprietorships. The average receipts for the nonemployer business wholesalers were about \$40,000.⁶ An unknown number of nonemployer wholesalers could import children's products.

5 Compliance, Reporting, and Recordkeeping Requirements of Draft Proposed Rule

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

⁶ 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).

applicable children's product safety rules; then one can infer the compliance of the untested units in the population.

Haphazard or nonpurposive methods of sample selection cannot provide a basis for believing that the samples are representative without additional information. 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 the all 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 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 one to make statistical inferences about the population of the products based upon results of tests on the selected samples.

The draft proposed rule would require that manufacturers document the procedures used to select the product samples for periodic testing and the basis for the 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 to the CPSC immediately upon request and provided that the manufacturer can translate them accurately into English within 48 hours—or any longer period negotiated with CPSC staff—upon a request by the CPSC to translate the records.

There will be some cost 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 even though the Commission has not mandated the use of statistical sampling techniques. Some manufacturers may have these skills in-house; others may need to hire consultants with these skills. There may also be some ongoing costs associated with selecting the representative samples once the procedures have been developed. There would also be some cost associated with documenting the procedure and maintaining the records that would be required by the draft proposed rule. CPSC staff welcomes comment on these costs and other impacts that the draft proposed rule could have on manufacturers.

6 Federal Rules that May Duplicate, Overlap, or Conflict with the Draft Proposed Rule

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

7 Alternatives for Reducing the Adverse Impact on Small Businesses

The Regulatory Flexibility Act requires agencies to consider alternatives to proposed rules that would accomplish the stated objectives of the applicable statutes and that would minimize the economic impact on small entities. At a minimum, agencies must consider:

1. the establishment of differing compliance or reporting requirements that take into account the resources available to small businesses;
2. the clarification, consolidation, or simplification of compliance and reporting requirements for small entities;
3. the use of performance rather than design standards; and
4. an exemption from coverage of the rule, or any part of the rule, for small entities.

One alternative considered by staff was to propose a less stringent alternative for selecting representative samples. The alternative would be to allow manufacturers to select samples using any method as long as the method 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. The manufacturer could not select samples that are manufactured and selected specifically to comply with a standard or requirement (often referred to as "golden samples"). Using this alternative, manufacturers could, for example, randomly or nonpurposively pull the samples for periodic testing from their finished goods inventory or from the next lot or batch when the periodic testing needs to be undertaken, thereby minimizing disruptions to the production processes.

This alternative was not incorporated in the draft proposed rule because staff thinks that it is necessary for the manufacturer to have a positive basis for their belief that the samples selected for periodic testing are, in fact, representative of the entire population of units produced during the periodic testing interval. If the manufacturer does not have a basis for believing that the samples selected are representative, the ability to make inferences regarding the compliance of the untested units produced during the interval is limited, and the continued compliance—as stated in section 14(i)(2)(B)(ii) of the CPSA—cannot be ensured.

Staff invites comments on these or any other alternatives to the draft proposed rule that could reduce the impact on small businesses. In providing such comments, staff requests that the comments provide specific suggestions and well-developed justifications for the suggestions.

TAB B:

**Draft Federal Register Notice for a Proposed Rule on
“Amendment to Regulation on Testing and Labeling Pertaining to Product
Certification Regarding Representative Samples for Periodic Testing of
Children’s Products”**

Billing Code 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1107

[CPSC Docket No. CPSC-2011-____]

**Amendment to Regulation on Testing and Labeling Pertaining to Product Certification
Regarding Representative Samples for Periodic Testing of Children’s Products**

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Consumer Product Safety Commission (“CPSC,” “Commission,” or “we”) is proposing to amend its regulations on testing and labeling pertaining to product certification.

The proposed rule would address the testing of representative samples to ensure continued compliance of children’s products with all applicable rules, bans, standards, and regulations.

The proposed rule also would establish a recordkeeping requirement associated with the testing of representative samples. We are taking this action to implement part of H.R. 2715 (Public Law 112-28).

DATES: Written comments must be received by [INSERT DATE 75 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CPSC-2011-____, by any of the following methods:

Electronic Submissions: Submit electronic comments in the following way:

Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. To ensure timely processing of comments, the Commission is no longer accepting comments submitted by electronic mail (e-mail), except through: <http://www.regulations.gov>.

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Written Submissions: Submit written submissions in the following way:

Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions), preferably in five copies, to: Office of the Secretary, Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7923.

Instructions: All submissions received must include the agency name and docket number for this proposed collection of information. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided to: <http://www.regulations.gov>. Do not submit confidential business information, trade secret information, or other sensitive or protected information electronically. Such information should be submitted in writing, with the sensitive portions clearly identified.

Docket: For access to the docket to read background documents or comments received, go to: <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Randy Butturini, Project Manager, Office of Hazard Identification and Reduction, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7562; e-mail rbutturini@cpsc.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction and Statutory Authority

Section 14(a)(2) of the Consumer Product Safety Act (CPSA), 15 U.S.C. 2063(a)(2), requires manufacturers and private labelers of any children's product that is subject to a children's product safety rule to submit 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 that certifies that such children's product complies with the children's product safety rule. 15 U.S.C. 2063(a)(2)(B). CPSC regulations, at 16 CFR part 1110, limit the certificate requirement to importers and domestic manufacturers. The manufacturer or importer of the children's product 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 such rule. This certificate is called a Children's Product Certificate ("CPC").

Further, former section 14(d)(2)(B) of the CPSA, 15 U.S.C. 2063(d)(2)(B), as originally provided in section 102 of the Consumer Product Safety Improvement Act of 2008 ("CPSIA"), requires 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;
- testing of random samples to ensure continued compliance;
- verifying that a children's product tested by a conformity assessment body complies with applicable children's product safety rules; and
- safeguarding against the exercise of undue influence on a third party conformity assessment body by a manufacturer or private labeler.

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 what was then known as section 14(d)(2)(B) of the CPSA and to implement parts of section 14(a) of the CPSA. Proposed § 1107.22, "Random Samples," would implement 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 H.R. 2715 into law. Among other things, H.R. 2715 replaced the CPSA's requirement for the testing of "random samples" with a requirement for the testing of "representative samples." Additionally, H.R. 2715 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.

Elsewhere in this **Federal Register**, we are publishing a final rule for part 1107 on those aspects of the rule left unchanged by H.R. 2715. However, because H.R. 2715 amended the CPSA to require the testing of "representative samples," we deleted § 1107.22 from the final rule, and we are issuing this proposed rule to implement the new statutory requirement for the testing of representative samples. Additionally, § 1107.26 of the final rule establishes requirements pertaining to recordkeeping. We have reserved § 1107.26(a)(4) in anticipation of a recordkeeping requirement related to representative samples. This proposed rule, therefore, would establish a new recordkeeping requirement for representative samples.

We are issuing this proposed rule pursuant to section 14(i)(2)(B) of the CPSA, as well as its implementing authority pursuant to section 3 of the CPSIA.

II. Description of the Proposed Rule

The proposal would amend Title 16 of the Code of Federal Regulations: Part 1107, titled "Testing and Labeling Pertaining to Product Certification." The amendment would implement section 14(i)(2)(B)(ii) of the CPSA, by amending § 1107.21, "Periodic Testing." The proposal

would require that periodic testing be conducted using representative samples. Additionally, the proposal would amend § 1107.26 to include a recordkeeping provision related to testing representative samples.

A. Proposed § 1107.21(f) – Testing representative samples

The proposal would create a new § 1107.21(f), which would state that a manufacturer must select representative product samples to be submitted to the third party conformity assessment body for periodic testing. We recognize that the proposed rule on “Testing and Labeling Pertaining to Product Certification” (75 FR 28336 (May 20, 2010)) would have treated “Random Samples” as a distinct section, rather than as a subparagraph within § 1107.21, “Periodic Testing.” However, because we have treated the requirement in section 14(i)(2)(B)(ii) of the CPSA as part of the periodic testing process, the proposed rule would place a requirement for the testing of representative samples in § 1107.21, rather than create a separate section.

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 of the applicable children’s product safety rules. Manufacturers must document the procedure used to select the product samples for periodic testing and document the basis for inferring the compliance of the product manufactured during the periodic testing interval from the results of the tested samples.

Proposed § 1107.21(f) would implement the requirement to test representative samples, by requiring each manufacturer of a children’s product to select samples for periodic testing known to be representative of the population of products manufactured since the last periodic test occurred (or since certification for the first periodic tests). In order for the test results of the

samples submitted to a third party conformity assessment body to infer compliance of the untested units of the children's product, the manufacturer must have knowledge that the tested samples are, indeed, representative of the product produced. Haphazard methods of sample selection cannot provide a basis for inferring the compliance of the untested units without additional information indicating that the samples are representative.

1. Representative Samples

Representative samples of a children's product selected for testing are comparable to the unselected portion of the children's product population with respect to compliance to the applicable children's product safety rule(s). To be representative, the manufacturer must have knowledge that, had other samples been chosen for testing, test results from those samples would have indicated the same compliance or noncompliance to the applicable children's product safety rule as the representative samples.

Determining that the selected samples are representative may be achieved in many ways, 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, that handlebar sample can be considered representative of the population of handlebars for the purpose of the complying with the handlebar stem test in 16 CFR § 1512.18(g).

Other methods that 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: incoming inspection of raw materials or component parts; process control data generated during product manufacture; and use of manufacturing techniques with intrinsic manufacturing uniformity, such as die casting.

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. 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 in H.R. 2715.

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. Testing to Ensure 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*, 10 samples are averaged to determine if the maximum burn rate exceeds 1.2 inches per second, as specified in 16 CFR § 1611.3. Because the maximum burn rate applies to the average, it is possible for one or more of the tested samples to exceed that burn rate when tested. In this circumstance, 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.

B. Proposed § 1107.26(a)(4) - Recordkeeping

Proposed § 1107.26(a)(4) would 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, as set forth in proposed § 1107.21(f) on periodic testing, 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.

The recordkeeping requirement for the testing of representative samples is intended to allow manufacturers to demonstrate continued compliance by establishing how the samples selected are representative of the population of products manufactured during the periodic testing interval and how the manufacturer can infer compliance of all products produced during this interval based on such testing.

III. Environmental Considerations

This proposed rule falls within the scope of the Commission's environmental review regulations at 16 CFR § 1021.5(c)(2), which provide a categorical exclusion from any requirement for the agency to prepare an environmental assessment or environmental impact statement for product certification rules.

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 Commission is proposing this rule in order to implement Section 14(i)(2)(B)(ii) of the CPSA. As originally enacted in 2008, this provision required the Commission to promulgate a regulation to establish protocols and standards for the testing of “random samples” to ensure that children’s products continue to comply with all applicable children’s product safety rules. H.R. 2715, which was enacted on August 12, 2011, amended the provision by substituting the term “representative” for the term “random,” in describing the samples that must be tested.

A. Objectives of the Rule

The objective of the rule is to reduce the risk of death and injury from consumer products, especially from products intended for children aged 12 years and younger. The proposed rule would accomplish this objective by requiring that manufacturers select the samples of children’s products for periodic testing (which will be required by 16 CFR § 1107.21), using a procedure that results in the selection of samples from a population that is representative of the unselected products and 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. (The term “manufacturer,” for purposes of this proposed rule, includes private labelers and importers of products manufacturer by foreign manufacturers.) Being able to infer the compliance of the untested units is how the continued compliance of the product is ensured.

B. Small Entities to Which the Rule Will Apply

By regulation (16 CFR part 1110), the domestic manufacturer or importer is responsible for ensuring that a consumer product is properly tested, and, based upon the testing results, certifying that the product conforms to all applicable consumer product safety rules. Therefore, the domestic manufacturer or importer 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 given in Table 1.

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

16 CFR Part # (or Test Method or Standard)	Description
1420	All-Terrain Vehicles
1203	Bicycle Helmets
1512	Bicycles
1513	Bunk Beds
1500.86(a)(5)	Clacker Balls
1500.86(a)(7) and (8)	Dive Sticks and Other Similar Articles
1505	Electrically Operated Toys or Articles
1615	Flammability of Children’s Sleepwear, Sizes 0 through 6X
1616	Flammability of Children’s Sleepwear, Sizes 7 through 14
1610	Flammability of Clothing Textiles
1632	Flammability of Mattresses and Mattress Pads
1633	Flammability (Open-Flame) of Mattress Sets
1611	Flammability of Vinyl Plastic Film
1219	Full-Size Cribs
1215	Infant Bath Seats
1216	Infant Walkers

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Sec. 101 of CPSIA (Test Method CPSC-CH-E1001-08, CPSC-CH-E1001-08.1 or 2005 CPSC Laboratory SOP)	Lead Content in Children’s Metal Jewelry
Sec. 101 of CPSIA (Test Method CPSC-CH-E1001-08 or CPSC-CH-E1001-08.1)	Lead Content in Children’s Metal Products
Sec. 101 of CPSIA (Test Method CPSC-CH-E1002-08 and/or CPSC-CH-E1002-08.1)	Lead Content in Children’s Non-Metal Products
1303	Lead Paint
1220	Non-Full-Size Cribs
1511	Pacifiers
Sec. 108 of CPSIA (Test Method CPSC-CH-C1001-09.3)	Phthalate Content of Children’s Toys and Child Care Articles
1510	Rattles
1501	Small Parts Rule
1630	Surface Flammability of Carpets and Rugs
1631	Surface Flammability of Small Carpets and Rugs
1217	Toddler Beds
(ASTM F963)	Toys

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 whose firms 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.

C. 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 that are subject to a product safety rule. Although there are more than 26,000 manufacturers that would be considered small in these categories, not all of these firms are engaged in manufacturing children’s products that are subject to a 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 *Surgical Appliance and Supplies Manufacturing* category includes crash helmets, but most of the other products in this category are not under the CPSC’s jurisdiction.

Table 2. Manufacturers

NAICS Code	Description	Small Firms	Total Firms
31411	Carpet and Rug Mills	244	262
315	Apparel Manufacturing	7,126	7,195
316211	Rubber and Plastic Footwear Manufacturing	43	45
316212	House Slipper Manufacturing	1	1
316219	Other Footwear Manufacturing	53	54
326299	All Other Rubber Product Manufacturing	622	666
336991	Motorcycle, Bicycle, and Parts Manufacturing	447	452
33712	Household and Institutional Furniture Manufacturing	6,058	6,154
33791	Mattress Manufacturing	427	441
339113	Surgical Appliance and Supplies Manufacturing	1,817	1,916
33991	Jewelry and Silverware Manufacturing	2,470	2,484
33992	Sporting and Athletic Goods Manufacturing	1,707	1,748
33993	Doll, Toy and Game Manufacturing	694	705
339942	Lead Pencil and Art Good Manufacturing	124	129
339999	All Other Miscellaneous Manufacturing	4,646	4,695
	Total Manufacturers	26,479	26,947

Source: U.S. Department of Commerce, Bureau of the Census, 2008 County Business Patterns, Number of Firms, Number of Establishments, Employment, and Annual Payroll by Small Enterprise Employment Sizes for the United States, NAICS Sectors: 2008. Available at:

http://www2.census.gov/econ/susb/data/2008/us_naicssector_small_emplsize_2008.xls, last accessed on 16 August 2011.

In addition to the manufacturers in Table 3, there were 25,184 nonemployer businesses classified in NAICS 315 (Apparel Manufacturing) and 61,180 classified in NAICS 3399 (Other Miscellaneous Manufacturers) in 2008. Nonemployer businesses are generally very small businesses with no employees. They are typically sole proprietorships, and they may or may not constitute the owner's principal source of income. The average receipts for the nonemployer businesses classified in *Apparel Manufacturing* was about \$31,000, and the average receipts for the nonemployer businesses classified as *Other Miscellaneous Manufacturers* was about \$41,000.⁷

D. Wholesalers

Wholesalers would be impacted by the rule if they import any children's product that is subject to a product safety rule. Wholesalers who obtain their products strictly from domestic manufacturers or from other wholesalers would not be impacted by the rule because the manufacturer or importer would be responsible for certifying the products. Table 3 shows the number of wholesalers by NAICS code that would cover most children's products that are subject to a product safety rule. According to SBA criteria, wholesalers are generally considered to be small entities if they have fewer than 100 employees. Although there are more than 78,000 wholesalers that would be considered small in these categories, not all of these firms are engaged in importing children's products that are subject to a 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*

⁷ U.S. Department of Commerce, Bureau of the Census, "Revised 2008 Nonemployer Statistics Table." Available at: <http://www.census.gov/econ/nonemployer/Revised%202008%20Data%20With%202009%20Methodology%20Applied.xls> (last accessed 16 August 2011).

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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. Wholesalers

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

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

In addition to the wholesalers tabulated in Table 3, the U.S. Census Bureau estimated that there were 206,072 nonemployer businesses classified in NAICS categories that could include wholesalers of children's products. Nonemployer businesses are generally very small sole

proprietorships. The average receipts for the nonemployer business wholesalers were about \$86,000.⁸ An unknown number of nonemployer wholesalers could import children’s products.

E. Retailers

Retailers that obtain all of their products from domestic manufacturers or wholesalers will not be directly impacted by the rule because the manufacturers or wholesalers would be responsible for the testing and certification of the children’s products. However, there are some retailers that 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 obtain all of their products from domestic wholesalers or manufacturers and would not be directly impacted by the rule.

Table 4. Retailers

NAICS Code	Description	SBA Size Standard (millions of dollars of annual	Criteria Used for Estimate of Small Firms	Small Firms	Total Firms
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⁸ U.S. Department of Commerce, Bureau of the Census, “Revised 2008 Nonemployer Statistics Table.” available at <http://www.census.gov/econ/nonemployer/Revised%202008%20Data%20With%202009%20Methodology%20Applied.xls> (last accessed 16 August 2011).

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		sales)	(millions of dollars of annual sales)		
441221	Motorcycle, ATV, and Personal Watercraft Dealers	<30	<25	4,794	4,879
4421	Furniture Stores	<19	<10	16,033	16,611
44813	Children's and Infant's Clothing Stores	<30	<25	2,057	2,074
44814	Family Clothing Stores	<25.5	<25	6,588	6,684
44815	Clothing Accessories Stores	<14	<10	2,757	2,774
44819	Other Clothing Stores	<19	<10	6,331	6,393
4482103	Children's & Juveniles' Shoe Stores	<25.5	<25	227	230
4482104	Family Shoe Stores	<25.5	<25	2,905	2,941
45111	Sporting goods stores	<14	<10	14,388	14,545
45112	Hobby, toy, & game stores	<25.5	<25	4,612	4,629
452	General Merchandise Stores	<30	<25	6,873	6,971
45322	Gift, Novelty, and Souvenir Store	<30	<25	19,297	19,339
454111	Electronic Shopping	<30	<25	11,374	11,646
454113	Mail Order Houses	<35.5	<25	5,281	5,645
4542	Vending machine operators	<10	<10	3,796	3,887
	Total Retailers			107,313	124,700

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

In addition to the retailers tabulated in Table 4, the U.S. Census Bureau estimated that there were 324,918 nonemployer businesses classified in NAICS categories that could include retailers of children's products. Nonemployer businesses are generally very small sole proprietorships. The average receipts for the nonemployer business wholesalers were about \$40,000.⁹ An unknown number of nonemployer wholesalers could import children's products.

⁹ 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).

F. Compliance, Reporting, and Recordkeeping Requirements of Proposed Rule

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

Haphazard or nonpurposive methods of sample selection cannot provide a basis for believing that the samples are representative without additional information. In many cases, a manufacturer's knowledge of the manufacturing processes or materials used in the process 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 if the production processes are controlled such that the all 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 materials or components, as well as 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 one to make statistical inferences about the population of the products, based upon results of tests on the selected samples.

The proposed rule would require that manufacturers document the procedures used to select the product samples for periodic testing and document the basis for that 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 provided that the manufacturer can translate them accurately into English within 48 hours—or any longer period negotiated with CPSC staff, upon a request by the CPSC to translate the records.

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 even though the Commission has not mandated the use of statistical sampling techniques. Some manufacturers may have these skills in-house; others may need to hire outside consultants with these skills. There also may be some ongoing costs associated with selecting the representative samples once the procedures have been developed. There also would be some costs associated with documenting the procedure and maintaining the records that would be

required by the proposed rule. We invite comment on these costs and other impacts that the proposed rule could have on manufacturers.

G. Alternatives for Reducing the Adverse Impact on Small Businesses

The Regulatory Flexibility Act requires agencies to consider alternatives to proposed rules that would accomplish the stated objectives of the applicable statutes and that would reduce the economic impact on small entities. At a minimum, agencies must consider:

1. the establishment of differing compliance or reporting requirements that take into account the resources available to small businesses;
2. the clarification, consolidation, or simplification of compliance and reporting requirements for small entities;
3. the use of performance rather than design standards; and
4. an exemption from coverage of the rule, or any part of the rule thereof, for small entities.

One alternative we considered was to propose less stringent alternatives for selecting representative samples. One alternative would be to allow manufacturers to select the samples using any method, provided that the method used would not purposively lead to the selection of samples that the manufacturers knows are more likely to comply with a standard or requirement than other samples, or select samples that are manufactured and chosen specifically to comply with a standard or requirement (often referred to as “golden samples”). For example, manufacturers could pull randomly or nonpurposively the samples for periodic testing from their finished goods inventory or from the next lot or batch when the periodic testing needs to be completed.

This alternative was not incorporated in the proposed rule because we think that it is necessary for the manufacturer to have a positive basis for their belief that the samples selected for periodic testing are, in fact, representative of the entire population of units produced during the periodic testing interval. If the manufacturer does not have a basis for believing that the samples selected are representative, then the ability to make inferences regarding the compliance of the untested units produced during the interval is limited, and the continued compliance, as stated in § 14(i)(2)(B)(ii) of the CPSA, cannot be ensured.

We invite comments on these or any other alternatives to the proposed rule that could reduce the impact on small businesses. In providing such comments, we request that the comments provide specific suggestions and well-developed justifications for the suggestions.

V. Paperwork Reduction Act

This proposed 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). We describe the provisions in this section of the document with an estimate of 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 invite comments 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.

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

Description: The proposed 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.

Description of Respondents: Manufacturers of children's products.

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 would be 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 March 2011, total compensation for management, professional, and related occupations for all workers in private industry was \$50.08 an hour. Therefore, the cost of

creating the record documenting a procedure for selecting representative samples could be estimated to be about \$200 (\$50.08 x 4 hours).¹⁰

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 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 proposed 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

¹⁰ Bureau of Labor Statistics, Employer Costs for Employee Compensation, Table 9 (March 2011). Available at: <http://www.bls.gov/ncs>.

approximately \$6.4 million (128,000 hours x \$50.08 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 million (640,000 hours x \$50.08 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 draft proposed 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 \$50.08 per hour) to approximately \$6.4 million (128,000 hours x \$50.08 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 \$6.4 million annually.

As noted above, we do not have empirical data for most of the numbers used in the examples above. We invite comments from manufacturers and others to gather better insight on the potential recordkeeping burden of the draft proposed rule.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), we have submitted the information collection requirements of this rule to OMB for review. Interested persons are requested to fax comments regarding information collection by [insert date 30 days after date of publication in the FEDERAL REGISTER], to the Office of Information and Regulatory Affairs, OMB (see ADDRESSES).

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 proposed 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

intends that any final rule based on this proposal would become effective on the same date as the rule on “Testing and Labeling Pertaining to Certification,” published elsewhere in this *Federal Register*, which is [insert date 15 months after date of publication in the FEDERAL REGISTER].

VIII. Request for Comments

The issuance of this proposed rule begins a rulemaking proceeding under sections 3 and 102 of the CPSIA that will establish performance and recordkeeping requirements for the testing of representative samples for periodic testing of children’s products. We invite interested persons to submit comments on any aspect of the proposed rule. Comments should be submitted in accordance with the instructions in the ADDRESSES section at the beginning of this notice.

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 proposes to amend Subpart C of 16 CFR part 1107, by adding a new § 1107.21(f) and an amended § 1107.25(a)(4), to read as follows:

Part 1107—Testing and Labeling Pertaining to Product Certification

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

* * *

§ 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.

* * *

§ 1107.26 Recordkeeping

(a) * * *

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(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;

DRAFT

Dated _____

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