THIS MATTER IS NOT SCHEDULED FOR A BALLOT VOTE.
A DECISIONAL MEETING FOR THIS MATTER IS SCHEDULED ON:
February 18, 2015

TO: The Commission
Alberta E. Mills, Acting Secretary

THROUGH: Patricia H. Adkins, Executive Director
Stephanie Tsacoumis, General Counsel

FROM: Patricia M. Pollitzer, Assistant General Counsel
David M. DiMatteo, Attorney, OGC

SUBJECT: Final Rule: Safety Standard for Frame Child Carriers

The Office of the General Counsel is providing for Commission consideration the attached draft final rule for publication in the Federal Register. The draft final rule would establish a mandatory safety standard for frame child carriers pursuant to section 104 of the Consumer Product Safety Improvement Act of 2008. If approved by the Commission, the draft final rule would incorporate the applicable voluntary standard without any modifications.

In addition, if approved by the Commission, the final rule would meet the requirement that the Commission issue an NOR for the frame child carriers standard because the draft final rule would amend 16 CFR part 1112 to include the mandatory safety stand for frame child carriers in the list of Commission issued NORs.

Please indicate your vote on the following options:

I. Approve publication of the attached document in the Federal Register, as drafted.

(Signature)   (Date)
II. Approve publication of the attached document in the Federal Register, with changes. (Please specify.)

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(Signature) ___________________  (Date) ____________

III. Do not approve publication of the attached document in the Federal Register.

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(Signature) ___________________  (Date) ____________

IV. Take other action. (Please specify.)

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(Signature) ___________________  (Date) ____________

Attachment: Draft Federal Register Notice: Final Rule to Establish a Safety Standard for Frame Child Carriers
CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1112 and 1230

Docket No. CPSC-2014-0011

Safety Standard for Frame Child Carriers

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: The Danny Keysar Child Product Safety Notification Act, section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), requires the United States Consumer Product Safety Commission (Commission or CPSC) to promulgate consumer product safety standards for durable infant or toddler products. These standards are to be “substantially the same as” applicable voluntary standards or more stringent than the voluntary standards if the Commission determines that more stringent requirements would further reduce the risk of injury associated with the products. The Commission is issuing a safety standard for frame child carriers in response to the direction under section 104(b) of the CPSIA. In addition, the Commission is amending its regulations regarding third party conformity assessment bodies to include the mandatory standard for frame child carriers in the list of Notices of Requirements (NOR) issued by the Commission.

DATES: The rule will become effective on [INSERT DATE 18 MONTHS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER.] The incorporation by reference of the publication listed in this rule is approved by the Director of the Federal Register as of [INSERT DATE 18 MONTHS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].
SUPPLEMENTARY INFORMATION:

I. Background and Statutory Authority

The Consumer Product Safety Improvement Act of 2008 (CPSIA, Pub. L. 110-314) was enacted on August 14, 2008. Section 104(b) of the CPSIA, part of the Danny Keysar Child Product Safety Notification Act, requires the Commission to: (1) examine and assess the effectiveness of voluntary consumer product safety standards for durable infant or toddler products, in consultation with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts; and (2) promulgate consumer product safety standards for durable infant and toddler products. These standards are to be “substantially the same as” applicable voluntary standards or more stringent than the voluntary standards if the Commission determines that more stringent requirements would further reduce the risk of injury associated with the product. The term “durable infant or toddler product” is defined in section 104(f)(1) of the CPSIA as “a durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years.”

On May 16, 2014, the Commission issued a notice of proposed rulemaking (NPR) for frame child carriers. 79 FR 28458. The NPR proposed to incorporate by reference the voluntary standard, ASTM F2549-14, Standard Consumer Safety Specification for Frame Child Carriers, with one proposed substitute provision that would provide clear pass/fail criteria for an existing test.
In this document, the Commission is issuing a mandatory safety standard for frame child carriers. As required by section 104(b)(1)(A), the Commission consulted with manufacturers, retailers, trade organizations, laboratories, consumer advocacy groups, consultants, and the public to develop this proposed standard, largely through the ASTM process. The rule incorporates by reference the most recent voluntary standard developed by ASTM International (formerly the American Society for Testing and Materials), ASTM F2549-14a, Standard Consumer Safety Specification for Frame Child Carriers. This most recent version of the ASTM voluntary standard includes the clear pass/fail criteria for an existing test that were proposed in the NPR.

In addition, the final rule amends the list of NORs issued by the Commission in 16 CFR part 1112 to include the standard for frame child carriers. Under section 14 of the Consumer Product Safety Act (CPSA), the Commission promulgated 16 CFR part 1112 to establish requirements for accreditation of third party conformity assessment bodies (or testing laboratories) to test for conformance with a children’s product safety rule. Amending part 1112 adds a NOR for the frame child carrier standard to the list of children’s product safety rules.

II. Product Description

The scope of ASTM F2549-14a defines a “frame child carrier” as “a product, normally of sewn fabric construction on a tubular metal or other frame, which is designed to carry a child, in an upright position, on the back of the caregiver.” The intended users of frame carriers are children who are able to sit upright unassisted and weigh between 16 pounds and 50 pounds. Frame carriers are intended to be worn on the back and suspended from both shoulders of the caregiver’s body in a forward- or rear-facing position. This type of carrier is often used for
hiking and closely resembles hiking/mountaineering backpacks not intended to be used for child transport.

III. Market Description

Staff identified 16 firms supplying frame child carriers to the U.S. market. Typically, frame child carriers cost from $100 to around $300. Additional firms may supply these products to U.S. consumers. Most of these firms specialize in manufacturing and/or distributing one of two distinct types of products: (1) children’s products, including durable nursery products; or (2) outdoor products, such as camping and hiking gear. The majority of the 16 known firms are domestic (including five manufacturers, eight importers, and one firm whose supply source could not be determined). The remaining two firms are foreign (including one manufacturer and one firm that imports products from foreign companies and distributes the products from outside of the United States).

The Commission expects that the frame child carriers of seven of these firms comply with ASTM F2549 because the firms either: (1) certify their carriers through the Juvenile Products Manufacturers Association (JPMA) (three firms); or (2) claim compliance with the voluntary standard (four firms). However, some of the suppliers of frame child carriers do not supply any other children’s products; and it is possible that these suppliers may be unfamiliar with the voluntary ASTM standards, a circumstance confirmed by one supplier that staff contacted during the initial regulatory flexibility analysis (IRFA) development. The Commission

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1 Since staff prepared the initial regulatory flexibility analysis, one importer has entered the market, another firm was purchased (remaining in the market), and a third has established an official U.S. distributor for their products. 
2 Staff made these determinations using information from Dun & Bradstreet and ReferenceUSA Gov, as well as firm websites. 
3 JPMA typically allows 6 months for companies with products in their certification program to shift to a new standard for testing and certification once the new standard is published. The version of the standard that firms currently are likely to be testing to is ASTM F2549-14. One revision of the standard has been published since then, but it will become effective for JPMA certification purposes before February 2015. However, many frame child carriers are expected to be compliant with ASTM F2549-14a without modification; and firms compliant with earlier versions of the standard are likely to remain compliant as the standard evolves.
staff attempted unsuccessfully to obtain information from several firms whose frame child
carriers do not claim compliance with the ASTM standard to determine the extent to which their
carriers might not comply. Staff’s testing indicates that some frame child carriers would not
meet all provisions of the ASTM F2549.

In 2013, the CPSC conducted a Durable Nursery Product Exposure Survey (DNPES) of
U.S. households with children under age 6. Data from the DNPES indicate that an estimated
2.38 million frame child carriers are in U.S. households with children under the age of 6 (with
95% probability that the actual value is between 1.8 million and 2.95 million). Data collected
also indicate that about 54 percent of the frame child carriers in U.S. households with children
under age 6 are in use (an estimated 1.28 million frame carriers, with 95% probability that the
actual value is between about 880,000 and 1.7 million).4

Staff could not estimate annual injuries because the number of National Electronic Injury
Surveillance System (NEISS) cases was insufficient to meet the CPSC Directorate for
Epidemiology (EPI) publication criteria. However, given that part of the publication criteria is
that the estimate must be 1,200 or greater over the period under consideration, presumably, there
would be, on average, fewer than 120 injuries annually over the approximately 10-year period
considered by EPI staff. The recent EPI update for the final briefing package is consistent with
this assumption.5

Combining the maximum annual emergency department-treated injury estimate with the
data collected for the DNPES yields less than about 0.94 emergency department-treated injuries

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4 These results are preliminary. While the data has undergone one stage of review and clean-up, this work is
ongoing.

5 Memorandum from Risana T. Chowdhury, Division of Hazard Analysis, Directorate for Epidemiology, dated
November 18, 2013, Subject: Frame Child Carriers-Related Deaths, Injuries, and Potential Injuries; January 1, 2003
– October 27, 2013; and memorandum from Risana T. Chowdhury, Division of Hazard Analysis, Directorate for
Epidemiology, dated September 30, 2014, Subject: Frame Child Carrier-Related Deaths, Injuries, and Potential
per 10,000 frame child carriers in use in U.S. households with children under age 6 annually
((120 injuries ÷ 1.28 million frame child carriers in use in U.S. households with children under age 6) x 10,000). 6

IV. Incident Data

The preamble to the NPR summarized the incident data reported to the Commission involving frame child carriers from January 1, 2003 through October 27, 2013. 79 FR 28459-60. In the NPR, CPSC’s Directorate for Epidemiology identified a total of 47 incidents, including 33 injuries and no fatalities related to frame child carriers. Since the NPR, the Commission has received two new reports involving frame child carriers from October 28, 2003 through September 28, 2014. One reported a frame child carrier falling off of a chair with a 14-month-old child in the carrier. The child sustained a head injury. The second report was of a frame child carrier whose straps and buckles disintegrated, but no injury was mentioned.

The hazards reported in the new incidents are consistent with the hazard patterns identified among the incidents presented in the NPR briefing package. Specifically, staff identified stability and structural integrity as the two top product-related hazards in the incident data presented in the NPR package. The hazard for one of the two new incidents is related to stability, and the other is related to the structural integrity of the product.

V. Overview of ASTM F2549

ASTM F2549, Standard Consumer Safety Specification for Frame Child Carriers, is the voluntary standard that addresses the identified hazard patterns associated with the use of frame child carriers and was first approved and published in December 2006, as ASTM F2549-06.

6 Using 95% confidence interval values for frame child carriers in use yields an annual estimate of 0.71 to 1.36 emergency department-treated injuries per 10,000 frame child carriers in use in U.S. households with children under age 6.
ASTM has revised the voluntary standard six times since then. ASTM F2549-14a is the most recent version, which was approved on July 1, 2014.

A. Proposed Rule

In the NPR, the Commission proposed to incorporate ASTM F2549-14, which addressed many of the hazard patterns identified for frame child carriers, with one addition: specifying criteria for the retention system performance test to provide clear pass/fail criteria for the frame child carrier’s restraints.

B. Current ASTM Standard for Frame Child Carriers (ASTM F2549-14a)

In May 2014, ASTM issued a ballot for ASTM F2549. That ballot contained language identical to the modification language proposed in the NPR regarding the pass/fail criteria associated with the retention system test. The ASTM subcommittee approved the ballot item. Therefore, the current version of the voluntary standard, ASTM F2549-14a, is identical to the requirements proposed in the NPR.

In this rule, the Commission incorporates by reference ASTM F2549-14a because the Commission’s proposed modification in the NPR has been adopted in ASTM F2549-14a. Thus, ASTM F2549-14a specifies criteria for the retention system performance test to provide clear pass/fail criteria for the carrier’s restraints.

VI. Response to Comments

The Commission received two comments in response to the NPR. A summary of each comment topic and response is provided below.

1. Economic Factors

   a. Definition of Domestic Manufacturer
Comment: One commenter questioned the number of small domestic manufacturers cited by CPSC staff and believed that the term “domestic manufacturer” should mean that the product is physically manufactured in the United States.

Response: CPSC staff uses U.S. Census Bureau guidelines to determine whether a firm is domestic and whether a firm is a manufacturer. Under these guidelines, domestic firms are firms filing tax returns in the United States. The U.S. Census uses the North American Industry Classification System (NAICS) to determine the type of business. Under this system, a manufacturer can be a firm/establishment that processes materials itself or a firm/establishment that contracts with others to process the materials. The U.S. Small Business Administration’s guidance on the Regulatory Flexibility Act (SBA Guidance) recommends using NAICS codes in combination with Census data to identify classes of small entities and estimate their number.7

b. Impact on Domestic Manufacturers

Comment: One commenter questioned what is meant by an insignificant impact and asked whether staff’s recommendation would be different if the proposed rule was found to have a significant impact on all or most small businesses.

The commenter also questioned the use of gross income rather than net income or profit, particularly as the higher costs of manufacturing domestically would decrease net income and profit while leaving gross income unaffected. The commenter suggested that this might, in turn, lead to an underestimate of the significance of the proposed rule on firms manufacturing only in the United States.

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Response: The Regulatory Flexibility Act (RFA) does not define “significant impact.” As stated in the SBA Guidance, the determination of “significance” will “vary depending on the economics of the industry or sector.” The SBA Guidance also notes that the applicable “agency is in the best position to gauge the small entity impacts of its regulations.” Generally, CPSC staff believes that an insignificant impact in the context of the regulatory flexibility analysis means that the impact is expected to be small enough that changes to a firm’s current business operations would be limited or largely unaffected.

Section 104 of the CPSIA requires that the Commission promulgate a standard that is either substantially the same as the voluntary standard or more stringent than such voluntary standard if the Commission determines that the more stringent standard would further reduce the risk of injury associated with a product. CPSC may not propose a less stringent standard based on economic considerations. At the NPR stage, the Commission proposed adopting the voluntary standard with the sole addition of specifying the pass/fail criteria for the existing retention system performance requirement. By doing so, the Commission proposed adopting the least stringent rule allowed by law. Therefore, the Commission’s proposed rule would have been the same even if the impact on each and every small business was found to be significant. The same holds true of the Commission’s final rule, which is to adopt the current voluntary standard without modification. CPSC’s ability to reduce the impact on small businesses is limited in this case to a later effective date, which would allow firms additional time to come into compliance, spreading out the associated costs.

The Directorate for Economic Analysis staff typically uses the gross revenue measure because these data are generally available. Furthermore, use of gross revenues as an appropriate
measure is consistent with the SBA Guidance. In the case of small manufacturers and importers of frame child carriers, no information on profits or net income was available; therefore, no analysis based on this information could be undertaken.

c. Baby Products Survey

Comment: The commenter questioned the Directorate for Economic Analysis’s use of the American Baby Group’s 2006 Baby Products Tracking Study, “which could be weighted by bias” and “may not have been adjusted for income and proclivities.”

Response: In the IRFA, staff acknowledged the bias inherent in the study. As noted in the IRFA, the data collected for the Baby Products Tracking Study do not represent an unbiased statistical sample because the data are drawn from American Baby magazine’s mailing lists. However, these data were used solely to estimate annual sales of frame child carriers in the United States and the potential injury risk associated with this product. The use of the Baby Products Tracking Study in no way influenced staff’s determination of whether the regulation’s impact on firms would be significant or not.

d. Cost/Benefits Disproportion

Comment: One commenter asked that the CPSC “keep the cost-benefit ratio appropriate,” noting that the lack of serious “or near serious injuries . . . over the past ten years” would mean minimal benefits associated with third party testing “while such testing costs would be extremely expensive for small domestic businesses.” The commenter requested alternatives, specifically self-certification, and noted that she does not consider a firm’s exit from the market an acceptable alternative.

Response: The CPSC did not conduct a cost-benefit analysis for the frame child carrier rule because the rule is being promulgated under the requirements of section 104 of the CPSIA.

8 Ibid.18.
which does not require a cost-benefit analysis. Staff conducted an IRFA to assess the impact of the rule on small domestic businesses. Benefits are not required to be considered as part of an IRFA.

As noted above, section 104 of the CPSIA requires the Commission to adopt a standard that is substantially the same as the voluntary standard or more stringent than such voluntary standard if the Commission determines that the more stringent standard would further reduce the risk of injury associated with a product. Thus, CPSC’s ability to reduce the impact on small firms is limited to providing a later effective date.

CPSC’s ability to address testing costs in the context of section 104 rulemaking likewise is limited. In particular, applicable legal requirements do not allow CPSC to modify the voluntary standard to reduce the testing costs imposed by a mandatory frame child carrier standard; CPSC is required to adopt either the voluntary standard or a more stringent standard.

The discussion in the IRFA of one small domestic manufacturer leaving the market was based on information supplied by the firm when contacted. In consideration of that concern and to allow small businesses additional time to prepare for the impact of the rule, the final rule provides an 18-month effective date. To address potential hazards during that 18-month period before the rule takes effect, CPSC could act to remove any unsafe frame child carriers from the market using its authorities under section 15 of the Consumer Product Safety Act (CPSA).

2. Availability of Testing Laboratories

Comment: One commenter stated that she had a problem finding laboratories that could conduct the proposed testing.

Response: In a follow-up phone conversation with the commenter, staff provided specific contacts for three laboratories. Although not yet accredited to test frame child carriers, all three
laboratories are capable of testing frame child carriers to the final rule because they have experience testing frame child carriers to the ASTM standard referenced in the final rule.

3. Testing Equipment Issues

One commenter raised several issues or questions regarding the test equipment specified in the ASTM standard.

a. **CAMI Dummy Availability**

*Comment:* One commenter was unable to secure the CAMI dummy due to its price and the lead-time needed to order it.

*Response:* Unfortunately, CAMI dummies are only available through the one company that makes them; thus, there are no less expensive versions available. However, there is no requirement for firms to perform testing themselves; thus, there is no requirement to purchase a CAMI dummy or any of the test equipment. Third party testing laboratories offer many services, not just certification testing. Testing laboratories can perform product assessments and pre-certification testing as well.

b. **CAMI Dummy Applicability**

*Comment:* One commenter believed the size of the test dummy required by the standard is not indicative of a typical user of a frame child carrier. In addition, the commenter noted that the test dummy does not take into account items such as seasonal clothing on the child, which could increase the overall size of the occupant.

*Response:* The CAMI dummy referenced in the ASTM standard is modeled after the average (50th percentile) 6-month-old child, which is the youngest user normally specified for these carriers. The CAMI dummy is used in the standard to simulate the youngest user because the hazards being addressed (falling through leg openings, etc.) are more likely to
occur with the youngest user. The older (larger) users are not as vulnerable to the specific hazards where testing requires using a CAMI dummy. Therefore, the test procedure uses a conservative approach and simulates use by the smallest (youngest) user. Adding a new test, or using an “older” dummy (or one wearing heavy clothes), would not capture any additional hazards and would only make the testing more expensive.

c. Test Sphere

Comment: One commenter stated that she could not find the test sphere.

Response: The test sphere is not an off-the-shelf product. The standard defines the test sphere as a sphere, 16.5 inches (419.1 mm) in diameter, which is fabricated from a smooth, rigid material and weighs 7.0 pounds (3.2 kg). Those are the only design specifications. Staff is aware of test spheres fabricated from wood, metal, or plastic. Any competent machine shop or woodworking facility should be able to make one to the correct weight and size.

d. Test Sphere vs. CAMI Dummy

Comment: One commenter believed the use of the test sphere for the leg opening test is not reasonable because the shape is different from a child, and a sphere cannot use a safety harness. The commenter requested that a CAMI dummy be used instead.

Response: The goal of this performance requirement is to model a worst-case-use scenario associated with a specific hazard; i.e., an occupant slipping both legs and body through one leg opening. If the product passes a conservative, worst-case scenario test, the product would be safe in that particular respect for all users. For the leg-opening test, the test sphere simulates the smallest user’s hip dimension. The requirement is intended to address the hazard associated with the smallest users who may be getting both legs/body into one leg hole and sliding out of the frame child carrier. Thus, the worst-case scenario is to take into account the
smallest user’s hip dimensions. Lastly, and more importantly, using a smooth, rigid, and consistently dimensioned sphere is more likely to provide repeatable results. This means that the same frame carrier would consistently pass (or fail) the test, irrespective of the test laboratory or technician running the test. The CAMI dummy is made from canvas fabric, and with age and use, the flexibility and texture of the dummy changes. Thus, a frame child carrier tested to the leg-opening requirement might fail the requirement if a worn CAMI dummy were used but would pass if a brand new CAMI dummy were used. Thus, staff agrees with ASTM that the test sphere is the right test probe. Leg opening tests are used in various other children’s product standards; and the use of test equipment, such as spheres and probes, to conduct these tests is common practice.

4. Pre-Certification Testing

*Comment:* One commenter expected to send products to a certified laboratory only after having pre-tested them, which she claims would not be possible because of the problems associated with obtaining the testing equipment.

*Response:* As mentioned in another response to a comment, firms are not required to pre-test their products before having the products tested by a third party laboratory for certification. It is, however, understandable that companies would like to be assured that their products will pass, before sending them out for certification testing. In that case, firms have multiple alternatives. They can purchase the equipment and undertake the testing themselves, or they can contract with a qualified testing laboratory to conduct the pre-testing.

5. Self-Certification

*Comment:* One commenter, a registered small batch manufacturer, asked why CPSC cannot apply the small batch rules for registered small batch manufacturers to the third party testing
requirements for section 104 rules. The commenter suggested removing the third party testing requirement from the rule and providing small batch manufacturers with the alternative to self-certify. The commenter noted that CPSC has already allowed for exemptions from the CPSIA’s third party testing requirements for small batch manufacturers.

Response: Section 14(a)(2) of the CPSA requires that all children’s products subject to a children’s product safety rule, like the rule for frame child carriers, must be third party tested. 15 U.S.C. 2063(a)(2). Section 14(g)(4) of the Consumer Product Safety Act allows exceptions to third party testing for small batch manufacturers. However, that provision does not allow the Commission to provide small batch manufacturers any alternative requirements or exemptions for rules for durable infant and toddler products promulgated under section 104. Id. 2063(g)(4)(C)(ii). The rule for frame child carriers is promulgated under the legal authority in section 104 of the CPSIA. Therefore, the Commission does not have the legal authority to allow for self-certification for small batch manufacturers for the frame child carrier rule.

6. Training Opportunities

Comment: One commenter noted that CPSC staff will be conducting training for buyers and sourcing professionals dealing in electrical-electric-appliances, apparel, and toys in China. The commenter was concerned that similar training with respect to the mandatory rule for frame child carriers would give a competitive advantage to importers and foreign manufacturers whose products are made offshore.

Response: CPSC staff routinely conducts industry training both abroad and in the United States. During fiscal year 2013, for instance, we conducted 12 training events for industry abroad. For the same period, we conducted 14 training events domestically. Moreover, the Office of Compliance participated in public or webcast meetings throughout fiscal year 2013 to
discuss newly issued and existing rules and requirements; these materials generally are made
available to the general public. Many of these materials are available at
www.slideshare.net/USCPSC for download and review. Since Fiscal Year 2012, we have
uploaded 120 presentations on a variety of topic areas to SlideShare. The total number of these
meetings was 88, the majority of which were domestic. Staff anticipates continuing such
training opportunities both abroad and domestically.

7. Compliance Issues

Comment: One commenter asked for clarification about what constitutes a different model of a
product and what changes to the frame child carrier would constitute enough of a difference to
require additional third party testing.

Response: Guidance regarding material change testing is available on the CPSC website, which
contains information about applicable definitions and legal requirements. It is a manufacturer’s
responsibility to determine when a product change constitutes a different model. How this
determination is made governs whether different models could require third party testing and
certification. A material change to the product’s design or manufacturing process, as well as a
new source of component parts for the product, could affect the product’s ability to comply with
the applicable children’s product safety rule and could be considered enough of a change to
require additional testing.

The frame child carrier rule is a children’s product safety rule subject to third party
testing. The manufacturer only has to retest the product if there is a material change. If the
material change only affects certain component parts; component part testing can be sufficient
for that component part only, so long as the material change will not affect the finished product's
ability to comply with the applicable children's product safety rules.
8. Effective Date

*Comment:* One commenter agreed with the proposed 6-month effective date for the standard, while another commenter expressed concerns about whether a domestic test laboratory would be willing to perform testing to the mandatory frame child carrier standard if only three U.S. firms were requesting third party testing. A second commenter suggested that the rule could impose “excessive costs,” damaging to the commenter’s firm.

*Response:* As previously noted, the sole alternative staff can recommend to help minimize the impact of the mandatory standard is a later effective date. A later effective date would allow manufacturers and test laboratories additional time to prepare for the rule’s requirements. A later effective date would reduce the economic impact on small firms in two ways. First, firms would be less likely to experience a lapse in production, which could result if firms are unable to develop compliant frame child carriers and third party test them within the required timeframe. Second, firms could spread costs over a longer time period, thereby reducing their annual costs and the present value of their total costs.

Staff does not agree with the second commenter’s concerns regarding the potential difficulty in securing a U.S. (or foreign) test laboratory accredited to test frame child carriers. Inquiries made of three domestic laboratories who are qualified to test frame child carriers indicated that these test laboratories already have the ASTM standard for frame child carriers in their accreditation scope. All three labs include the ASTM standard in their accreditation and intend to apply for CPSC acceptance for testing to the regulation after a final rule is published. Staff believes that laboratories will be able to complete the necessary procedures to permit testing under the new frame carrier rule within the 18-month period before effectiveness of the rule.
However, CPSC staff cannot rule out a significant impact on small businesses whose frame child carriers do not comply with the final rule. Therefore, as discussed above, the final rule provides an 18-month effective date to reduce the impact of the mandatory standard, to the extent possible, on small businesses.

VII. Final Rule

A. Final Rule for Part 1230 and Incorporation by Reference

Section 1230.2 of the final rule provides that frame child carriers must comply with ASTM F2549-14a. The Office of the Federal Register (OFR) has regulations concerning incorporation by reference. 1 CFR part 51. The OFR recently revised these regulations to require that, for a final rule, agencies must discuss in the preamble of the rule ways that the materials the agency incorporates by reference are reasonably available to interested persons and how interested parties can obtain the materials. In addition, the preamble of the rule must summarize the material. 1 CFR 51.5(b).

In accordance with the OFR’s requirements, the discussion in this section summarizes the provisions of ASTM F2549-14a. Interested persons may purchase a copy of ASTM F2549-14a from ASTM, either through ASTM’s website or by mail at the address provided above and in the rule. One may also inspect a copy of the standard at the CPSC’s Office of the Secretary, U.S. Consumer Product Safety Commission, or at NARA, as discussed above. We note that the Commission and ASTM arranged for commenters to have “read only” access to ASTM F 2549-14a during the NPR’s comment period.
The CPSC is incorporating by reference ASTM F2549-14a because ASTM F2549-14a includes the Commission’s proposed modification in the NPR to specify criteria for the retention system performance test to provide clear pass/fail criteria for the carrier’s restraints.

ASTM F2549-14a contains requirements covering:

- sharp points
- small Parts
- lead in paint
- flammability requirements
- scissoring, shearing, pinching
- openings
- exposed coil springs
- locking and latching (for carriers that fold for storage)
- unintentional folding (for carriers with kick stands that can stand freely)
- labeling
- protective components
- structural integrity
- leg openings (to help prevent smaller occupants from falling out of the carrier through a single leg opening)
- dynamic strength (tests the frame, fasteners, and seams/stitching under dynamic conditions to help prevent breakage or separation)
- static load (ensures the carrier can hold three times the maximum recommended weight)
- stability (for carriers that can stand freely)
DRAFT: JANUARY 29, 2015

- restraints (requires that all carriers have a restraint system and also provides a method for testing the restraints), and

- handle integrity (helps prevent the handle from breaking or separating when it is pulled with three times the maximum recommended weight).

B. Amendment to 16 CFR Part 1112 To Include NOR for Frame Child Carriers

Standard

The final rule amends part 1112 to add a new section 1112.15(b)(38) that lists 16 CFR part 1230, Safety Standard for Frame Child Carriers as a children’s products safety rule for which the Commission has issued an NOR. Section XIII of the preamble provides additional background information regarding certification of frame child carriers and issuance of an NOR.

VIII. Effective Date

The Administrative Procedure Act (APA) generally requires that the effective date of the rule be at least 30 days after publication of the final rule. 5 U.S.C. 553(d). The safety standard for frame child carriers and the corresponding changes to the part 1112 rule regarding requirements for third party conformity assessment bodies will become effective 18 months after publication of the final rule in the Federal Register. The rule provides an 18-month effective date to allow firms whose frame child carriers may not comply with the voluntary ASTM standard additional time to come into compliance with the mandatory frame child carrier rule.

Of the nine supplying firms contacted, four provided information on the time table required for redevelopment. Eighteen months reflects the maximum length of time these firms indicated might be necessary and will allow the greatest flexibility to small firms that may be significantly affected by the mandatory frame child carrier standard.
IX. Regulatory Flexibility Act

A. Introduction

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601–612, requires agencies to consider the impact of proposed and final rules on small entities, including small businesses. Section 604 of the RFA requires that agencies prepare a final regulatory flexibility analysis (FRFA) when promulgating final rules, unless the head of the agency certifies that the rule will not have a significant impact on a substantial number of small entities. The FRFA must describe the impact of the rule on small entities. Specifically, the final regulatory flexibility analysis must contain:

- a statement of the need for, and objectives of, the rule;
- a statement of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a statement of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments;
- the response of the agency to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration in response to the proposed rule, and a detailed statement of any change made to the proposed rule in the final rule as a result of the comments;
- a description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available;
- a description of the projected reporting, recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for the preparation of the report or record; and
• a description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected.

B. Reason for Agency Action

The Danny Keysar Child Product Safety Notification Act, section 104 of the CPSIA, requires the CPSC to promulgate mandatory standards for durable infant or toddler products that are substantially the same as, or more stringent than, the voluntary standard. Infant carriers are included in the definition of “durable infant or toddler products” subject to section 104 of the CPSIA. CPSC staff worked closely with ASTM stakeholders to develop the requirements and the pass/fail criteria associated with the retention system test procedures that have been incorporated into ASTM F2549-14a, which forms the basis for the mandatory standard.

C. Other Federal Rules

The frame child carrier mandatory standard will have implications for two separate, existing federal rules: (1) Testing and Labeling Pertaining to Product Certification (16 CFR part 1107); and (2) Requirements Pertaining to Third Party Conformity Assessment Bodies (16 CFR part 1112).

The testing and labeling rule (16 CFR part 1107) requires that manufacturers of children’s products subject to product safety rules, certify, based on third party testing, that their children’s products comply with all applicable safety rules. Because frame child carriers will be subject to a mandatory rule, they will also be subject to the third party testing requirements when the rule becomes effective.
In addition, section 14(a)(2) of the CPSA requires the third party testing of children’s products to be conducted by CPSC-accepted laboratories. Section 14(a)(3) of the CPSA requires the Commission to publish a notice of requirements (NOR) for the accreditation of third party conformity assessment bodies (i.e., testing laboratories) to test for conformance with each children’s product safety rule. These NORs are set forth in 16 CFR part 1112. The final rule is amending part 1112 to include frame child carriers in the list of NORs issued by the Commission.

D. Impact on Small Businesses

There are approximately 16 firms currently known to be marketing frame child carriers in the United States, 14 of which are domestic. Under SBA guidelines, a manufacturer of frame child carriers is categorized as small if the entity has 500 or fewer employees, and importers and wholesalers are considered small if they have 100 or fewer employees. We limited our analysis to domestic firms because SBA guidelines and definitions pertain to U.S.-based entities. Based on these guidelines, about 11 of the identified 16 firms are small—four domestic manufacturers, six domestic importers, and one domestic firm with an unknown supply source. Additional unknown small domestic frame child carrier suppliers operating in the U.S. market may exist.

The impact of the final frame child carrier rule on the domestic manufacturers and importers considered to be small depends upon two factors: (1) whether, and the degree to which, their frame child carriers comply with the voluntary standard; and (2) the importance of frame child carriers to the firm’s overall product line. The effect of these two factors on small manufacturers and small importers is discussed below.
Small Manufacturers

Aside from third party testing requirements, discussed below, the final rule is likely to have little or no impact on the three (of four) small domestic manufacturers whose frame child carriers are compliant with the ASTM voluntary standard currently in effect for JPMA testing and certification purposes (ASTM F2549-14). We anticipate these firms will remain compliant with the voluntary standard as the standard changes because the firms follow, and in at least one case, participate actively in the voluntary standard development process. Therefore, compliance with the evolving voluntary standard is part of an established business practice. ASTM F2549-14a, the voluntary standard that the final rule incorporates by reference as the mandatory standard for frame child carriers, will be in effect already for JPMA testing and certification purposes before the mandatory standard goes into effect. These firms are likely to be in compliance based on their history.

The remaining small manufacturer would experience some economic impacts of unknown size. Based on discussions with a company representative, this firm does not know whether its products comply with the voluntary standard. When contacted by staff prior to the NPR, the firm was unaware of the ASTM standard. Based on subsequent staff conversations, the firm has not yet tested its products to the voluntary standard. Initially, the company’s representative indicated that the firm would likely discontinue production of its frame child carriers, regardless of whether they complied with the frame child carriers rule. However, subsequent information from the company suggests that the company likely will stay in the market and modify its frame child carriers, if necessary, to meet the final rule. This firm produces many other products and has indicated that frame child carriers do not represent a large portion of the firm’s product line. However, the extent of the changes that may be required to
meet the mandatory standard is unknown, as is the exact percentage of revenues that frame child carriers constitute for the firm. Because we have no basis for quantifying the size of the impact, we cannot rule out a significant economic impact for this firm.9

The 18-month effective date for the final frame child carrier rule should help reduce the impact of the final rule on the known small manufacturer whose frame child carriers may not comply with the rule. This would give the firm additional time to develop new or modified products and spread costs over a longer time frame.

Under section 14 of the CPSA, once the new frame child carrier requirements become effective, all manufacturers will be subject to the additional costs associated with the third party testing and certification requirements under the testing rule, Testing and Labeling Pertaining to Product Certification (16 CFR part 1107). Third party testing will include any physical and mechanical test requirements specified in the final frame child carrier rule; lead testing is already required, and testing for phthalates may also be required. Third party testing costs are in addition to the direct costs of meeting the mandatory frame child carriers standard.

CPSC staff contacted several frame child carrier suppliers regarding testing costs. Two firms provided estimates that included both physical and mechanical testing to the current ASTM standard, as well as lead and phthalate testing. Firms must test for lead and may be required to test for phthalates regardless of any rule for frame child carriers. Including lead and phthalate testing, one firm estimated testing costs to be $800 to $1,100 per unit tested, and the other firm estimated the costs to be about $1,300 per unit. Estimates provided by durable nursery product suppliers subject to other section 104 rulemakings indicate that around 40 percent to 50 percent of testing costs can be attributed to structural requirements, with the remaining 50 percent to 60

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9 It should be noted that the company representative believes that the impact of the rule on the firm will be significant. However, much of the perceived impact is due to third party testing costs which are considered separately later in this section.
percent resulting from chemical testing (e.g., lead and phthalates). Therefore, staff estimates the ASTM voluntary standard portion of the frame child carrier testing cost estimates to be $320 to $550 per sample tested ($800 x .4 to $1,100 x .5) and $520 to $650 per sample tested ($1,300 x .4 to $1,300 x .5), respectively. A third frame child carrier supplier provided an estimate of $500 to $750 for testing to the ASTM standard separately. These estimates demonstrate that testing costs can vary widely. Elements that can influence costs include where the testing is performed and whether a firm can negotiate rates based on volume for one or more products.

Staff’s review of the frame child carriers market shows that, on average, each small domestic manufacturer supplies three different models of frame child carriers to the U.S. market annually. Therefore, if third party testing were conducted every year, third party testing costs for each manufacturer would be about $960 ($320 x 3) to $2,250 ($750 x 3) annually, if only one sample were tested for each model. Based on an examination of each small domestic manufacturer’s revenues from recent Dun & Bradstreet (D&B) or ReferenceUSAGov reports, the impact of third party testing to ASTM F2549-14a will be significantly less than 1 percent of revenue for the three small domestic manufacturers for whom revenue data are available (i.e., testing costs less than 1 percent of gross revenue). Although the testing and labeling rule (16 CFR part 1107) is not explicit regarding the number of samples firms will need to test to meet the “high degree of assurance” criterion, more than 20 units per model would be required before the testing costs of any of the three small manufacturers with available revenue data would exceed 1 percent of gross revenue. However, testing costs could be significant for the one small manufacturer for which revenue data were unavailable, given that the entity only recently entered the frame child carriers market and manufactures no other products.

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10 One of these firms commented that their actual testing costs will be higher than estimated in the NPR. However, even if the firm’s testing costs were twice those estimated here, testing costs are unlikely to exceed 1 percent of the firm’s publically reported gross revenue.
Small Importers

As noted above, six small firms import frame child carriers, with two of them currently importing compliant carriers. Absent a mandatory regulation, these two small importers of frame child carriers would likely remain compliant with new versions of the voluntary standard. Given that the two small importers have developed a pattern of compliance with the ASTM voluntary standard as the voluntary standard evolves, and that the final rule is a soon-to-be-effective voluntary standard for JPMA testing, ASTM F2549-14a, the two small importers of compliant products would likely experience little or no direct costs if the final rule is implemented.

The extent of the economic impact on the four small importers with frame child carriers that do not comply with the voluntary standard will depend upon the product changes required to comply and how their supplying firms respond. Because no small importers with noncompliant frame child carriers responded to requests for information, staff cannot estimate the precise economic impact on these firms.

However, in general, if their supplying firm comes into compliance, the importer could elect to continue importing the frame child carriers. Any increase in production costs experienced by their suppliers from changes made to meet the mandatory standard may be passed on to the importers. If an importer decides that it is unwilling or unable to accept the increased costs, or if the importer’s supplier decides not to comply with the mandatory standard, there are three alternatives available. First, importers could find another supplier of frame child carriers. This could result in increased costs, as well, depending, for example, on whether the alternative supplier must modify their carriers to comply with the mandatory standard. Second, firms could import a different product in place of their frame child carriers. This alternative
would help mitigate the economic impact of the mandatory standard on these firms. Finally, importers could stop importing frame child carriers and make no other changes to their product line.

As with manufacturers, all importers will be subject to third party testing and certification requirements, and consequently, will be subject to costs similar to those for manufacturers, if their supplying foreign firm(s) does not perform third party testing. These costs appear unlikely to exceed 1 percent of gross revenue for the two small domestic importers for which revenue information is available, unless more than 10 or 30 units per model were required to be tested to provide a “high degree of assurance,” respectively. The impact on the other four small importers could not be determined or quantified, and thus, we cannot rule out a significant economic impact.

E. Alternatives

Section 104 of the CPSIA requires that the Commission promulgate a standard that is either substantially the same as the voluntary standard or more stringent. Therefore, the final frame child carrier rule (adoption of the voluntary standard, ASTM F2549-14a, with no modifications) is the minimum required by law. Consequently, the sole recommendation that staff can make to minimize (but not eliminate) the rule’s economic impact is a later effective date. As discussed above, a later effective date would reduce the economic impact on small frame child carrier firms in two ways.

Because the economic impact of the frame child carriers rule on small firms could not be determined or quantified, staff cannot rule out a significant impact. Therefore, the final rule has an 18-month effective date, which was the maximum estimated period of time that frame child carrier firms familiar with the ASTM standard advised staff the firms would need for new
product development. The minimum period of time estimated was 6 months, but only one of the four firms that responded to this question supported that time estimate. Of the nine supplying firms that staff contacted, four provided information on the time table required for redevelopment. Eighteen months reflects the maximum length of time these firms indicated might be necessary and will allow the greatest flexibility to small firms that may be significantly affected by the mandatory frame child carriers standard.

X. Environmental Considerations

The Commission’s regulations address whether we are required to prepare an environmental assessment or an environmental impact statement. These regulations provide a categorical exclusion for certain CPSC actions that normally have “little or no potential for affecting the human environment.” Among those actions are rules or safety standards for consumer products. 16 CFR 1021.5(c)(1). The rule falls within the categorical exclusion.

XI. Paperwork Reduction Act

This 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. 3501–3521). The preamble to the proposed rule (79 FR 28466 through 28467) discussed the information collection burden of the proposed rule and specifically requested comments on the accuracy of our estimates. Sections 8 and 9 of ASTM F2549-14a contain requirements for marking, labeling, and instructional literature. These requirements fall within the definition of “collection of information,” as defined in 44 U.S.C. 3502(3).

OMB has assigned control number 3041-0166 to this information collection. The Commission did not receive any comments regarding the information collection burden of this proposal. However, the final rule makes modifications regarding the information collection
burden because the number of estimated suppliers subject to the information collection burden is now estimated at 16 firms, rather than the 15 firms initially estimated in the proposed rule.

Accordingly, the estimated burden of this collection of information is modified as follows:

Table 1 – Estimated Annual Reporting Burden

<table>
<thead>
<tr>
<th>16 CFR Section</th>
<th>Number of Respondents</th>
<th>Frequency of Responses</th>
<th>Total Annual Responses</th>
<th>Hours per Response</th>
<th>Total Burden Hours</th>
</tr>
</thead>
<tbody>
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<td>1230.2(a)</td>
<td>16</td>
<td>3</td>
<td>48</td>
<td>1</td>
<td>48</td>
</tr>
</tbody>
</table>

XII. Preemption

Section 26(a) of the CPSA, 15 U.S.C. 2075(a), provides that if a consumer product safety standard is in effect and applies to a product, no state or political subdivision of a state may either establish or continue in effect a requirement dealing with the same risk of injury unless the state requirement is identical to the federal standard. Section 26(c) of the CPSA also provides that states or political subdivisions of states may apply to the Commission for an exemption from this preemption under certain circumstances. Section 104(b) of the CPSIA refers to the rules to be issued under that section as “consumer product safety rules,” thus, implying that the preemptive effect of section 26(a) of the CPSA would apply. Therefore, a rule issued under section 104 of the CPSIA will invoke the preemptive effect of section 26(a) of the CPSA when the rule becomes effective.

XIII. Certification and Notice of Requirements (NOR)

Section 14(a) of the CPSA imposes the requirement that products subject to a consumer product safety rule under the CPSA, or to a similar rule, ban, standard, or regulation under any other Act enforced by the Commission, must be certified as complying with all applicable
CPSC-enforced requirements. 15 U.S.C. 2063(a). Section 14(a)(2) of the CPSA requires that certification of children’s products subject to a children’s product safety rule be based on testing conducted by a CPSC-accepted third party conformity assessment body. Section 14(a)(3) of the CPSA requires the Commission to publish a NOR for the accreditation of third party conformity assessment bodies (or laboratories) to assess conformity with a children’s product safety rule to which a children’s product is subject. The “Safety Standard for Frame Child Carriers,” to be codified at 16 CFR part 1230, is a children’s product safety rule that requires the issuance of an NOR.

The Commission published a final rule, Requirements Pertaining to Third Party Conformity Assessment Bodies, 78 FR 15836 (March 12, 2013), which is codified at 16 CFR part 1112 (referred to here as part 1112). This rule became effective on June 10, 2013. Part 1112 establishes requirements for accreditation of third party conformity assessment bodies (or laboratories) to test for conformance with a children’s product safety rule in accordance with section 14(a)(2) of the CPSA. Part 1112 also codifies a list of all of the NORs that the CPSC had published at the time part 1112 was issued. All NORs issued after the Commission published part 1112, such as the standard for frame child carriers, require the Commission to amend part 1112. Accordingly, the Commission is now amending part 1112 to include the standard for frame child carriers in the list of other children’s product safety rules for which the CPSC has issued NORs.

Laboratories applying for acceptance as a CPSC-accepted third party conformity assessment body to test to the new standard for frame child carriers would be required to meet the third party conformity assessment body accreditation requirements in 16 CFR part 1112, Requirements Pertaining to Third Party Conformity Assessment Bodies. When a laboratory
meets the requirements as a CPSC-accepted third party conformity assessment body, the laboratory can apply to the CPSC to have 16 CFR part 1230, *Safety Standard for Frame Child Carriers*, included in its scope of accreditation of CPSC safety rules listed for the laboratory on the CPSC website at: [www.cpsc.gov/labsearch](http://www.cpsc.gov/labsearch).

CPSC staff conducted a FRFA as part of the process of promulgating the part 1112 rule (78 FR 15836, 15855-58), as required by the RFA. Briefly, the FRFA concluded that the accreditation requirements would not have a significant adverse impact on a substantial number of small laboratories because no requirements were imposed on laboratories that did not intend to provide third party testing services. The only laboratories that were expected to provide such services were those that anticipated receiving sufficient revenue from the mandated testing to justify accepting the requirements as a business decision.

Based on similar reasoning, amending 16 CFR part 1112 to include the NOR for the frame child carrier standard will not have a significant adverse impact on small laboratories. Based upon the relatively small number of laboratories in the United States that have applied for CPSC acceptance of the accreditation to test for conformance to other juvenile product standards, we expect that only a few laboratories will seek CPSC acceptance of their accreditation to test for conformance with the frame child carrier standard. Most of these laboratories will have already been accredited to test for conformance to other juvenile product standards, and the only costs to them would be the cost of adding the frame child carrier standard to their scope of accreditation. Costs should be negligible, as these laboratories are already familiar with the requirements for CPSC accreditation under 16 CFR part 1112 and have experience with this process for other durable nursery products under section 104 of the CPSIA. As a consequence,
the Commission could certify that the NOR for the frame child carriers standard will not have a
significant impact on a substantial number of small entities.

List of Subjects

16 CFR Part 1112

   Administrative practice and procedure, Audit, Consumer protection, Reporting and
recordkeeping requirements, Third party conformity assessment body.

16 CFR Part 1230

   Consumer protection, Imports, Incorporation by reference, Infants and children, Labeling,
Law enforcement, and Toys.

For the reasons discussed in the preamble, the Commission amends Title 16 of the Code
of Federal Regulations, as follows:

PART 1112—REQUIREMENTS PERTAINING TO THIRD PARTY CONFORMITY
ASSESSMENT BODIES

1. The authority citation for part 1112 continues to read as follows:


2. Amend Part 1112.15 by adding paragraph (b)(36) to read as follows:

§ 1112.15 When can a third party conformity assessment body apply for CPSC acceptance
for a particular CPSC rule and/or test method?

* * * * *

(b) (38) 16 CFR part 1230, Safety Standard for Frame Child Carriers.

* * * * *

3. Add part 1230 to read as follows:
PART 1230 - SAFETY STANDARD FOR FRAME CHILD CARRIERS

Sec.

1230.1 Scope.

1230.2 Requirements for Frame Child Carriers.


§ 1230.1 Scope.

This part establishes a consumer product safety standard for frame child carriers.

§ 1230.2 Requirements for frame child carriers.

Each frame child carrier must comply with all applicable provisions of ASTM F2549-14a, Standard Consumer Safety Specification for Frame Child Carriers, approved on July 1, 2014. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from ASTM International, 100 Bar Harbor Drive, P.O. Box 0700, West Conshohocken, PA 19428; http://www.astm.org/cpsc.htm. You may inspect a copy at the Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone 301-504-7923, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:

Staff Briefing Package

Frame Child Carriers
Section 104 of the Consumer Product Safety Improvement Act of 2008, Draft Final Rule

January 28, 2015
Table of Contents

Briefing Memorandum........................................................................................................................................... iii

TAB A: Engineering Update and Response to Comments: Frame Child Carrier Draft Final Rule Briefing Package ................................................................................................................................................. 14


TAB C: Durable Nursery Products: Summary Update of Frame Child Carriers Product Safety Recalls from January 1, 2003 to October 6, 2014 and Responses to Compliance Comments .... 23

TAB D: Final Regulatory Flexibility Analysis of the Staff-Recommended Final Rule for Frame Child Carriers and the Accreditation Requirements for Conformity Assessment Bodies for Testing Conformance to the Frame Child Carrier Standard ..................................................................................... 26
Memorandum

This document has been electronically approved and signed.

January 29, 2015

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Stephanie Tsacoumis, General Counsel
Patricia H. Adkins, Executive Director
Robert J. Howell, Deputy Executive Director for Safety Operations

FROM: George A. Borlase, Assistant Executive Director,
Office of Hazard Identification and Reduction

Patricia Edwards, Project Manager, Frame Child Carriers,
Division of Mechanical Engineering, Directorate for Engineering Sciences

SUBJECT: Frame Child Carriers, Section 104 of the Consumer Product Safety Improvement Act of 2008, Draft Final Rule

I. INTRODUCTION

Section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA) is the Danny Keysar Child Product Safety Notification Act. This Act requires the U.S. Consumer Product Safety Commission (CPSC or the Commission) to: (1) examine and assess voluntary safety standards for certain infant or toddler products, and (2) promulgate mandatory consumer product safety standards that are substantially the same as the voluntary standards or more stringent than the voluntary standards if the Commission determines that more stringent standards would further reduce the risk of injury associated with these products. The list of products in section 104 includes infant carriers.

Infant carriers is a category that covers a variety of products, including hand-held infant carriers, hand-held bassinet/cradles, soft infant and toddler carriers, slings, and frame child carriers.

This briefing package includes staff’s responses to comments received in response to the frame child carrier notice of proposed rulemaking (NPR). This package also assesses the current frame child carrier voluntary standard and presents staff’s recommendations for a draft final rule to address potential hazards associated with these products.
II. BACKGROUND

A. Rulemaking History

In May 2014, the Commission published an NPR for frame child carriers (79 Federal Register 28458, May 16, 2014). The NPR proposed to incorporate by reference the voluntary standard, ASTM F2549-14, Standard Consumer Safety Specification for Frame Child Carriers, with one modification to the retention system requirements to strengthen the voluntary standard (strikeout represents removed text, underline represents added text):

6.5 Retention System:
6.5.1 A retention system, including a shoulder restraint, shall be provided to secure the occupant in a seated position in any of the manufacturer’s recommended use positions when tested in accordance with 7.5.
6.5.2 Before shipment, the manufacturer shall attach the retention system in such a manner that it will not detach in normal usage.
6.5.3 If the retention system includes a crotch restraint designed to work with a lap belt, it shall be designed such that its use is mandatory when the retention system is in use.
6.5.4 When tested in accordance with 7.5, the restraint system and its closing means (for example, a buckle) shall not break, disengage or separate at any seam and all fasteners shall not release or suffer damage that impairs the operation and function of the restraint system. At the end of the tests, the CAMI dummy shall not be released fully or fall out of the carrier.

The Commission proposed this modification because, as written in F2549-14, the ASTM standard stated a test procedure for the restraint system, but did not contain any pass/fail criteria associated with the test. This proposed modification did not add any additional requirements to the standard; the modification only clarified how to assess an existing requirement.

B. ASTM Voluntary Standard Overview (TAB A)

ASTM F2549, Standard Consumer Safety Specification for Frame Child Carriers, is the voluntary standard that addresses the identified hazard patterns associated with the use of frame child carriers and was first approved and published in December 2006, as ASTM F2549-06. ASTM has revised the voluntary standard six times since then. ASTM F2549-14 is the version the Commission proposed to incorporate by reference in the NPR. It was approved on January 1, 2014.
In May 2014, ASTM issued another ballot for this standard. That ballot contained language that was identical to the modification language proposed in the NPR regarding the pass/fail criteria associated with the retention system test. This ballot item was approved. Thus, the language is now included in the latest version of the standard, F2549-2014a, which was approved on July 1, 2014. Therefore, the current version of the voluntary standard, ASTM F2549-14a, is identical to the requirements proposed in the NPR.

III. DISCUSSION

A. Overview of New Incident Data (Tab B)

In the NPR briefing package, CPSC staff from the Directorate for Epidemiology identified a total of 47 incidents, including 33 injuries and no fatalities related to frame child carriers that were reported to have occurred from January 2003 through October 27, 2013. Since the extraction of that data presented in the NPR briefing package, CPSC staff has received two new reports involving frame child carriers. One reported a frame carrier falling off of a chair with a 14-month-old child in it; the child sustained a head injury. The second report was of a frame carrier whose straps and buckles disintegrated; no injury was mentioned.

The hazards reported in the new incidents are consistent with the hazard patterns identified among the incidents presented in the NPR briefing package. Specifically, stability and structural integrity were identified as the two top product-related hazards in the incident data presented in the NPR package. The hazard for one of the two new incidents is related to stability, while the other is related to the structural integrity of the product.

B. Staff Responses to NPR Comments

All of the issues raised in the NPR comments, and staff’s responses, are discussed in this section of the briefing memorandum. Staff’s responses to technical, compliance, and economic comments can be found in Tab A (Engineering Sciences), Tab C (Office of Compliance), and Tab D (Economic Analysis), respectively.

The CPSC received comments from two different sources regarding the NPR:

The Juvenile Products Manufacturers Association (JPMA). Mark S. Fellin, the Director of Regulatory and Legislative Affairs at JPMA, submitted a comment dated July 16, 2014. In the comment, Mr. Fellin states that JPMA agrees with CPSC staff’s recommendation to make changes to the current ASTM standard by specifying requirements for the retention system performance test to provide clear pass/fail criteria for the carrier’s restraint system. The letter
also mentions that JPMA agrees with staff’s determination that a 6-month effective date is sufficient time to ensure compliance with the proposed mandatory standard.

**Tough Traveler** – Nancy Gold, President of Tough Traveler, a small domestic manufacturer of many products, including frame child carriers, submitted comments on behalf of the company. The documents associated with the Tough Traveler comments include a letter from Nancy Gold, dated July 19, 2014; a phone log between Patricia Edwards and Ms. Gold; a comment letter from Ms. Gold, dated July 30, 2014; and a supplemental comment letter from Ms. Gold, dated August 1, 2014. Ms. Gold raised several issues in her comments; many of the issues dealt with third party testing, which is beyond the scope of the frame child carrier rulemaking. Other issues raised specifically addressed frame child carriers. Each issue, and staff’s responses, are discussed below.

1) **Economic Factors** – Tough Traveler submitted several comments/questions related to the initial regulatory flexibility analysis (IRFA).

**a) Domestic Manufacturer Definition**

The commenter questioned the number of small domestic manufacturers cited by CPSC staff and believes that the term “domestic manufacturer” should mean that the product is physically manufactured in the United States.

Response: CPSC staff uses U.S. Census Bureau guidelines to determine whether a firm is domestic and whether a firm is a manufacturer. Under these guidelines, domestic firms are firms filing tax returns in the United States. The U.S. Census uses the North American Industry Classification System (NAICS) to determine the type of business. Under this system, a manufacturer can be a firm/establishment that processes materials itself or a firm/establishment that contracts with others to process the materials. The U.S. Small Business Administration’s guidance on the Regulatory Flexibility Act (SBA Guidance) recommends using NAICS codes in combination with Census data to identify classes of small entities and estimate their number.¹

**b) Impact on Domestic Manufacturers**

The commenter questioned what is meant by an insignificant impact and asked whether staff’s recommendation would be different if the staff-recommended rule was found to have a significant impact on all or most small businesses.

The commenter also questioned the use of gross income rather than net income or profit, particularly as the higher costs of manufacturing domestically would decrease net income and profit while leaving gross income unaffected. This might, in turn, lead to an underestimate of the significance of the proposed rule on firms manufacturing only in the United States, the commenter suggested.

Response: The Regulatory Flexibility Act (RFA) does not define “significant impact.” As reflected in the SBA Guidance, the determination of “significance” will “vary depending on the economics of the industry or sector.” The SBA Guidance also notes that the applicable “agency is in the best position to gauge the small entity impacts of its regulations.” Generally, CPSC staff believes that an insignificant impact in the context of the regulatory flexibility analysis means that the impact is expected to be small enough that changes to a firm’s current business operations would be limited or largely unaffected.

Section 104 of the CPSIA requires that the Commission promulgate a standard that is either substantially the same as the voluntary standard or more stringent. CPSC may not propose a less stringent standard based on economic considerations. At the NPR stage, the Commission recommended adopting the voluntary standard with the sole addition of specifying the pass/fail criteria for the existing retention system performance requirement. By doing so, the Commission proposed adopting the least stringent rule allowed by law. Therefore, staff’s recommendation to the Commission at the NPR stage would have been the same even if the impact on each and every small business was found to be significant. The same holds true of the staff’s recommended final rule, which is to adopt the current voluntary standard without modification. CPSC’s ability to reduce the impact on small businesses is limited in this case to a later effective date, which would allow firms additional time to come into compliance, spreading out the associated costs.

EC staff typically uses the gross revenue measure because these data are generally available. Furthermore, use of gross revenues as an appropriate measure is consistent with the SBA Guidance. In the case of small manufacturers and importers of frame child carriers, no information on profits or net income was available; therefore, no analysis based on this information could be undertaken.

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2 Ibid: 18.
c) Baby Products Survey

The commenter questioned EC staff’s use of the American Baby Group’s 2006 Baby Products Tracking Study, “which could be weighted by bias” and “may not have been adjusted for income and proclivities.”

Response: In the IRFA, EC staff acknowledged the bias inherent in the study. As noted in the IRFA, the data collected for the Baby Products Tracking Study does not represent an unbiased statistical sample because it is drawn from American Baby magazine’s mailing lists. However, this data were used solely to estimate annual sales of frame child carriers in the United States and the potential injury risk associated with this product. The use of the Baby Products Tracking Study in no way influenced the staff’s determination of whether the regulation’s impact on firms would be significant or not.

d) Cost/Benefits Disproportion

The commenter asked that the CPSC “keep the cost-benefit ratio appropriate,” noting that the lack of serious “or near serious injuries . . . over the past ten years” would mean minimal benefits associated with third party testing “while such testing costs would be extremely expensive for small domestic businesses.” The commenter requested alternatives, specifically self-certification, and noted that he/she does not consider a firm exit from the market an acceptable alternative.

Response: The CPSC did not conduct a cost-benefit analysis for the frame child carrier rule because the rule is being promulgated under the requirements of Section 104 of the CPSIA, which does not require a cost-benefit analysis. Staff conducted an IRFA of the impact on small domestic businesses. Benefits are not considered as part of an IRFA. EC staff’s discussion in the IRFA of one small domestic manufacturer leaving the market was based on information supplied by the firm when contacted.

As noted above, section 104 of the CPSIA requires adoption of a standard that either is substantially the same as the voluntary standard or more stringent. Thus, CPSC’s ability to reduce the impact on small firms is limited to providing a later effective date.

CPSC’s ability to address testing costs in the context of Section 104 rulemaking likewise is limited. In particular, there are no alternatives that CPSC staff could recommend that would reduce the testing costs imposed by a mandatory frame child carrier standard because the proposed rule is the minimum required by the
CPSIA. Consequently, staff now recommends an 18-month effective date to reduce the impact on small businesses to the extent possible. Ongoing compliance activities would still be used to remove any unsafe frame child carriers from the market.

2) **Effective Date** - Although JPMA agreed with the proposed 6-month effective date for the standard, Tough Traveler expressed concerns about whether a domestic test laboratory would be willing to perform testing to the mandatory frame child carrier standard if only three U.S. firms were requesting third party testing. The commenter went on to say that the rule could, therefore, impose “excessive costs” damaging to their firm.

**Response:** As previously noted, the sole alternative staff can recommend to help minimize the impact of the mandatory standard is a later effective date. A later effective date would allow suppliers additional time to prepare for the rule’s requirements. A later effective date would reduce the economic impact on small firms in two ways. One, firms would be less likely to experience a lapse in production, which could result if they are unable to develop compliant frame carriers and third party test them within the required timeframe. Two, firms could spread costs over a longer time period, thereby reducing their annual costs, as well as the present value of their total costs.

CPSC staff cannot rule out a significant impact on small businesses whose frame carriers do not comply with the final rule. Four frame child carrier suppliers provided staff with an estimate of the time it would require each firm to develop a compliant product. One firm indicated that 6 months would be sufficient, but the other three firms thought that more time would be required, on average 12 months. One of these three thought that it might take them as long as 18 months to develop a compliant product, which is consistent with estimates for other durable nursery products. Therefore, as discussed above, staff is recommending an 18 month effective date. This will reduce the impact of the mandatory standard on small businesses to the maximum extent possible, while still allowing compliance activities to remove any unsafe frame child carriers from the market.

Staff does not agree with the second commenter’s concerns regarding the potential difficulty in securing a U.S. (or foreign) test laboratory accredited for frame child carriers. Inquiries made of three domestic laboratories indicated they all include the ASTM standard in their accreditation and intend to apply for CPSC acceptance for testing to the regulation after a final rule is published.
3) **Availability of Testing Laboratories** – Tough Traveler stated that there was a problem finding laboratories that could do the testing proposed in the NPR.

**Response:** In a follow-up phone conversation with the commenter, staff provided specific contacts for three laboratories to the commenter. Although not yet accredited, all three laboratories are capable of testing frame child carriers to the NPR because they have experience testing these carriers to the ASTM standard referenced in the NPR. In addition, as mentioned in the response above, all three laboratories intend to apply for CPSC acceptance for testing to the regulation.

4) **Testing Equipment Issues** - Tough Traveler raised several issues or questions regarding the test equipment specified in the ASTM standard. The specific issues raised in the comment, and staff’s responses, follow:

a) **CAMI Dummy Availability**

   Tough Traveler was unable to secure the CAMI dummy due to its price and the lead-time needed to order it.

   **Response:** Unfortunately, the CAMI dummy is only available through the one company that makes them; and thus, there are no less expensive versions available. However, there is no requirement for firms to perform testing themselves; thus, there is no requirement to purchase a CAMI dummy or any of the test equipment. Third party testing laboratories offer many services, not just certification testing. Testing laboratories can perform product assessments and pre-certification testing as well.

b) **CAMI Dummy Applicability**

   Tough Traveler believes the size of the test dummy required by the standard is not indicative of a typical user of a frame child carrier. In addition, items such as seasonal clothing on the child would not be taken into account.

   **Response:** The CAMI dummy referenced in the ASTM standard is modeled after the average (50th percentile) 6-month old child, which is the youngest user normally specified for these carriers. The CAMI dummy is used in the standard to simulate the youngest user because the hazards being addressed (falling through leg openings, etc.) are more likely to occur with the youngest user. The older (larger) users are not as vulnerable to the specific hazards where
testing requires using a CAMI dummy. Therefore, the test procedure uses a conservative approach and simulates use by the smallest (youngest) user. Adding a new test, or using an “older” dummy (or one wearing heavy clothes), would not capture any additional hazards and would only make the testing more expensive.

c) **Test Sphere**

The test sphere has not been found by Tough Traveler.

**Response:** The test sphere is not an off-the-shelf product. It is defined as a sphere, 16.5 inch (419.1 mm) in diameter, which is fabricated from a smooth, rigid material and weighs 7.0 pounds (3.2 kg). Those are the only design specifications. These test spheres have been known to be fabricated from wood, metal, or plastic. Any competent machine shop or woodworking facility should be able to fabricate one to the correct weight and size. As mentioned previously, there is no requirement for firms to perform testing themselves; thus, there is no requirement to purchase any of the test equipment. Third party testing laboratories can perform product assessments and pre-certification testing as well.

d) **Test Sphere vs. CAMI Dummy**

Tough Traveler believes the use of the test sphere for the leg opening test does not appear to be reasonable, considering that the shape is different from a child, and a sphere cannot use a safety harness. The commenter requests that a CAMI dummy be used instead.

**Response:** The goal of this performance requirement is to model a worst-case-use scenario associated with a specific hazard; *i.e.*, an occupant slipping both legs and body through one leg opening. If the product passes a conservative, worst-case scenario test, the product should be safe in that particular respect for all users. For the leg-opening test, the test sphere simulates the smallest user’s hip dimension. The requirement is intended to address the hazard associated with the smallest users who may be getting both legs/body into one leg hole and sliding out of the frame child carrier. Thus, the worst-case scenario takes into account the smallest user’s hip dimensions. Lastly, and more importantly, using a smooth, rigid and consistently dimensioned sphere is more likely to provide repeatable results. This means that the same frame carrier would consistently pass (or fail) the test, irrespective of the test lab or technician running the test. The CAMI dummy is made from canvas fabric, and with age and use, the flexibility and texture of the
dummy changes. Thus, a frame child carrier tested to the leg-opening requirement might fail the requirement if a worn CAMI dummy is used, but would pass if a brand new CAMI dummy was used. Thus, staff agrees with ASTM that the test sphere is the right tool for this test. Leg opening tests are found in various other children’s product standards; and test equipment such as spheres and probes to conduct these tests are commonly used in other children’s product standards.

5) **Pre-Certification Testing** - Tough Traveler expects to send products to a certified lab only after having pre-tested them, which would not be possible because of the problems associated with obtaining the testing equipment.

Response: As mentioned in another response to a comment, there is no requirement for firms to pre-test their products before having them tested by a third party laboratory for certification. It is, however, understandable that companies would like to be assured that their products will pass before sending them out for certification testing. In that case, firms have different avenues they can pursue. They can purchase the equipment themselves and learn how to do the testing, or they can contract with one of the qualified testing laboratories to do the pre-testing for them.

6) **Self-Certification** - Tough Traveler, which is a registered small batch manufacturer, asked why CPSC cannot apply the small batch rules for registered small batch manufactures to the third party testing requirements for section 104 rules. Tough Traveler suggested removing the third party testing requirement from the proposed rule and providing small batch manufacturers with the alternative to self-certify. Tough Traveler noted that CPSC has already allowed for exemptions from the CPSIA’s third party testing requirements for small batch manufacturers.

Response: Section 14(g)(4)(C)(ii) of the Consumer Product Safety Act allows exceptions to third party testing for small batch manufacturers. However, that provision does not allow the Commission to provide small batch manufacturers any alternative requirements or exemptions for rules for durable infant and toddler products promulgated under section 104. The rule for frame child carriers is promulgated under the legal authority in section 104 of the CPSIA. Additionally, section 14(a)(2) requires that all children’s products subject to a children’s product safety rule (if finalized the rule for frame child carriers would be a children’s product safety rule), must be third party tested. Therefore, unfortunately, the Commission does not have the legal authority to allow for self-certification for small batch manufacturers for the frame child carrier rule.
7) **Training Opportunities** – Tough Traveler commented that CPSC staff will be conducting training for buyers and sourcing professionals dealing in electrical-electric-appliances, apparel and toys, in China. The commenter was concerned that if similar training was offered in China, with respect to the mandatory rule for frame child carriers, that it would give a competitive advantage to importers and foreign manufacturers whose products are made offshore.

Response: CPSC staff conducts industry training abroad and in the United States. During fiscal year 2013, we conducted 12 training events for industry abroad. For the same period, the CPSC Small Business Ombudsman, Mr. Neal Cohen, conducted 14 small business training events domestically. Also in the same time period, the Office of Compliance participated in public or webcast meetings to discuss newly issued and existing rules and requirements. The total number of these meetings was 88, the majority of which were domestic.

Materials from many of these training sessions are available at [www.slideshare.net/USCPSC](http://www.slideshare.net/USCPSC) for download and review. Since Fiscal Year 2012, we have uploaded 120 presentations on a variety of topic areas to SlideShare.

8) **Compliance Issues**- Tough Traveler wanted clarification about what constitutes a different model of a product and what changes to the frame child carrier would constitute enough of a difference to require additional third party testing.

Response: Guidance regarding material change testing is available on the CPSC website, which contains information regarding applicable definitions and legal requirements. It is a manufacturer’s responsibility to determine when a product change constitutes a different model. How this determination is made governs whether different models could require third party testing and certification. A material change to the product’s design or manufacturing process, as well as a new source of component parts for the product, could affect the product’s ability to comply with the applicable children’s product safety rule and could be considered enough of a change to require additional testing. If the Commission approves staff’s draft final rule, the frame child carrier rule would be a children’s product safety rule covered by a standard. The manufacturer does not have to test the whole product again if there is not a material change or if the material change only affects certain component parts; component part testing can be sufficient for that component part only, so long as the material change will not affect the finished product's ability to comply with the applicable children's product safety rules.
C. Regulatory Flexibility Analysis

Staff identified 16 firms supplying frame child carriers to the U.S. market, although additional firms may supply these products to U.S. customers. Based on U.S. Small Business Administration guidelines, 11 of the 16 firms are small businesses, including four domestic manufacturers, six domestic importers, and one domestic firm with an unknown supply source.

The potential economic impact of the staff-recommended draft final standard on these firms is described in the Directorate for Economic Analysis memorandum (Tab D). Aside from third party testing costs, the draft final rule is likely to have little or no impact on the small manufacturers (three firms) and importers (two firms) whose frame child carriers comply with the ASTM voluntary standard currently in effect for JPMA testing and certification purposes. Because compliance with the voluntary standard is part of the established business practice of these firms, it is expected that they will also comply with ASTM F2549-14a, which staff recommends that the Commission incorporate by reference. For the remaining small manufacturer, the extent of the changes that may be required to meet the draft mandatory standard are unknown, as is the precise percentage of revenues that frame child carriers constitutes for the firm. Because we have no basis for quantifying the size of the impact, we cannot rule out a significant economic impact on this small manufacturer.

The economic impact on the four small importers of frame child carriers currently believed to be noncompliant will depend upon the extent of the changes required to come into compliance and the response of their supplying firms. Because no small importer with noncompliant frame child carriers responded to staff’s information request, we cannot estimate the economic impact on these firms. However, even if the supplying firms passed all of the compliance costs onto the importers, several alternatives are available to these small importers (including import a frame child carrier from a different supplier, replace the carrier with a different product, or remove the carrier from their product line) that could help mitigate the economic impact of the draft mandatory standard on these firms.

In addition to the requirements of the draft final rule, there will be additional costs associated with third party testing, which will be triggered when the final rule goes into effect. The cost of testing is unlikely to exceed one percent of gross revenue for the three small domestic manufacturers or the two small domestic importers for which revenue data was available. It is possible, however, that testing costs will exceed one percent of gross revenues for the remaining small manufacturer and four small importers for which revenue data was not available.

The staff-recommended 18-month effective date should help reduce the impact of the staff-recommended draft final rule on the small manufacturer and the four small importers whose
frame child carriers may not comply with the rule. This would give the firms additional time to develop new/modified products and spread costs over a longer time frame.

D. Effective Date of Draft Final Rule

The Administrative Procedure Act (APA) generally requires that the effective date of a rule be at least 30 days after publication of the final rule (5 U.S.C. 553(d)). In the NPR, the Commission proposed a 6-month effective date. Based on comments, CPSC staff believes that the Commission should set an effective date for the standard 18 months after publication of the draft final rule for products manufactured or imported on or after that date. This should allow small businesses to spread costs over a longer period of time to lessen the impact of the new rule.

IV. STAFF RECOMMENDATION

CPSC staff recommends that the Commission incorporate by reference the voluntary standard, ASTM F2549-14a, with no modifications. Staff is recommending this version, in lieu of the version referenced in the NPR (ASTM F2549-14), because ASTM F2050-14a is identical to the NPR.

Staff is also recommending an effective date of 18 months after publication of the draft final rule to help small businesses spread costs over a longer period of time.
TAB A: Engineering Update and Response to Comments: Frame Child Carrier Draft Final Rule Briefing Package
October 9, 2014

TO: Patricia L. Edwards, Frame Child Carriers Project Manager
Division of Mechanical Engineering, Directorate for Engineering Sciences

THROUGH: Joel Recht, Ph.D.
Assistant Executive Director for Engineering Sciences

Mark Kumagai, P.E., Director
Division of Mechanical Engineering
Directorate for Engineering Sciences

FROM: Kevin K. Lee, Mechanical Engineer
Division of Mechanical Engineering
Directorate for Engineering Sciences

SUBJECT: Engineering Update and Response to Comments: Frame Child Carrier Draft Final Rule Briefing Package

I. INTRODUCTION

Section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA) is the Danny Keysar Child Product Safety Notification Act. This Act requires the U.S. Consumer Product Safety Commission (CPSC or the Commission) to: (1) examine and assess voluntary safety standards for certain infant or toddler products, and (2) promulgate mandatory consumer product safety standards that are substantially the same as the voluntary standards or more stringent than the voluntary standards if the Commission determines that more stringent standards would further reduce the risk of injury associated with these products. The list of products in section 104 includes infant carriers.

In May 2014, the Commission published a notice of proposed rulemaking (NPR) for frame child carriers (79 Federal Register 28458, May 16, 2014). The NPR proposed to incorporate by reference the voluntary standard, ASTM F2549-14, Standard Consumer Safety Specification for Frame Child Carriers, with a modification to the retention system to strengthen the ASTM standard, which is discussed later.
This memorandum discusses an update to the ASTM standard and provides responses to comments that are technically related.

II. ASTM Standard Update

The NPR proposed incorporating by reference the 2014 version of the ASTM frame child carrier voluntary standard, Standard Consumer Safety Specifications for Frame Child Carriers (F2549-14). The NPR also included one modification to the voluntary standard, which pertains to the retention (restraints) system of the carrier. That modification is detailed below (strikeout represents removed text, underline represents added text):

6.5 Retention System:
6.5.1 A retention system, including a shoulder restraint, shall be provided to secure the occupant in a seated position in any of the manufacturer’s recommended use positions when tested in accordance with 7.5.
6.5.2 Before shipment, the manufacturer shall attach the retention system in such a manner that it will not detach in normal usage.
6.5.3 If the retention system includes a crotch restraint designed to work with a lap belt, it shall be designed such that its use is mandatory when the retention system is in use.
6.5.4 When tested in accordance with 7.5, the restraint system and its closing means (for example, a buckle) shall not break, disengage or separate at any seam and all fasteners shall not release or suffer damage that impairs the operation and function of the restraint system. At the end of the tests, the CAMI dummy shall not be released fully or fall out of the carrier.

The Commission proposed this modification because, as written in F2549-14, the ASTM standard did not contain any pass/fail criteria associated with the retention test. With the addition of section 6.5.4, the NPR contains a pass/fail criterion for the retention system performance requirement. This change does not add any additional requirements to the standard; it only clarifies how to assess an existing requirement.

The modification outlined in the NPR was balloted by ASTM for inclusion in F2549, in spring 2014. ASTM passed the balloted revision and on July 1, 2014, F2549-14a was approved. Thus, at this time, the current ASTM standard, F2549-14a is identical to the requirements proposed in the NPR.
III. Responses to Technical Comments

Availability of Testing Laboratories

Comment: One commenter stated that there was a problem finding laboratories that could conduct the proposed testing.

Response: In a follow-up phone conversation with the commenter, specific contacts for three laboratories were provided to the commenter. All three laboratories are capable of testing frame child carriers to the NPR and have performed testing on these carriers to the ASTM standard referenced in the NPR.

Testing Equipment Issues

Comment: One commenter raised several issues or questions regarding the test equipment specified in the ASTM standard. The specific issues raised in the comment, and staff’s responses, follow:

CAMI Dummy Availability— The commenter was unable to secure the CAMI dummy due to its price and the lead-time needed to order it. The commenter believes that the cost is unreasonable for small firms.

Response: Unfortunately, the CAMI dummy is only available through the one company that makes them. Thus, there are no cheaper versions available. However, there is no requirement for firms to perform testing themselves. Thus, there is no requirement to purchase a CAMI dummy or any of the test equipment. Third party testing laboratories offer many services, not just certification testing. Third party testing laboratories can perform product assessments and pre-certification testing as well.

CAMI Dummy Sizing – The size of the test dummy required by the standard is not indicative of a typical user of a frame child carrier. In addition, things such as seasonal clothing on the child would not be taken into account.

Response: The CAMI dummy referenced in the ASTM standard is modeled after the average (50th percentile) 6-month old child, which is the youngest user normally specified for these carriers. The use of the CAMI dummy in the standard is to simulate the youngest user because the hazards being addressed are more likely to occur with the youngest user. The older (larger) users are not as vulnerable to the specific hazards where testing requires using a CAMI dummy. Therefore, the test procedure uses a conservative approach and
simulates use by the smallest (youngest) user. Adding a new test, or using an “older” dummy (or one wearing heavy clothes) would not capture any additional hazards, and would only make the testing more expensive.

*Test Sphere Availability – The test sphere has not been found.*

Response: The test sphere is not an off-the-shelf product. It is defined as a sphere, 16.5 inch (419.1 mm) in diameter, which is fabricated from a smooth, rigid material, and weighs 7.0 pounds (3.2 kg). Those are the only specifications. These test spheres have been known to be fabricated from wood, metal, or plastic. Any competent machine shop or woodworking facility should be able to fabricate one to the correct weight and size. As mentioned previously, there is no requirement for firms to perform testing themselves. Thus, there is no requirement to purchase any of the test equipment. Third party testing laboratories can perform product assessments and pre-certification testing as well.

*Test Sphere vs. CAMI Use – The use of the test sphere for the leg opening test does not appear to be reasonable considering that the shape is different from a child and a sphere cannot use a safety harness. The commenter requests that a CAMI dummy be used instead.*

Response: The goal of this performance requirement is to model a worst-case use scenario associated with a specific hazard; i.e., an occupant slipping both legs and body through one leg opening. By using a conservative, worst-case scenario in the testing, one can be rest assured that if the product passes the test, it would be safe for all users. For the leg-opening test, the test sphere simulates the smallest user’s hip dimension. The requirement is intended to address the hazard associated with the smallest users who may be getting both legs/body into one leg hole and sliding out of the frame child carrier. Thus, the worst-case scenario is to take into account the smallest user’s hip dimensions. Lastly, and more importantly, using a smooth, rigid and consistently dimensioned sphere is more likely to provide repeatable results. This means that the same frame carrier would consistently pass (or fail) the test, irrespective of the test lab or technician running the test. The CAMI dummy is made from canvas fabric, and with age and use, the flexibility and texture of the dummy changes. Thus, a frame child carrier tested to the leg-opening requirement might fail the requirement if a worn CAMI dummy is used, but would pass if a brand new CAMI dummy was used. ASTM uses the test sphere because it does not present the same issues as the CAMI dummy. Staff agrees with ASTM. Leg opening tests are used in various other children’s product standards and the use of test equipment, such as spheres and probes to conduct these tests, is common practice.
Pre-Certification Testing

Comment: One commenter stated that the commenter would expect to send products to a certified lab only after having pre-tested them, which would not be possible because of the problems associated with obtaining the testing equipment.

Response: As mentioned in another response to a comment, there is no requirement for firms to do pre-testing of their products before having them tested by a third party laboratory for certification. It is, however, understandable that companies would like to be assured that their products will pass, before sending them out for certification. In that case, firms have different avenues they can pursue. They can purchase the equipment themselves and learn how to do the testing, or they can contract with one of the qualified testing laboratories to do the pre-testing for them.

IV. Conclusion

ESME staff recommends that the Commission incorporate by reference the voluntary standard, ASTM F2549-14a, Standard Consumer Safety Specifications for Frame Child Carriers, with no modifications.
Memorandum

Date: September 30, 2014

TO: Patricia L. Edwards
    Project Manager, Child Frame Carriers Project
    Division of Mechanical Engineering
    Directorate for Engineering Sciences

THROUGH: Kathleen Stralka
         Associate Executive Director
         Directorate for Epidemiology

FROM: Risana Chowdhury
      Division of Hazard Analysis
      Directorate for Epidemiology


I. Introduction

This memorandum updates the data in the Frame Child Carriers notice of proposed rulemaking (NPR) briefing package presented to the Commission in April 2014. The time frame covered, in the previous data extraction, was January 1, 2003−October 27, 2013. This memorandum includes frame child carrier-related incident data reported to CPSC staff since October 28, 2013 through September 4, 2014.\(^3\)

\(^3\) This analysis was prepared by CPSC staff. It has not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.

\(^4\) Not all of these incidents are addressable by an action the CPSC could take. It is not the purpose of this memorandum, however, to evaluate the addressability of the incidents, but rather, to quantify the number of fatalities and injuries reported to CPSC staff and to provide, when feasible, estimates of emergency department-treated injuries.
CPSC databases do not have a dedicated product code for identifying frame child carriers. Instead, the frame child carrier incidents were identified from a subset of products coded as 1527 (baby carriers or slings (backpacks)), 1548 (baby carriers, not specified), and 1549 (other baby carriers). No national estimates, based on emergency department-treated injuries, were feasible because data collection for 2014 is not yet closed. However, these injuries, treated as incident cases, have been included with the anecdotal injuries associated with frame child carriers.

II. Incident Data

In the NPR briefing package, CPSC staff from the Directorate for Epidemiology identified a total of 47 incidents, including 33 injuries and no fatalities, related to frame child carriers. The injuries reportedly occurred from January 2003 through October 27, 2013. Since the extraction of that data presented in the NPR briefing package, CPSC staff has received two new reports involving frame child carriers. One reported a frame carrier falling off of a chair with a 14-month-old child in it; the child sustained a head injury. The second report was of a frame carrier with disintegrated straps and buckles; no injury was mentioned.

III. Hazard Pattern Identification

The hazards reported in the new incidents were no different from the hazard patterns identified among the incidents presented in the NPR briefing package. Specifically, stability and structural integrity were identified as the two top product-related hazards in the incident data presented in the NPR package. Among the two new incidents described in the earlier section, the hazard for one is related to stability and the other is associated with the structural integrity of the product.

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5 The CPSC databases searched were the In-Depth Investigation (INDP) file, the Injury or Potential Injury Incident (IPII) file, the Death Certificate (DTHS) file and the National Electronic Injury Surveillance System (NEISS). Date of extraction data was 09/05/14. The reported deaths and incidents are not a complete count of all that occurred during this time period. However, they do provide a minimum number of deaths and incidents occurring during this time period and illustrate the circumstances involved in the incidents related to frame child carriers.
TAB C: Durable Nursery Products: Summary Update of Frame Child Carriers Product Safety Recalls from January 1, 2003 to October 6, 2014 and Responses to Compliance Comments
Memorandum

Date: October 9, 2014

TO : Patricia L. Edwards, Frame Child Carriers Project Manager
     Division of Mechanical Engineering, Directorate for Engineering Sciences

THROUGH: Robert J. Howell, Acting Executive Director, EXC
         Mary F. Toro, Director, Regulatory Enforcement, CRE
         Troy Whitfield, Lead Compliance Officer, Mechanical Hazards Team

FROM : Julio Alvarado, Compliance Officer, Mechanical Hazards Team

SUBJECT : Durable Nursery Products: Summary Update of Frame Child Carriers Product Safety Recalls from January 1, 2003 to October 6, 2014 and Responses to Compliance-Related Comments

Purpose

This memorandum provides compliance information relevant for the drafting of a safety standard for frame child carriers. Section 104 of the Consumer Product Safety Improvement Act of 2008, Pub. L. No. 110-314, 122 Stat. 3016 (August 14, 2008) (CPSIA), also known as the Danny Keysar Child Product Safety Notification Act, requires the Commission to study and develop safety standards for durable infant and toddler products, which includes frame child carriers. In May 2014, the Commission issued a notice of proposed rulemaking (NPR) for frame child carriers (79 Federal Register 28458, May 16, 2014). At this time, CPSC staff is recommending a draft final rule for a frame carrier standard for Commission consideration. The rule addresses the hazards associated with frame carriers through structural integrity, stability, leg opening, and restraint requirements. This memorandum summarizes the product safety recalls stemming from defect investigations conducted by the Office of Compliance and Field Operations (Compliance) involving frame carriers. In addition, this memorandum provides staff’s responses to compliance-related comments to the NPR.

Compliance Investigation Information

In the NPR briefing package, Compliance staff reviewed the recalls and related press releases on frame child carriers from January 1, 2003 to October 6, 2014. During that time, there were a total of two consumer-level recalls involving frame carriers. The two recalls were the result of structural integrity issues. The first recall involved frame carriers that had shoulder straps loosening from the body of the carrier. The second recall involved frame carriers that were...
sold without the bolts that attached the carrier’s main frame to the metal stand, posing a fall hazard to the child in the carrier. Since the NPR, there have been no new consumer-level recalls of frame child carriers.

**Compliance Staff Response to NPR Comments**

*Comment:* One commenter wanted clarification about what constitutes a different model of a product and what changes to the frame child carrier would constitute enough of a difference to require additional third party testing.

*Response:*

Guidance regarding material change testing is available on the CPSC website, which contains information regarding applicable definitions and legal requirements. It is a manufacturer’s responsibility to determine when a product change constitutes a different model. How this determination is made governs whether different models could require third party testing and certification.

A material change to the product’s design or manufacturing process, as well as a new source of component parts for the product, could affect the product’s ability to comply with the applicable children’s product safety rule and could be considered enough of a change to require additional testing.

If the Commission approves staff’s draft final rule, the frame child carrier rule would be a children’s product safety rule covered by a standard. The manufacturer does not have to test the whole product again if there is not a material change or if the material change only affects certain component parts; component part testing can be sufficient for that component part only, so long as the material change will not affect the finished product's ability to comply with the applicable children's product safety rules.
TAB D: Final Regulatory Flexibility Analysis of the Staff-Recommended Final Rule for Frame Child Carriers and the Accreditation Requirements for Conformity Assessment Bodies for Testing Conformance to the Frame Child Carrier Standard
Memorandum

TO: Patricia L. Edwards  
   Project Manager, Frame Carriers  
   Division of Mechanical Engineering  
   Directorate for Engineering Sciences

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: Jill L. Jenkins, Ph.D.  
   Economist  
   Directorate for Economic Analysis

SUBJECT: Final Regulatory Flexibility Analysis of the Staff-Recommended Final Rule for Frame Child Carriers and the Accreditation Requirements for Conformity Assessment Bodies for Testing Conformance to the Frame Child Carrier Standard

Introduction

On May 16, 2014, the CPSC published a notice of proposed rulemaking (NPR) in the Federal Register (FR) (79 FR 28458). The proposed rule incorporated by reference the voluntary ASTM International (formerly known as the American Society for Testing and Materials) standard for frame child carriers (F2549-14), with the addition of specific pass/fail criteria for the existing retention system performance requirement. Since the NPR, ASTM has published F2549-14a, which includes the pass/fail criteria for the retention system performance requirement proposed by the Commission. Therefore, staff recommends adopting by reference ASTM F2549-14a, with no modifications.

This memorandum evaluates the potential economic impact of the staff-recommended final frame child carrier standard on small entities, including small businesses, as required by the Regulatory Flexibility Act (RFA). Section 604 of the RFA requires that agencies prepare a final regulatory flexibility analysis (FRFA) when the Commission promulgates a final rule, unless the head of the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The FRFA must describe the impact of the rule on small
entities and identify any alternatives that may reduce the impact. Specifically, the FRFA must contain:

1. a statement of the need for, and objectives of, the rule;
2. a statement of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a statement of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments;
3. the response of the agency to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration in response to the proposed rule, and a detailed statement of any change made to the proposed rule in the final rule as a result of the comments;
4. a description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available;
5. a description of the projected reporting, recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirements and the type of professional skills necessary for the preparation of reports or records; and
6. a description of the steps the agency has taken to minimize the significant economic impact on small entities, consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the rule, and why each one of the other significant alternatives to the rule considered by the agency, which affect the impact on small entities, was rejected.

The Product

“Frame child carriers” are defined in ASTM F2549-14a, *Standard Consumer Safety Specification for Frame Child Carriers*, as “a product, normally of sewn fabric construction on a tubular metal or other frame, which is designed to carry a child, in an upright position, on the back of the caregiver.” Based on a market review conducted early in the rulemaking process, the definition was expanded to include frame child carriers intended to accommodate children from 16 pounds to 50 pounds (the limit had been 40 pounds) in an unassisted, upright position. The child is carried suspended from both of the adult wearer’s shoulders in a forward- or rear-facing position. This type of carrier is often used for hiking and typically closely resembles hiking/mountaineering backpacks not intended to be used for child transport.⁶

The Market for Frame Child Carriers

Staff identified 16 firms supplying frame child carriers to the U.S. market, typically costing from $100 to around $300, although additional firms may supply these products to U.S.

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⁶ Staff has identified one product on the U.S. market that would likely be covered by ASTM F2549-14a but does not closely resemble a hiking backpack.
consumers. Most of these firms specialize in the manufacture and/or distribution of one of two distinct types of products: (1) children’s products, including durable nursery products; or (2) outdoor products, such as camping and hiking gear. The majority of the 16 known firms are domestic (including five manufacturers, eight importers, and one firm whose supply source could not be determined). The remaining two firms are foreign (including one manufacturer and one firm that imports products from foreign companies and distributes the products from outside of the United States).  

Staff expects that the frame child carriers of seven of these firms are compliant with ASTM F2549 because the firms either: (1) certify their carriers through the Juvenile Products Manufacturers Association (JPMA) (three firms); or (2) claim compliance with the voluntary standard (four firms). However, some of the suppliers of frame carriers do not supply any other children’s products; and it is possible that these suppliers may be unfamiliar with the voluntary ASTM standards, a circumstance confirmed by one supplier that staff contacted during the initial regulatory flexibility analysis (IRFA) development. Staff unsuccessfully attempted to obtain information from several firms whose frame child carriers do not claim compliance with the ASTM standard regarding the extent to which their carriers do not comply.

In 2013, the CPSC conducted a Durable Nursery Product Exposure Survey (DNPES) of U.S. households with children under age 6. Data from the DNPES indicate that there are an estimated 2.38 million frame child carriers in U.S. households with children under the age of 6 (with 95% probability that the actual value is between 1.8 million and 2.95 million). Data collected also indicate that about 54 percent of the frame child carriers in U.S. households with children under age 6 are in use (an estimated 1.28 million frame carriers, with 95% probability that the actual value is between about 880,000 and 1.7 million).

Staff could not estimate annual injuries because the number of National Electronic Injury Surveillance System (NEISS) cases was insufficient to meet the CPSC Directorate for Epidemiology (EPI) publication criteria. However, given that part of the publication criteria is that the estimate must be 1,200 or greater over the period under consideration, presumably, there would be, on average, fewer than 120 injuries annually over the approximately 10-year period considered by EPI staff. The recent EPI update for the final briefing package is consistent with this assumption.

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7 Since the initial regulatory flexibility analysis (IRFA) was conducted, one importer has entered the market, another firm was purchased (remaining in the market), and a third has established an official U.S. distributor for their products.  
8 Staff made these determinations using information from Dun & Bradstreet and ReferenceUSAGov, as well as firm websites.  
9 JPMA typically allows 6 months for companies with products in their certification program to shift to a new standard for testing and certification once the new standard is published. The version of the standard that firms currently are likely to be testing to is ASTM F2549-14. One revision of the standard has been published since then, but it will become effective for JPMA certification purposes before February 2015. However, many frame carriers are expected to be compliant with ASTM F2549-14a without modification; and firms compliant with earlier versions of the standard are likely to remain compliant as the standard evolves.  
10 These results are preliminary. While the data has undergone one stage of review and clean-up, this work remains ongoing.  
11 Memorandum from Risana T. Chowdhury, Division of Hazard Analysis, Directorate for Epidemiology, dated November 18, 2013, Subject: Frame Child Carriers-Related Deaths, Injuries, and Potential Injuries; January 1, 2003
Combining the maximum annual emergency department-treated injury estimate with the data collected for the DNPES yields less than about 0.94 emergency department-treated injuries per 10,000 frame child carriers in use in U.S. households with children under age 6 annually \((120 \text{ injuries} \div 1.28 \text{ million frame child carriers in use in U.S. households with children under age 6}) \times 10,000\). \(^{12}\)

**Need for, and Objectives of, the Draft Final Rule**

The Danny Keysar Child Product Safety Notification Act requires the CPSC to promulgate mandatory standards for durable infant or toddler products that are substantially the same as, or more stringent than, the voluntary standard. Infant carriers are included in the definition of “durable infant or toddler products” subject to section 104 of the CPSIA. CPSC staff has been generally involved with the voluntary frame child carrier standard, reviewing and assessing ASTM F2549 since its inception. More recently, staff helped develop the revised leg opening and dynamic strength tests that have been added to ASTM F2549 since the staff review and consultation process commenced in April 2012. \(^{13}\) Additionally, CPSC staff worked with ASTM on the modification to the voluntary standard proposed in the May 2014 frame child carrier NPR that has since been incorporated into the most recent version of the voluntary standard ASTM F2549-14a.

**Requirements of the Staff-Recommended Final Rule**

CPSC staff recommends adopting the voluntary ASTM standard for frame child carriers (F2549-14a) without modification. Firms whose carriers do not comply will need to evaluate their products, determine what changes would be required to meet the standard, and decide how to proceed. Noncompliant products would need to be removed from the U.S. market or modified to meet the ASTM standard F2549-14a. Some of the more significant requirements from ASTM F2549-14a are presented below. Changes made since the NPR are in italics:

- Locking and latching mechanisms—intended to prevent unintentional folding of the carrier while in use.
- Unintentional folding—intended to prevent unintentional folding of any stand designed to keep the carrier upright while standing freely.
- Leg openings—intended to prevent smaller children from slipping through a single leg opening. This requirement was modified for version F2549-13 to, among other changes, mimic real-world adjustments better by using a CAMI infant dummy as an occupant surrogate.

\(^{12}\) Using the 95% confidence interval values for frame child carriers in use yields an annual estimate of 0.71 to 1.36 emergency department-treated injuries per 10,000 frame child carriers in use in U.S. households with children under age 6.

\(^{13}\) Lee, 2013.
• Dynamic strength—along with the static load requirements, intended to prevent breaks/disengagement of the frame or fasteners, seam separation, or retention system slippage during use. This was modified for version F2549-14 to accommodate the manufacturer’s recommended maximum weight; prior versions of the standard used a 40-pound weight for the test procedure, regardless of whether the carrier was intended to accommodate heavier children.

• Static load—along with the dynamic strength requirements, intended to prevent breaks/disengagement of the frame or fasteners, seam separation, or retention system slippage during use.

• Stability—intended to prevent carriers with stands designed to keep the carrier upright from tipping over while standing freely.

• Retention systems—such systems, including shoulder restraints, are required and must be attached prior to shipment. The pass/fail criteria proposed in the May 2014 NPR was added in version F2549-14a.

• Handle integrity—intended to prevent the frame or handle from breaking, disengaging, or separating during use.

The voluntary standard also includes: (1) torque and tension tests to prevent removal of components; (2) requirements to prevent entrapment and cuts (minimum and maximum opening size, coverage of exposed coil springs, small parts, hazardous sharp edges or points, smoothness of wood parts, and edges that can scissor, shear, or pinch); (3) marking and labeling requirements; (4) requirements for the permanency and adhesion of labels; (5) requirements for instructional literature; and (6) toy accessory requirements. ASTM F2549-14a includes no reporting or recordkeeping requirements.

**Issues Raised by Public Comments**

Several comments were submitted in response to the NPR that related to the IRFA. The full comments and their responses can be found in the briefing memorandum, but they include:

1. What constitutes a domestic manufacturer? CPSC staff uses U.S. Census Bureau guidelines to determine whether a firm is domestic, as well as whether it is a manufacturer.

2. What is meant by an insignificant impact? The impact is expected to be small enough that changes to a firm’s current business operations would be limited or largely unaffected.

3. Would the proposed rule have been different if most or all small businesses were found to be significantly impacted? No, the statute requires adoption of the voluntary standard or a more stringent standard; the Commission has no legal ability to adopt a less stringent standard. Thus, by proposing the adoption of the voluntary standard without any additional requirements, the Commission has adopted the least stringent (and least burdensome) rule allowed by law.
4. Why was gross income used rather than net income or profit? Use of gross income data is consistent with SBA guidance and such data were readily available, while net income/profit data was not.

5. Why was the American Baby Group’s survey used when the data could be biased? The survey data was not used to determine the impact of the proposed rule on firms, and therefore, no bias entered into the IRFA.

6. The cost-benefit ratio should be kept “appropriate” and alternatives should be provided for the proposed rule. No cost benefit analysis was required or conducted for the rule. The CPSIA, the legal basis for the frame child carrier regulation, requires only that a reduction in the risk of injury be considered. The statute does not permit adoption of a less stringent standard than the voluntary standard, even when it would reduce the impact on small firms. A later effective date is permitted, however, and has been incorporated in response to a comment.

No changes were made to the substance of the mandatory standard in the staff-recommended rule on the basis of the above comments. However, one public comment submitted in response to the NPR resulted in a change to the staff-recommended effective date. The commenter said that the rule would cause “damaging economic significance” to their company and requested that the Commission consider “alternatives to decrease the cost to small domestic businesses.” Four frame child carrier suppliers provided information on the timeframe required to develop a compliant product. The minimum amount of time was 6 months, but all but one firm believed it would take a longer amount of time. Most believed that at least 12 months would be required and one firm thought it would take as long as 18 months. Given the commenter’s concern about the “damaging economic significance” to their company and staff’s inability to rule out a significant economic impact on at least one small firm (i.e., the impact could not be determined or quantified), staff now recommends an 18 month effective date to reduce the impact on small businesses.

Other Federal or State Rules

There are two federal rules that would interact with the frame child carrier mandatory standard: (1) Testing and Labeling Pertaining to Product Certification (16 C.F.R. part 1107); and (2) Requirements Pertaining to Third Party Conformity Assessment Bodies (16 C.F.R. part 1112).

The testing and labeling rule (16 C.F.R. part 1107) requires that manufacturers of children’s products subject to product safety rules certify, based on third party testing, that their children’s products comply with all applicable safety rules. Because frame child carriers will be subject to a mandatory children’s product safety rule, they will also be subject to the third party testing requirements, including record keeping, at the time when the frame child carrier rule becomes effective.

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In addition, the 16 C.F.R. part 1107 rule requires the third party testing of children’s products to be conducted by CPSC-accepted laboratories. Section 14(a)(3) of the Consumer Product Safety Act (CPSA) requires the Commission to publish a notice of requirements (NOR) for the accreditation of third party conformity assessment bodies (i.e., testing laboratories) to test for conformance with each children’s product safety rule. Existing NORs that have been issued by the Commission are listed in 16 C.F.R. part 1112. Consequently, staff recommends that the Commission finalize an amendment to 16 C.F.R. part 1112 that would add the frame child carrier rule to the list of rules for which the Commission has issued an NOR.

**Impact on Small Businesses**

There are approximately 16 firms currently known to be marketing frame child carriers in the United States, 14 of which are domestic. Under U.S. Small Business Administration (SBA) guidelines, a manufacturer of frame child carriers is categorized as small if the entity has 500 or fewer employees, and importers and wholesalers are considered small if they have 100 or fewer employees. We limited our analysis to domestic firms because SBA guidelines and definitions pertain to U.S.-based entities. Based on these guidelines, about 11 of the identified 16 firms are small—four domestic manufacturers, six domestic importers, and one domestic firm with an unknown supply source. There may be additional unknown small domestic frame child carrier suppliers operating in the U.S. market.

The impact of the staff-recommended final rule on the domestic manufacturers and importers considered to be small depends upon two factors: (1) whether, and the degree to which, their frame child carriers comply with the voluntary standard; and (2) the importance of frame child carriers to the firm’s overall product line. The effect of these two factors on small manufacturers and small importers is discussed below.

**Small Manufacturers**

Aside from third party testing requirements, which we discuss below, the staff-recommended final rule is likely to have little or no impact on the three (of four) small domestic manufacturers whose frame child carriers are compliant with the ASTM voluntary standard currently in effect for JPMA testing and certification purposes (F2549-14). These firms are anticipated to remain compliant with the voluntary standard as it changes because they follow, and in at least one case, participate actively in the voluntary standard development process. Therefore, compliance with the evolving voluntary standard is part of an established business practice. ASTM F2549-14a, the voluntary standard that staff recommends the Commission adopt by reference as the frame child carrier rule, will be in effect already for JPMA testing and certification purposes, before the mandatory standard becomes final; and these firms are likely to be in compliance based on their history.

The remaining small manufacturer would experience some economic impacts of unknown size. Based on discussions with a company representative, this firm does not know whether its products comply with the voluntary standard. When contacted by EC staff prior to the NPR, the firm was unaware of the ASTM standard and it does not appear that the firm has been able to test...
its products during the intervening period of time. Initially the company’s representative indicated that the firm would likely discontinue production of its frame child carriers regardless of whether they complied with the frame child carrier rule or not. However, it now seems likely that the company will stay in the market and modify its frame child carriers if necessary to meet the final rule. This firm produces many other products and has indicated that frame child carriers do not represent a large portion of the firm’s product line. However, the extent of the changes that may be required to meet the mandatory standard are unknown, as is the precise percentage of revenues that frame child carriers constitutes for the firm. Because we have no basis for quantifying the size of the impact, we cannot rule out a significant economic impact for this firm.\(^\text{15}\)

The staff-recommended 18-month effective date should help reduce the impact of the staff-recommended final rule on the known small manufacturer whose frame child carriers may not comply with the rule. This would give the firm additional time to develop new/modified products and spread costs over a longer time-frame.

Under section 14 of the CPSA, once the new frame child carrier requirements become effective, all manufacturers will be subject to the additional costs associated with the third party testing and certification requirements under the testing rule, \textit{Testing and Labeling Pertaining to Product Certification} (16 C.F.R. part 1107). Third party testing will include any physical and mechanical test requirements specified in the final frame child carrier rule. Firms must test for lead and may be required to test for phthalates regardless of any rule for frame child carriers. Third party testing costs are in addition to the direct costs of meeting the frame child carrier standard.

CPSC staff contacted several firms regarding testing costs. Two firms provided estimates that included both physical and mechanical testing to the ASTM standard, as well as lead and phthalate testing. Firms must test for lead and may be required to test for phthalates regardless of any rule for frame child carriers. Including lead and phthalate testing, one firm estimated testing costs to be \(800 - 1,100\) per unit tested and the other firm estimated the costs to be about \(1,300\) per unit. Estimates provided by suppliers for other section 104 rulemakings indicate that around 40 percent to 50 percent of testing costs can be attributed to structural requirements, with the remaining 50 percent to 60 percent resulting from chemical testing (\textit{e.g.}, lead and phthalates). Therefore, staff estimates the ASTM voluntary standard portion of these testing cost estimates to be \(320\) to \(550\) per sample tested (\(800 \times .4\) to \(1,100 \times .5\)) and \(520\) to \(650\) per sample tested (\(1,300 \times .4\) to \(1,300 \times .5\)), respectively. A third firm provided an estimate of \(500\) - \(750\) for testing to the ASTM standard separately. As can be seen from these estimates, testing costs can vary widely. Elements that can influence costs include where the testing is performed and whether a firm can negotiate rates based on volume for one or more products.

Staff’s review of the frame child carrier market shows that, on average, each small domestic manufacturer supplies three different models of frame child carriers to the U.S. market annually. Therefore, if third party testing were conducted every year, third party testing costs for each

\(^{15}\) It should be noted that the company representative believes that the impact of the rule on the firm will be significant. However, much of the perceived impact is due to third party testing costs which are considered separately later in this section.
manufacturer would be about $960 ($320 x 3) to $2,250 ($750 x 3) annually, if only one sample were tested for each model. Based on an examination of each small domestic manufacturers’ revenues from recent Dun & Bradstreet (D&B) or ReferenceUSAGov reports, the impact of third party testing to ASTM F2549-14a will be significantly less than one percent of revenue for the three small domestic manufacturers for whom revenue data is available (i.e., testing costs less than one percent of gross revenue). Although the testing and labeling rule (16 C.F.R. part 1107) is not explicit regarding the number of samples firms will need to test to meet the “high degree of assurance” criterion, more than 20 units per model would be required before the testing costs of any of the three small manufacturers with available revenue data would exceed one percent of gross revenue.\(^{16}\) However, testing costs could be significant for the one small manufacturer for which revenue data was unavailable, given that they are a recent entrant to the frame child carrier market and manufacture no other products.

**Small Importers**

As noted above, there are six small importers of frame back carriers, with two of them currently importing compliant carriers. In the absence of a mandatory regulation, these two small importers of frame child carriers would likely remain in compliance with new versions of the standard. Given that the two small importers have developed a pattern of compliance with the ASTM voluntary standard as it evolves and that the staff-recommended final rule is the voluntary standard, ASTM F2549-14a, the two small importers of compliant products would likely experience little or no direct costs if the staff recommendation was implemented.

The extent of the economic impact on the four small importers with noncompliant frame child carriers will depend upon the product changes required to come into compliance and the response of their supplying firms. Because no small importers with noncompliant frame child carriers responded to requests for information, staff cannot estimate the precise economic impact on these firms.

However, in general, if their supplying firm comes into compliance, the importer could elect to continue importing the frame child carriers. Any increase in production costs experienced by their suppliers as a result of changes made to meet the mandatory standard may be passed on to the importers. If an importer decides that they are unwilling or unable to accept the increased costs, or if their supplier decides not to comply with the mandatory standard, there are three alternatives courses of action available. First, they could find another supplier of frame child carriers. This could result in increased costs as well, depending, for example, on whether the alternative supplier must modify their carriers to comply with the mandatory standard. Second, they could import a different product in place of their frame child carriers. This alternative would help mitigate the economic impact of the mandatory standard on these firms. Finally, they could stop importing frame child carriers and make no other changes to their product line.

\(^{16}\) One of these firms commented that their actual testing costs will be higher than estimated in the NPR. However, even if the firm’s testing costs were twice those estimated here, it is unlikely that testing costs would exceed one percent of the firm’s publically reported gross revenue.
As with manufacturers, all importers will be subject to third party testing and certification requirements, and consequently, will be subject to costs similar to those for manufacturers if their supplying foreign firm(s) does not perform third party testing. It does not appear likely that these costs would exceed one percent of gross revenue for the two small domestic importers for which revenue information is available, unless more than 10 or 30 units per model were required to be tested to provide a “high degree of assurance,” respectively. The impact on the other four small importers could not be determined or quantified, and thus, we cannot rule out a significant economic impact.

**Alternatives**

Section 104 of the Consumer Product Safety Improvement Act (CPSIA) requires that the Commission promulgate a standard that is either substantially the same as the voluntary standard or more stringent. Therefore, the staff-recommended final frame child carrier rule (adoption of the voluntary standard, ASTM F2549-14a, with no modifications) is the minimum required by law. Consequently, the sole recommendation that staff can make to minimize (but not eliminate) the rule’s impact is a longer effective date. A later effective date would reduce the economic impact on small frame child carrier firms in two ways. One, firms would be less likely to experience a lapse in production/importation, which could result if they are unable to comply and third party test within the required timeframe. Two, firms could spread costs over a longer time period, thereby reducing their annual costs, as well as the present value of their total costs.

Because the economic impact on small firms could not be determined or quantified, staff cannot rule out a significant impact. Therefore, staff is now recommending an 18 month effective date, which was the maximum period of time frame child carrier firms familiar with the ASTM standard estimated they would need for new product development.

**Small Business Impacts of the Accreditation Requirements for Testing Laboratories**

In accordance with section 14 of the CPSA, all children’s products that are subject to a children’s product safety rule must be tested by a CPSC-accepted third party conformity assessment body (i.e., testing laboratory) for compliance with applicable children’s product safety rules. Testing laboratories that want to conduct this testing must meet the NOR pertaining to third party conformity testing. NORs have been codified for existing rules at 16 C.F.R. part 1112. Consequently, staff recommends that the Commission finalize the proposed amendment to 16 C.F.R. part 1112 that would establish the NOR for testing laboratories that want to test frame back carriers for compliance with the frame child carrier final rule. This section assesses the impact of the amendment on small testing laboratories.

A Final Regulatory Flexibility Analysis (FRFA) was conducted as part of the promulgation of the original 1112 rule (78 FR 15836, 15855-58), as required by the RFA. Briefly, the FRFA concluded that the accreditation requirements would not have a significant adverse impact on a substantial number of small laboratories because no requirements were imposed on laboratories that did not intend to provide third party testing services. The only laboratories that were
expected to provide such services were those that anticipated receiving sufficient revenue from the mandated testing to justify accepting the requirements as a business decision.

Based on similar reasoning, amending 16 C.F.R. part 1112 to include the NOR for the frame child carrier standard will not have a significant adverse impact on small laboratories. Moreover, based upon the number of laboratories in the United States that have applied for CPSC acceptance of the accreditation to test for conformance to other juvenile product standards, we expect that only a few laboratories will seek CPSC acceptance of their accreditation to test for conformance with the frame child carrier standard. Most of these laboratories will have already been accredited to test for conformance to other juvenile product standards, and the only costs to them would be the cost of adding the frame child carrier standard to their scope of accreditation. As a consequence, the Commission could certify that the NOR for the frame child carrier standard will not have a significant impact on a substantial number of small entities.