



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
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This document has been electronically
approved and signed.

DATE: August 23, 2017

BALLOT VOTE SHEET

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Mary T. Boyle, General Counsel
Patricia H. Adkins, Executive Director

FROM: Patricia M. Pollitzer, Assistant General Counsel
Mary A. House, Attorney, OGC

SUBJECT: Final Rule: Safety Standard for Infant Bouncer Seats

BALLOT VOTE DUE Tuesday, August 29, 2017

The Office of the General Counsel is providing for Commission consideration the attached draft final rule for publication in the *Federal Register*. Pursuant to section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), the draft final rule would incorporate by reference the voluntary standard, ASTM F2167-17, *Standard Consumer Safety Specification for Infant Bouncer Seats*, as the mandatory federal safety standard for infant bouncer seats. Staff's recommended draft final rule includes two modifications to warning label content and placement to strengthen the requirements and further reduce the risk of injury associated with falls from infant bouncer seats. Additionally, the draft final rule amends the Commission's regulation regarding third party conformity assessment bodies to include the mandatory standard for infant bouncer seats in the list of notices of requirements issued by the Commission.

Please indicate your vote on the following options:

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

(Signature)

(Date)

CPSC Hotline: 1-800-638-CPSC(2772) ★ CPSC's Web Site: <http://www.cpsc.gov>

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

(Signature)

(Date)

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

(Signature)

(Date)

- IV. Take other action. (Please specify.)

(Signature)

(Date)

Attachment: Draft *Federal Register* Notice: Final Rule for Safety Standard for Infant Bouncer Seats

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Billing Code 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1112 and 1229

[Docket No. CPSC-2015-0028]

Safety Standard for Infant Bouncer Seats

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 standard, if the Commission determines that more stringent requirements would further reduce the risk of injury associated with the product. The Commission is issuing this final rule establishing a safety standard for infant bouncer seats (bouncer seats) in response to the direction of section 104(b) of the CPSIA. Additionally, the Commission is finalizing an amendment to 16 CFR part 1112 to include 16 CFR part 1229 in the list of notice of requirements (NORs) issued by the Commission.

DATES: This rule will become effective [INSERT DATE 6 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 6 MONTHS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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FOR FURTHER INFORMATION CONTACT: Keysha Walker, Compliance Officer, U.S.

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SUPPLEMENTARY INFORMATION:

I. Background and Statutory Authority

The CPSIA was enacted on August 14, 2008. Section 104(b) of the CPSIA 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. Standards issued under section 104 are to be “substantially the same as” the applicable voluntary standards or more stringent than the voluntary standard, 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,” and the statute specifies twelve categories of products that are included in the definition, including walkers, carriers and various types of children’s chairs. When issuing a regulation governing product registration under section 104, the Commission determined that an “infant bouncer” falls within the definition of a “durable infant or toddler product.” 74 FR 68668 (Dec. 29, 2009); 16 CFR 1130.2(a)(15).

On October 19, 2015, the Commission issued a notice of proposed rulemaking (NPR) for infant bouncer seats. 80 FR 63168. The NPR proposed to incorporate by reference the 2015 version of the voluntary standard, ASTM F2167 *Standard Consumer Safety Specification for Infant Bouncer Seats* (ASTM F2167), as a mandatory consumer product safety rule with several

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modifications to the content, format, and placement of warning labels and instructions, to strengthen the standard.

In this document, the Commission is issuing a mandatory consumer product safety standard for bouncer seats. 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 rule, largely through the ASTM process. Based on revisions to the voluntary standard since the NPR published, the final rule incorporates by reference the most recent voluntary standard for infant bouncer seats, developed by ASTM International, ASTM F2167-17, with two modifications related to warning label content and placement. These modifications strengthen the standard by requiring a more stringent warning to caregivers to use the restraints, even if an infant falls asleep in the bouncer, and requires the fall hazard warning to be placed on the upper seat back of the bouncer seat, to ensure that caregivers read and heed the warning. The Commission's more stringent requirements are intended to further reduce the risk of injury to infants that fall from, and with, bouncer seats, especially bouncer seats that are placed on an elevated surface.

Additionally, the final rule amends the list of NORs issued by the Commission in 16 CFR part 1112 to include the standard for infant bouncer seats. Under section 14 of the 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 conformity with a children's product safety rule. Amending part 1112 adds an NOR for the infant bouncer seat standard to the list of children's product safety rules.

II. Product Description

A. Definition of “Bouncer Seats”

Section 1.2 of ASTM F2167-17 defines an “infant bouncer seat” as: “a freestanding product intended to support an occupant in a reclined position to facilitate bouncing by the occupant, with the aid of a caregiver or by other means.” Additionally, section 1.2 states that infant bouncer seats are intended for “infants who have not developed the ability to sit up unassisted (approximately 0 to 6 months of age).”

Bouncer seats vary widely in style and complexity, but typically, bouncer seats consist of a cloth cover stretched over a wire or tubular frame. Wire frame bouncers have two designs. The forward bend design is constructed with the seating area supported from the front side of the product. The second wire frame design is a rear bend design. In the rear bend design, the seat is supported from the rear side of the product. Other bouncer designs are also currently available, including, but not limited to, products with individual wire legs, solid bases, and spring designs. These infant bouncer designs use different methods to support the seat and are intended for “bouncing,” as defined in ASTM F2167.

All bouncer seats support the child in an inclined position, and some brands have adjustable seat backs. Various bouncer seat models include a “soothing unit” that vibrates or bounces the chair, and may play music or other sounds. Most bouncer seats also feature an accessory bar with attached toys that are, or at some point will be, within the child’s reach. Most of the bouncer seat models examined by Commission staff provide a 3-point restraint system, consisting of wide cloth crotch restraints and short adjustable waist straps with plastic buckles. Only two models of bouncer seats reviewed by CPSC for the NPR employed upper body restraints. Many bouncer seat brands also include an “infant insert,” intended for use to support smaller babies. Tabs C and D, Staff Briefing Package: Infant Bouncer Seats Notice of Proposed

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Rulemaking, dated September 30, 2015 (Staff NPR Briefing Package), available at:

<http://www.cpsc.gov/Global/Newsroom/FOIA/CommissionBriefingPackages/2015/ProposedRuleSafetyStandardforInfantBouncerSeatSeptember302.pdf>.

B. Market Description

For the final rule, staff identified 23 firms supplying infant bouncer seats to the U.S. market, with several firms moving into or out of the market since the NPR was published. The 23 identified firms primarily specialize in the manufacture and/or distribution of children's products, including durable nursery products. Eight of the 23 known firms are domestic manufacturers and 8 are domestic importers. The remaining seven firms are foreign (four manufacturers, two importers, and one retailer).¹ Tab C, Staff Briefing Package: Final Rule for Infant Bouncer Seats, dated August 23, 2017 (Staff Final Rule Briefing Package), available at: **[Insert URL]**.

Staff expects that the infant bouncer seats of 14 of these firms already comply with ASTM F2167 because the firms either: (1) have their bouncers certified by the Juvenile Products Manufacturers Association (JPMA) (five firms); (2) claim compliance with the voluntary standard (eight firms); or (3) have been tested to the ASTM standard by CPSC staff (one firm).²

III. Incident Data

For the NPR, CPSC's Directorate for Epidemiology, Division of Hazard Analysis, described 277 reported incidents involving bouncer seats, including 11 fatalities and 51 injuries, occurring between January 1, 2006 and February 2, 2015. The incidents described in the NPR were based on reports involving victims 12 months old and younger in the Injury or Potential

¹ Staff categorized each firm using information from Dun & Bradstreet and ReferenceUSAGov, as well as firm websites.

² JPMA typically allows six months for products in their certification program to shift to a new standard once it is published. Therefore, firms are likely already complying with ASTM F2167-16, which was published in May 2016. Firms are not expected to comply with the recently published ASTM F2167-17 until December 2017.

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Injury Incident (IPII), In-Depth Investigation (INDP), and Death Certificates (DTHS) databases (collectively referred to as Consumer Product Safety Risk Management System data, or CPRMS data). A detailed discussion of the incidents and hazard patterns developed for the NPR can be found in Tab A of the Staff NPR Briefing Package.

A. CPRMS Data

For the final rule, CPSC staff reviewed bouncer seat incident reports in CPRMS from February 2, 2015 through July 6, 2016. CPSC staff found 70 incident reports in addition to those discussed in the NPR, including one fatality and three injuries. The fatality involved a 4-month-old female who died after suffering a fractured skull injury when the infant bouncer she was seated in fell from a table. Two of the reported injuries were head contusions. A 5-month-old male sustained a head contusion when a bouncer seat bent backward to the floor. A 6-month-old male sustained a head contusion when a bouncer cover came off of the wire frame and the infant flipped forward, striking his head on the battery compartment. In another reported incident, the victim suffered minor leg burns from a hot metal bar under a bouncer cover. Tab A, Staff Final Rule Briefing Package.

Staff did not identify any hazards in the updated incident data that were not included in the hazard patterns described in the NPR (product design, structural integrity, toy bar-related, stability, chemical/electric hazards, restraints, hazardous environment), which specifically identified product design and structural integrity as the top two product-related hazards (in terms of frequency of occurrence). Staff found that product design and structural integrity continue to be the top two product-related hazards (in terms of frequency) for the updated CPRMS data. Of the 70 new incident reports involving bouncer seats, 51 incident reports described issues with product design, and 13 incident reports described issues with structural integrity. Staff determined that almost all of the issues with product design were related to lopsided or low-

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riding bouncer frames. Data for the final rule can be found in Tab A of the Staff Final Rule Briefing Package.

B. NEISS Data

For the NPR, CPSC staff found 672 bouncer-related incidents, including two fatalities, reported in the National Electronic Injury Surveillance System (NEISS) records retrieved for bouncer incidents from January 1, 2006 to December 31, 2013, involving children 12 months old and younger. Staff found that 385 cases, or an estimated 9,200 injuries, occurred in hazardous environments (counters, tables, and other elevated surfaces).

Staff updated information on bouncer-related incidents from the NEISS records for the final rule. From January 1, 2014 through December 31, 2015, staff found 202 additional NEISS records describing infant bouncer incidents. Staff's inspection of the updated NEISS data revealed that 100 cases, or an estimated 2,800 injuries, took place in hazardous environments. The remaining 102 cases, or an estimated 2,800 injuries, took place on the floor or an unknown location. Staff found no additional fatalities in the NEISS data during this time frame. Staff estimates that 4,700 (85%) bouncer injuries involved the head and face.

Estimated NEISS Bouncer Injuries, 2006-2015 (age 0-1)

Year	Cases	Estimated Injuries
2006	67	1,400
2007	66	1,700
2008	74	1,600
2009	86	2,200
2010	94	2,300
2011	121	3,400
2012	90	2,500
2013	74	2,100
2014	98	2,900
2015	104	2,700
2006-2015	877	22,800

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Based on the annual estimates provided in the table, staff found a statistically significant upward trend (p-value of 0.006) in the estimated emergency department-treated injuries involving bouncers for victims under 1-year-old from 2006 to 2015.

IV. Product Recalls

The NPR described two recalls of infant bouncer seats since January 2006, involving two different firms, one recall in April 2007³ (involving breakage of a tubular steel frame) and another recall in July 2009⁴ (involving small, sharp metal objects that could protrude through the bouncer fabric). No injuries were associated with either product at the time of the recall. See Tab E, Staff NPR Briefing Package. For the final rule, staff reports that no additional recalls involving bouncer seats have occurred.

V. Overview and Assessment of ASTM F2167

A. Overview

The voluntary standard for infant bouncer seats, ASTM F2167, *Standard Consumer Safety Specification for Infant Bouncer Seats*, is intended to minimize the risk of injury or death to infants in bouncer seats associated with falls from elevated surfaces, product disassembly or collapse, stability, and suffocation. ASTM F2167 was first approved in December 2001, and the standard published in January 2002. Since then, ASTM has revised the standard 11 times. Tab C of the Staff NPR Briefing Package includes a description of these revisions through 2015.⁵

³ CPSC link to recalled product: <http://www.cpsc.gov/en/Recalls/2007/Infant-Bouncer-Seats-Recalled-Due-to-Frame-Failure/>.

⁴ CPSC link to recalled product: <http://www.cpsc.gov/en/Recalls/2009/BabySwede-LLC-Recalls-Bouncer-Chairs-Due-to-Laceration-Hazard/>.

⁵ Prior to the NPR publishing in October 2015, ASTM F2167 was revised several times as part of the rulemaking consultation process. In February 2014 (ASTM F2167-14) the standard was revised to improve the sideward and rearward stability tests. Additionally in 2014, ASTM F2167-14a included changes to the stability test to make the ASTM standard more strict, to address tip-over incidents, and to add requirements and test procedures to address incidents involving battery leakage, corrosion, and overheating.

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More recently, in May 2016, ASTM revised the standard to add specific developmental guidance for caregivers about when to stop using the bouncer, and ASTM removed a general requirement for banned toys or other articles because those requirements do not apply to infant bouncer seats. As discussed below, the standard was subsequently revised in June of 2017 to incorporate changes recommended by ASTM's Ad Hoc Task Group⁶ concerning warning label formatting requirements, and to add a requirement that limits the maximum weight of an occupant in an infant bouncer seat. The June 2017 version of the voluntary standard also removed a requirement for manufacturers of bouncer seats to change the model number whenever the product underwent a significant structural or design modification. We agree with ASTM that although changing the model number represents a best practice, most ASTM standards do not include the statement, and such practice does not impact the safety of the product.

B. Assessment of the Voluntary Standard

For the NPR, CPSC staff examined the relationship between the performance requirements in ASTM F2167-15 and each of the hazard patterns staff identified in the incident data for bouncer seats. Tab C, Staff NPR Briefing Package. Based on staff's assessment, the Commission issued the NPR proposing to incorporate ASTM F2167-15 with the following modifications to warnings content, placement, and format:

- Revised content of the warnings, markings, and instructions:
 - modify text in the warnings stating to use the restraints “*even if baby is sleeping*”;

⁶ The Ad Hoc Task Group was formed by ASTM and consists of members of the various voluntary standards groups whose standards are affected by the durable nursery product rules. The purpose of the Ad Hoc Task Group is to harmonize the wording and warning label format of durable infant and toddler products. Ad Hoc Task Group recommendations for warning statements were originally published as a reference document titled, “Ad Hoc Wording – May 4, 2016,” as part of the F15 Committee Documents, and subsequently, the recommendations were revised and published in October 2016, with the title, “Ad Hoc Approved Wording, Revision A – October 17, 2016” (Ad Hoc Approved Wording).

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- change the text in the warnings to read, “stop using when baby starts trying to sit up”; and
- change the developmental guidance in the instructions, if stated, to read: “from birth (or “0”) until baby starts trying to sit up.”
- Restricted the fall hazard label on the front surface of the bouncer to be adjacent to the area where the child’s head would rest, and modified the visibility test to reflect this requirement.
- Specified a standard format (including black text on a white background, table design, bullet points, and black border) for the warnings on the product and in the instructions.

The most recent version of the voluntary standard for bouncer seats, ASTM F2167-17, was approved on June 1, 2017, and published in June 2017. ASTM F2167-17 includes modified and new performance and labeling requirements developed by ASTM in conjunction with stakeholders and CPSC staff on the ASTM subcommittee task group, to address the hazards associated with bouncer seats. ASTM F2167-17 addresses several of the hazards identified by the Commission in the NPR. Accordingly, after reviewing and considering comments received in response to the NPR, as well as the work of the Ad Hoc Task Group, the Commission incorporates by reference ASTM F2167-17, with two modifications that were identified in the NPR related to warning content and warning placement, as the mandatory safety standard for infant bouncer seats. Below we assess ASTM F2167-17 and explain how it differs from what the Commission proposed.

1. Content of the Warnings, Markings, and Instructions

The NPR proposed to incorporate by reference ASTM F2167-15, with modifications to warning, marking, and instruction requirements. ASTM F2167-15 advised caregivers: “Always use restraints. Adjust to fit snugly.” Based on the incident data that relate deaths to suffocation among unrestrained infants while they slept, and relate serious head injuries to unrestrained infants due to falls from bouncer seats that are placed on elevated surfaces and falls from

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bouncer seats that are being carried by caregivers, the Commission stated in the NPR that the voluntary standard was inadequate to address the risk of injury to infants from falls out of bouncer seats, or the risk of suffocation among unrestrained infants who are sleeping. In the NPR, the Commission proposed warning language stating: “Adjust to fit snugly, *even if baby is sleeping.*” Tab D, Staff NPR Briefing Package.

The newest version of the voluntary standard, ASTM F2167-17, still does not require a warning statement that caregivers should use the restraints, even if an infant is asleep. We disagree with this approach. We note that some NPR commenters were concerned by the addition of language to the product warnings regarding sleep because such language may suggest that bouncer seats are intended to be used for long-term, unattended, sleep. However, CPSC staff advises that young infants, such as those who are intended to use bouncer seats, spend more time asleep than awake.⁷ Infants spending more than brief periods in a bouncer seat will fall asleep on occasion (and caregivers will place infants to sleep in bouncer seats under some circumstances), just as infants will fall asleep in strollers, swings, and car-seat carriers. It may be counterintuitive, and therefore unlikely to occur to consumers, that products made for infants’ use, especially those that have features intended to sooth and comfort infants, would be unsafe places for infants to sleep. In fact, despite claims that bouncer seats are not intended for children to sleep in, CPSC staff found that some manufacturers’ marketing suggests that bouncers are intended for sleep as well as play. Moreover, incident data and Health Sciences’ assessment demonstrate that the severity of injury from a fall from a bouncer seat increases for a child who is unrestrained. Accordingly, in the final rule, the Commission requires that the fall hazard warning state that caregivers should use the restraints, *even if baby falls asleep.*

⁷ For example, see the American Academy of Pediatrics website, <http://www.healthychildren.org/English/ages-stages/baby/sleep/Pages/default.aspx>.

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Based on staff's recommendation and the work of the Ad Hoc Task Group, the final rule uses the phrase "falls asleep" instead of the phrase "is sleeping" that the Commission had proposed in the NPR. This change aligns with wording approved by the Ad Hoc Task Group, which is "*Never leave child unattended, even if child falls asleep.*" The Ad Hoc Task Group intends for this warning to be used on products for infants who are likely to fall asleep in the product, but which are not intended for periods of unattended sleep (*i.e.* bouncers, swings, infant rockers, and handheld carriers).⁸ The Commission notes that the final rule does not preclude manufacturers from including an additional statement indicating that bouncers are not intended for long term sleep. Accordingly, the required fall and suffocation warning label text regarding use of restraints for the final rule is:

- Always use restraints and adjust to fit snugly, even if baby falls asleep.

ASTM F2167-17 includes the other modifications the Commission had proposed for warning statement requirements. Specifically, sections 8.5.2.1 and 9.2.1 Fig. 11 of ASTM F2167-17 requires text in the warnings to state: "stop using when baby starts trying to sit up." ASTM F2167-17 requires additional text in the suffocation hazard warning label to limit the maximum weight for an occupant in an infant bouncer seat. The rationale for ASTM's change is based on surveillance of the marketplace, which demonstrated that some manufacturers have weight limits that do not correlate to the developmental milestones contemplated in the current warnings. Section 8.5.2.1 of ASTM F2167-17 requires text in the warnings to instruct caregivers to: "STOP using bouncer when baby starts trying to sit up or has reached [insert manufacturer's recommended maximum weight, not to exceed 20 lb], whichever comes first."

⁸ During the April 2017 ASTM meetings, several Ad Hoc Task Group members requested the removal of this sentence from the Ad Hoc recommendations because no subcommittee had adopted the sentence. In the discussions, some manufacturers stated that these products are not appropriate for sleep, stating that the language "even if baby falls asleep," may mislead caregivers. The Ad Hoc Group balloted the removal of the sentence in June 2017; however, the ballot received multiple negative votes and did not pass.

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2. Warning Label Placement and Visibility Test

The NPR proposed a modification to ASTM F2167-15's requirement for label placement. ASTM F2167-15 required that the fall hazard label be placed on the front surface of the bouncer seat back so that it is visible when a newborn CAMI dummy is placed in the bouncer seat. In the NPR, the Commission assessed this provision of the voluntary standard and found that it did not adequately address the risk of injury to infants falling from bouncer seats placed on elevated surfaces, a foreseeable misuse of infant bouncer seats. Tab D, Staff NPR Briefing Package. To strengthen the standard and further reduce the risk of injury, the NPR proposed that the fall hazard warning label be on the front surface of the bouncer seat, adjacent to where the child's head would rest, and the NPR also modified the visibility test. ASTM F2167-17 retains the fall hazard warning placement and corresponding visibility test from ASTM F2167-15. Thus, the current voluntary standard still does not address the Commission's concern about the visibility of the fall hazard warning.

NPR Commenters expressed concern that some products were designed with insufficient space in the area adjacent to the child's head to accommodate the necessary warning labels. Commenters were also concerned about the repeatability of the visibility test proposed in the NPR. We note, however, that staff's research on the seat back space, including models with narrow seat backs, did not corroborate the commenters' concerns. Nevertheless, to enhance test repeatability and to address the comments regarding insufficient seat back space for warning labels, the final rule allows a larger area for warning label placement than proposed in the NPR and clarifies the corresponding visibility test.

The visibility test in the final rule is based on ASTM F2167-17. Using the CAMI dummy, as shown in Figure 1 below, the allowable area for warning label placement starts from

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a dotted line that crosses the junctions of underarm and both sides of the torso of the CAMI dummy.



Figure 1. Warning Label Placement

This observable line expands the seat back space allowed for warning labels and clarifies the precision of the visibility test, both of which address commenter concerns.

3. Warning Label Format

The NPR proposed modifications to the requirements in ASTM F2167-15 regarding the format of warning labels noting that ASTM F2167-15 did not provide for a consistent warning label format across infant bouncer seats. Staff evaluated the warnings format in the voluntary standard and recommended that the Commission establish minimum requirements for presenting the hazard information that are consistent with best practices to attract and maintain attention, as well as aid reading and comprehension. Tab D, Staff NPR Briefing Package. Accordingly, the NPR proposed to specify a standard format (including black text on a white background, table design, bullet points, and black border) for the warnings on bouncer seats and in the instructions.

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Since the NPR published in 2015, ASTM's Ad Hoc Task Group issued recommendations regarding warnings intended to apply across juvenile products. These recommendations, based on ANSI Z535.4, *American National Standard for Product Safety Signs and Labels*, have been incorporated into ASTM F2167-17. The Commission notes that Human Factors staff regularly cites ANSI Z535.4 as a baseline in developing warning materials, including those proposed in the bouncer seat NPR. The approved Ad Hoc Task Group recommendations are very similar to the ANSI Z535.4, with modifications to make the recommendations more stringent. The recommendations provide noticeable and consistent warning labels on infant bouncer seats and across juvenile products. Accordingly, for the final rule, the Commission incorporates by reference ASTM F2167-17, without any modifications to the formatting provisions.

VI. Response to Comments

CPSC received six comments in response to the NPR, including a joint letter submitted by four consumer advocacy groups. Three commenters supported the changes proposed in the NPR, and the remaining commenters expressed concern over the Commission's proposed modifications. We summarize and respond to the commenters below.

A. Warning Label Location

Comment 1: One commenter stated that the proposed requirement for the fall hazard warning label to be adjacent to an infant's head would necessitate a wider seat back to accommodate a warning label in multiple languages, which is desirable for international sales. According to the same commenter, the ASTM F15.21 Subcommittee had already evaluated this location and concluded that other locations above and below the infant's head were considered to be just as visible as the locations adjacent to an infant's head. A second commenter stated that the proposed fall hazard label visibility test procedure is not specific and can be misinterpreted

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by test labs. This commenter suggested using the test protocol in the current ASTM standard that uses the CAMI newborn dummy.

Response 1: Based on the incident data and research, the final rule requires that the fall hazard warning label be placed near the child's face. This location allows caregivers to notice the label while making eye contact with the infant, and potentially creates mental images of the consequence ("skull fracture") of not complying with the instructions because the warning label would be placed next to the body part at risk. Tab D, Staff NPR Briefing Package.

Commenters claim that the area on the infant bouncer adjacent to an infant's head could be severely limited in some cases due to the design of the seat back and allowance needed for stitching tolerances. CPSC staff's research did not corroborate this claim. Tab D, Staff NPR Briefing Package. Accordingly, the NPR, 80 FR at 63179-80, invited commenters to provide information on costs and design changes that would be required if the label were required to be next to an infant's head. Staff reports that during the ASTM Ad Hoc Task Group meetings held in January and February 2016, manufacturers provided several examples of juvenile products, including infant bouncer seats, to demonstrate difficulties associated with warning label placement in proposed locations. However, NPR commenters provided neither cost estimates, nor specific comments, other than stating that the location would require a wider seat back and would limit representing multiple languages.

To resolve concerns about the amount of space for warning label placement and address the Commission's concern about an effective warning label, the final rule states the test procedure language in ASTM F2167-17, but clarifies the allowable area for the fall hazard warning label. The fall hazard warning label must be visible when placed above an imaginary horizontal line that crosses through the junctions of underarm and side of the torso (armpits) on both left and right of the CAMI, and not obscured by any part of the dummy. A warning label

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located at or around the infant's shoulders can address the visibility and caregiver motivational concerns expressed in the Human Factors staff memorandum for the NPR (Tab D), and also provide additional surface area to accommodate the recommended warning label.

B. Warning Label Format

Comment 2: Two commenters recommended against the proposed formatting requirements. Commenters specifically highlighted the following proposed warning formatting requirements:

- A heavy black border around the label,
- Delineating message panels with solid lines,
- Black text on white message panel,
- Bullet points preceding precautionary statements,
- Choosing a background color for the signal word panel based on a best contrast against the product material, and
- Using non-condensed style font.

Commenters stated that, in general, ASTM standards provide flexibility to manufacturers to pick colors and formatting features that are most appropriate for the product. One commenter recommended delaying the publication of the final rule for any and all warnings requirements until the warnings format and content revisions proposed in the NPR can be reviewed by ASTM Ad Hoc Task Group, balloted through the ASTM process, and then implemented into F2167. The same commenter also indicated that the formatting requirements in the bouncer NPR and several other NPRs are inconsistent with each other.

Response 2: Human Factors staff at CPSC employs the ANSI Z535.4, *American National Standard for Product Safety Signs and Labels* as a baseline to develop warning materials. Since the NPR was published, the ASTM Ad Hoc Task Group met and made recommendations for

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warning label formatting across juvenile products. The ASTM Ad Hoc Task Group's recommendations are based on ANSI Z535.4 and are more stringent than the ANSI Z535 series. ASTM 2167-17 now incorporates recommendations made by the Ad Hoc Task Group. Accordingly, the final rule incorporates by reference ASTM 2167-17 without any modifications to warning label format.

C. Warning Label Content

Comment 3: Two commenters recommended against the proposed addition of “even if baby is sleeping” to the end of the precautionary statement: “Always use restraints. Adjust to fit snugly.” One commenter believes that this statement implies that sleeping in a bouncer is acceptable and may encourage caregivers to use the product for extended periods of sleep. The second commenter believes that this statement contradicts the warning to never leave children unattended.

Response 3: Incident data associated with bouncer seats demonstrate that unrestrained infants suffer serious head injuries from falls and get into compromised positions that may result in suffocation. Tab A, Staff NPR Briefing Package; Tab A, Staff Final Rule Briefing Package. Young infants will sleep in bouncers as they spend more time asleep than awake. Tab D, Staff NPR Briefing Package. Some bouncers in the market include references to calming and soothing features of a bouncer, as well as appropriateness for short periods of sleep in a bouncer, such as “Your child can also sleep for short periods of time in the bouncer if he or she is content doing so.” Based on incident data, the final rule requires that the warning statement reference sleep to reflect this foreseeable product use scenario and to address the risk of injury from falls.

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In October 2016, the ASTM Ad Hoc Task Group approved a recommended warning to address products likely to be used for short-term sleep.⁹ The Commission agrees with the Ad Hoc Task Group's language and has modified the warning in the final rule to use the phrase "even if child falls asleep" to align with the Ad Hoc Task Group's language. Manufacturers who produce bouncers in which infants should not be allowed to sleep may add language to their warnings statements alerting caregivers to this issue.

Comment 4: One commenter recommended that the ASTM subcommittee reach a consensus on the need for the additional proposed language: "Stop using bouncer when baby starts trying to sit up."

Response 4: At the January 12, 2016 ASTM meeting, the F15.18 subcommittee on Infant Bouncer Seats reviewed and agreed with the Commission's proposed language on developmental guidance. ASTM balloted and approved the proposed language, and such language has been included in ASTM F2167 since the 2016 version of the standard.

D. Other Warning Label Issues

Comment 5: Two commenters recommended that the warning label be attached on the product using embroidery or stamping to increase its permanency.

Response 5: The ASTM standard does not require a certain type of attachment for labels but requires the labels to be tested per section 7.8 to determine the labels' permanency. A similar permanency test procedure is used in other ASTM standards. No data were provided by the commenter, and the Commission has no information suggesting that these requirements are ineffective. Accordingly, the Commission incorporates by reference ASTM F2167-17, without any modification to section 7.8.

⁹ The recommended wording is as follows: "Products likely to be used for infants who are sleeping (*i.e.* bouncers, swings, infant rockers, handheld carriers) that are not intended for periods of unattended sleep, would benefit from this warning about unattended use. *Never leave child unattended, even if child falls asleep.*"

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Comment 6: Three commenters recommended using pictures to clarify warning messages.

Response 6: The Commission acknowledges that well-designed graphics can be useful to increase the noticeability of the warnings as they help capture a user's attention. Pictograms are also helpful for users with limited or no English literacy. However, the design of effective graphics can be difficult. To avoid confusing consumers, a warning pictogram should be developed with an empirical study and well tested on the target audience. Although the Commission may take action in the future if it believes graphic symbols are needed to reduce the risk of injury associated with bouncer seats, the rule permits, but does not mandate, such supporting graphics.

VII. Incorporation by Reference

Section 1229.2(a) of the final rule provides that infant bouncer seats must comply with applicable sections of ASTM F2167-17. The OFR has regulations concerning incorporation by reference. 1 CFR part 51. These regulations require that, for a final rule, agencies must discuss in the preamble to the rule the way in which materials that the agency incorporates by reference are reasonably available to interested persons, and how interested parties can obtain the materials. Additionally, the preamble to the rule must summarize the material. 1 CFR 51.5(b).

In accordance with the OFR's requirements, the discussion in section VIII of this preamble summarizes the required provisions of ASTM F2167-17. Interested persons may purchase a copy of ASTM F2167-17 from ASTM, either through ASTM's website, or by mail at the address provided in the rule. A copy of the standard may also be inspected at the CPSC's Office of the Secretary, U.S. Consumer Product Safety Commission, as discussed above. Note that the Commission and ASTM arranged for commenters to have "read only" access to ASTM F2167-15 during the NPR's comment period.

VIII. Description of the Final Rule

Section 1229.2(a) of the final rule for infant bouncer seats incorporates by reference ASTM F2167-17 with two modifications, as stated in section 1229.2(b), related to the content and placement of warnings. Section 1229.2(a) includes the following key provisions summarized below: scope, terminology, general requirements, performance requirements, test methods, marking and labeling, and instructional literature. As described below, section 1229.2(b) includes modifications to test methods (section 1229.2(b)(1)), marking and labeling (section 1229.2(b)(2)-(3)), and instructional literature (section 1229.2(b)(4)).

Scope. Section 1 of ASTM F2167-17 states the scope of the standard, detailing what constitutes an “infant bouncer seat.” As stated in section II.A of this preamble, the Scope section defines an “infant bouncer seat” as “a freestanding product intended to support an occupant in a reclined position to facilitate bouncing by the occupant, with the aid of a caregiver or by other means.” ASTM F2167-17 states that infant bouncer seats are intended for “infants who have not developed the ability to sit up unassisted (approximately 0 to 6 months of age).”

Terminology. Section 3 of ASTM F2167-17 provides definitions of terms specific to this standard.

General Requirements. Section 5 of ASTM F2167-17 addresses numerous hazards with several general requirements, most of which are also found in the other ASTM juvenile product standards. Several requirements reference an existing CPSC standard. The following general requirements apply to bouncer seats. Where the ASTM standard relies on a CPSC mandatory standard, the mandatory standard is cited in parentheses next to the requirement:

- Hazardous sharp points and edges (16 CFR 1500.48 and 1500.49);
- Small parts (16 CFR part 1501);
- Lead in paint (16 CFR part 1303);

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- Wood parts;
- Latching and locking mechanisms;
- Scissoring, shearing, and pinching;
- Openings;
- Exposed coil springs;
- Protective components;
- Permanency of labels and warnings; and
- Toys (ASTM F963).

Performance Requirements and Test Methods. Sections 6 and 7 of ASTM F2167-17 contain performance requirements specific to bouncer seats, as well as test methods that must be used to assess conformity with such requirements. Accordingly, the final rule includes performance requirements for the following:

- Restraints;
- Stability (forward, sideward, and rearward);
- Slip Resistance
- Structural Integrity;
- Dynamic and Static Load;
- Disassembly/Collapse;
- Drop Test;
- Toy Bar Attachment Integrity; and
- Battery Compartment.

Additionally, section 7 of ASTM F2167-17 includes test procedures to ensure the permanency of labels and warnings, and a fall hazard visibility test. The test procedure in

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section 1229.2(b)(1) of the final rule replaces the fall hazard visibility test in section 7.11.3.1 of ASTM F2167-17, as described in section V.B.2 of this preamble.

Marking and Labeling. Section 8 of ASTM F2167-17 requires products to be marked or labeled with manufacturing information and relevant product warnings. Warning label requirements for bouncer seats in section 8.4.5 of ASTM F2167-17 require two groups of warning statements, a fall hazard warning and a suffocation warning. ASTM F2167-17 includes warning language and formatting requirements for both falls and suffocation warnings. Section 8.4.7.1 requires the fall hazard warning to be placed on the front surface of the infant bouncer seat back, so that it complies with the visibility requirement in section 7.11.

Section 1229.2(b)(2) of the final rule replaces the content of the fall hazard warning in section 8.5.1.1 of ASTM F2167-17. Section 1229.3(b)(3) of the final rule replaces the content of the suffocation hazard warning in sections 8.5.2.1 and 8.5.3 in ASTM F2167-17. Changes to warning content and the visibility test for the placement of the fall hazard warning are outlined in section V.B.1-2 of this preamble.

Instructional Literature. Section 9 of ASTM F2167-17 requires that instructions be provided with bouncer seats and be easy to read and understand. Additionally, the section contains requirements relating to instructional literature contents, including warnings.

Section 1229.2(b)(4) of the final rule replaces the content of sections 9.2.1 and 9.2.2 of ASTM F2167-17. These sections contain example warning labels or references to example warning labels. The content of the example warning labels in section 1229.2(b)(4) reflects changes to the content of the fall hazard warning and suffocation hazard warning in sections 1229.2(b)(2) and (3) of the final rule. Changes to the instructional literature that relate to warnings content are outlined in section V.B.1-2 of this preamble.

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IX. Effective Date

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). CPSC generally considers 6 months to be sufficient time for suppliers of durable infant and toddler products to come into compliance with a new standard under section 104 of the CPSIA. Six months is also the period that the Juvenile Products Manufacturers Association (JPMA) typically allows for products in the JPMA certification program to transition to a new standard once that standard is published. The Commission proposed a 6-month effective date in the NPR for infant bouncer seats and we received no comments on the proposed effective date. Accordingly, the final rule for bouncer seats, as well as the amendment to part 1112, has a 6-month effective date.

X. Regulatory Flexibility Act

A. Introduction

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601-612, requires that agencies review a proposed rule and a final rule for the rule's potential economic impact on small entities, including small businesses. Section 604 of the RFA generally 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 economic impact on a substantial number of small entities. Staff prepared a FRFA that is available at Tab C of the Staff Final Rule Briefing Package. We provide a summary of the FRFA below.

The final rule is unlikely to have a significant economic impact on the five domestic manufacturers of infant bouncer seats. Of the six small importers, a significant economic impact cannot be ruled out for four of the importers, either as a result of the final rule requirements or the resulting third party testing costs. Therefore, the Commission cannot rule out a significant economic impact for four of the 11 firms (36 percent) operating in the U.S. market for bouncers.

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B. The Product

An infant bouncer seat is defined in ASTM F2167-17, *Standard Consumer Safety Specification for Infant Bouncer Seats*, as “a freestanding product intended to support an occupant in a reclined position to facilitate bouncing by the occupant, with the aid of a caregiver or by other means.” These products vary widely in price; they can be purchased for as little as \$20, but can also easily cost more than \$200.

C. The Market for Infant Bouncer Seats

For the FRFA, the Commission identified 23 firms supplying infant bouncer seats to the U.S. market, with several firms moving into or out of the market since the NPR. These firms primarily specialize in the manufacture and/or distribution of children’s products, including durable nursery products. Eight of the 23 known firms are domestic manufacturers and eight are domestic importers. The remaining seven firms are foreign (4 manufacturers, 2 importers, and 1 retailer).¹⁰ We expect that the infant bouncer seats of 14 of these firms already comply with ASTM F2167 because the firms either: (1) have their bouncers certified by JPMA (five firms); (2) claim compliance with the voluntary standard (eight firms); or (3) have been tested to the ASTM standard by CPSC staff (one firm).¹¹

D. Impact on Small Businesses

The Commission is aware of approximately 23 firms currently marketing infant bouncer seats in the United States, 16 of which are domestic. Under U.S. Small Business Administration (SBA) guidelines, a manufacturer of infant bouncer seats is categorized as small if it has 500 or fewer employees, and importers and wholesalers are considered small if they have 100 or fewer

¹⁰ Staff categorized each firm using information from Dun & Bradstreet and ReferenceUSAGov, as well as firm websites.

¹¹ JPMA typically allows six months for products in their certification program to become compliant with a new voluntary standard once it is published. Therefore, firms are likely already complying with ASTM F2167-16, which was published in May 2016. They are not expected to comply with the recently published ASTM F2167-17 until December 2017.

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employees. We have limited our analysis to domestic firms because SBA guidelines and definitions pertain to U.S.-based entities. Based on these guidelines, the Commission determined that about 11 of the 23 firms are small—five domestic manufacturers and six domestic importers. Additional unknown small domestic infant bouncer seat suppliers may be operating in the U.S. market.

1. Small Manufacturers

The economic impact of the final rule for infant bouncer seats should be small for the five small domestic manufacturers. Each firm has an established history of compliance with the ASTM standard for infant bouncers and is therefore expected to be compliant with ASTM F2167-17, the version of the voluntary standard upon which the final rule is based, by the time the mandatory standard becomes final.

None of these firms includes more than four languages in their warnings and redesign is not expected. Based upon staff's inspection of their products, we expect products to have more than sufficient space for the required warning labels under the modified warning label for the final rule without the products seeming cluttered.

Under section 14 of the CPSA, once the new infant bouncer seat requirements become effective, all manufacturers will be subject to the third party testing and certification requirements under the CPSA and the Testing and Labeling Pertaining to Product Certification rule (16 CFR part 1107) (1107 rule). Third party testing will include any physical and mechanical test requirements specified in the final infant bouncer seats rule. Manufacturers and importers should already be conducting required lead testing for bouncer seats.

Third party testing costs are in addition to the direct costs of meeting the infant bouncer seats standard. The Initial Regulatory Flexibility Analysis (IRFA) prepared for the NPR concluded that we could not rule out a significant economic impact, given that we do not know

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specifically how much the third party requirement adds to testing costs or precisely how many models are needed to meet the “high degree of assurance” standard but that it was unlikely to be economically significant for most small manufacturers (*i.e.*, testing costs would be less than 1 percent of gross revenue). Given that these firms are already testing to the voluntary standard and the Commission received no public comments about third party testing, the Commission believes that it is unlikely that third party testing would have a significant economic impact on any of the five small manufacturers.

2. Small Importers

a. Small Importers with Compliant Infant Bouncer Seats

As noted in the IRFA, imported bouncers tend to be produced to meet the requirements for several trading partners simultaneously, including their different labeling requirements. Producers for international markets typically address labeling requirements for their various trading partners by simply providing a warning that covers all required safety issues in multiple languages. Specificity regarding warning label location impacts the practicability of replicating the warning label in multiple languages. This could mean that foreign producers will need to design a product for the U.S. market or reduce the number of languages used for warnings on U.S.-bound bouncer seats.

The final rule provides additional space for warning label placement than that proposed in the NPR. With this additional space, reducing on-product warning languages should be a more viable alternative for firms than it was under the NPR proposal. Firms would not need to reduce the number of languages for their on-product warnings for the final rule as significantly as that required in the NPR. The additional space addresses the location requirement in the final rule, while ensuring that the appearance of bouncers remains comparable to firms’ competitor products (for which one to three languages is typical).

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Three small importers of infant bouncer seats are currently in compliance with the voluntary standard; these firms likely would continue compliance as new versions of the voluntary standard are published. One importer is unlikely to experience a significant economic impact, even if the importer opted to redesign its bouncers to accommodate more than eight warning label languages. The cost estimate to redesign an infant bouncer (based on information from several firms) is between \$200,000 and \$300,000, which is less than 1 percent of this firm's revenue. The remaining two small importers of compliant bouncer seats might experience significant economic costs, based on the same comparison (*i.e.*, \$200,000 to \$300,000 could represent more than 1 percent of their annual revenue). Although the Commission does not expect that these firms would require space for warning labels in more than eight languages, we cannot rule out a significant economic impact for one of these two firms, given an extremely low revenue level compared to estimated costs for redesign. The second firm appears to have the option of exiting the bouncer market without experiencing a significant impact.

b. Small Importers with Noncompliant Infant Bouncer Seats

Three firms import bouncers that do not comply with the voluntary standard. The bouncers for these firms will require changes to come into compliance with the voluntary standard as well as modifications to meet the warning label requirements in the final rule. In the absence of information on precisely what changes would be required to bring the bouncer seats supplied by all three firms into compliance with the final rule (as well as information on sales revenue for all three firms), the Commission cannot rule out a significant economic impact for any of these firms.

The magnitude of the economic impact on the three firms with noncompliant infant bouncer seats will depend upon the cost of the changes required and the degree to which their supplying firms pass on any increases in production costs associated with changes to the product

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needed to meet the mandatory standard (a redesign is estimated to cost between \$200,000 to \$300,000). Two of the firms are directly tied to their foreign suppliers and therefore, finding an alternate supply source would not be a viable alternative. However, given this close relationship, it seems likely that their foreign suppliers would have an incentive to work with their U.S. subsidiaries to maintain an American market presence. One of those two firms likely would only avoid a significant economic impact if their supplier absorbed 100 percent of the cost of a redesign. The third firm imports and wholesales a wide variety of children's products. We do not know, however, how much of the firm's revenue is due to bouncer sales and cannot determine what impact discontinuing bouncer sales might have on the third firm should the firm be unable to find a supplier of bouncers that comply with the standard.

Based on the additional space provided in the final rule for placement of the fall hazard warning label, two of these firms should not require modifications to meet the requirement in the final rule (although they would have required modifications under the NPR).

c. Third Party Testing Costs for Small Importers

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. Half of the bouncer seat importers (3 of 6) are already testing their products to verify compliance with the ASTM standard, and any costs would be limited to the incremental costs associated with third party testing over the current testing regime.

The Commission was able to obtain revenue data for one of the small importers with noncompliant bouncers. For that importer, third party testing costs, considered alone and apart from any additional performance requirements due to the final rule, would not exceed one percent of gross revenue unless around 12 units per model required testing to provide the "high

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degree of assurance” required by 16 CFR part 1107. The Commission has no basis for estimating the size of the impact for the remaining two importers of noncompliant bouncers.

E. Summary of Impacts

The Commission is aware of 11 small firms, five domestic manufacturers and six domestic importers, currently marketing infant bouncer seats in the United States. With regards to the five domestic manufacturers, the Commission considers it unlikely that testing costs would have a significant impact on any of these firms. Of the six small importers, a significant economic impact cannot be ruled out for four of the importers either as a result of the final rule requirements or the resulting third party testing costs. Therefore, the Commission cannot rule out a significant economic impact for four of the 11 firms (36 percent) operating in the U.S. market for bouncers.

F. Alternatives

One of the alternatives to reduce the impact on small entities discussed in the NPR was to adopt the voluntary standard with all of the modifications to the on-product warning labels, except for the location specificity (*i.e.*, next to the child’s head). Based on comments received, the requirements regarding on-product warning label placement have been modified in the final rule (*i.e.*, up from the child’s armpits on either side). This modification provides additional room and will reduce the economic impact of the warning label location specificity on small suppliers. The Commission could further reduce the economic impact on small entities by eliminating the location requirement for the fall hazard warning entirely. However, this would reduce the effectiveness of the fall hazard warning label. The location for the fall hazard warning “allows caregivers to notice the label while making eye contact with the infant, and potentially creates mental images of the consequence (“skull fracture”) of not complying with the instructions...” Tab D, Staff NPR Briefing Package; Tab B, Staff Final Rule Briefing Package.

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The Commission considered two additional alternatives discussed in the NPR that might minimize the economic impact on small entities: (1) adopt ASTM F2167-17 with no modifications; and (2) allow a later effective date.

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, adopting ASTM F2167-17 with no modifications is the least stringent rule allowed by law. This alternative would reduce the impact on all of the known small businesses supplying infant bouncers to the U.S. market. If it were adopted, it should eliminate any economic impact related to warning label changes, but firms would continue to be affected by third party testing requirements. However, adopting ASTM F2167-17 without modification would not adequately address the fall hazard scenario identified in the incident data and would reduce the effectiveness of the fall hazard warning label.

Finally, the Commission could reduce the final rule's impact on small businesses by setting a later effective date. A later effective date would reduce the economic impact on firms in two ways. 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. Also, firms could spread costs over a longer time period, thereby reducing their annual costs, as well as the present value of their total costs. However, the Commission received no comments asserting that firms would not have sufficient time to comply with the proposed 6 month effective date. Accordingly, the Commission declines to extend the effective date of the final rule.

G. 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

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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 CFR part 1112. Consequently, the Commission finalizes an amendment to 16 CFR part 1112 that establishes an NOR for those testing laboratories that want to test for compliance with the bouncers final rule. This section assesses the impact of the amendment on small laboratories.

A 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 the rule to include the NOR for the bouncer 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 infant bouncer seat 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 bouncer standard to their scope of accreditation, a cost that test laboratories have indicated is extremely low when they are already accredited for other section 104 rules. As a consequence, the Commission certifies that the NOR for the infant bouncer seat standard will not have a significant impact on a substantial number of small entities.

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XI. Environmental Considerations

The Commission’s regulations address whether the agency is required to prepare an environmental assessment or an environmental impact statement. Under these regulations, a rule that has “little or no potential for affecting the human environment,” is categorically exempt from this requirement. 16 CFR 1021.5(c)(1). The final rule for bouncer seats falls within the categorical exemption.

XII. Paperwork Reduction Act

The final rule for infant bouncer seats contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The preamble to the proposed rule (80 FR at 63181-82) discussed the information collection burden of the proposed rule and specifically requested comments on the accuracy of our estimates. OMB has assigned control number 3041-0174 to this information collection. We did not receive any comment regarding the information collection burden of the proposal. However, the final rule makes modifications regarding the information collection burden because the number of estimated manufacturers subject to the information collection burden is now estimated at 23 manufacturers rather than the 22 manufacturers 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

16 CFR Section	Number of Respondents	Frequency of Responses	Total Annual Responses	Hours per Response	Total Burden Hours
1229	23	4	92	1	92

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Our estimate is based on the following:

Section 8.1 of ASTM F2167-17 requires that all infant bouncer seats and their retail packaging be permanently marked or labeled as follows: the manufacturer, distributor, or seller name, place of business (city, state, mailing address, including zip code), and telephone number; and a code mark or other means that identifies the date (month and year as a minimum) of manufacture.

CPSC is aware of 23 firms that supply bouncer seats in the U.S. market. For PRA purposes, we assume that all 23 firms use labels on their products and on their packaging already. All firms will need to make some modifications to their existing labels. We estimate that the time required to make these modifications is about 1 hour per model. Each of the 23 firms supplies an average of four different models of bouncer seats. Therefore, we estimate the burden hours associated with labels to be 92 hours annually (1 hour x 23 firms x 4 models per firm = 92 hours annually).

We estimate the hourly compensation for the time required to create and update labels is \$33.58 (U.S. Bureau of Labor Statistics, “Employer Costs for Employee Compensation,” March 2017, Table 9, total compensation for all sales and office workers in goods-producing private industries: <http://www.bls.gov/ncs/>). Therefore, we estimate the annual cost to industry associated with the labeling requirements in the final rule to be approximately \$3,089 (\$33.58 per hour x 92 hours = \$3,089.36). This collection of information does not require operating, maintenance, or capital costs.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), we have submitted the information collection requirements of this final rule to the OMB.

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XIII. Preemption

Section 26(a) of the CPSA, 15 U.S.C. 2075(a), provides that when 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.” Therefore, the preemption provision of section 26(a) of the CPSA applies to this final rule issued under section 104.

XIV. Amendment to 16 CFR part 1112 to Include NOR for Bouncer Seat Standard

The CPSA establishes certain requirements for product certification and testing. 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). Certification of children’s products subject to a children’s product safety rule must be based on testing conducted by a CPSC-accepted third party conformity assessment body. *Id.* 2063(a)(2). The Commission must publish an NOR for the accreditation of third party conformity assessment bodies to assess conformity with a children’s product safety rule to which a children’s product is subject. *Id.* 2063(a)(3). The *Safety Standard for Infant Bouncer Seats*, to be codified at 16 CFR part 1229, 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). Part 1112 became effective on June 10, 2013 and

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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 bouncer seats, require the Commission to amend part 1112. Accordingly, the Commission is now amending part 1112 to include the standard for infant bouncer seats 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 infant bouncer seats 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 1229, *Safety Standard for Infant Bouncer Seats*, included in its scope of accreditation of CPSC safety rules listed for the laboratory on the CPSC Web site at: www.cpsc.gov/labsearch.

As required by the RFA, staff conducted a FRFA when the Commission issued the part 1112 rule (78 FR 15836, 15855-58). Briefly, the FRFA concluded that the accreditation requirements would not have a significant adverse impact on a substantial number of small test laboratories because no requirements were imposed on test laboratories that did not intend to provide third-party testing services. The only test 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. Moreover, a test laboratory would

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only choose to provide such services if it anticipated receiving revenues sufficient to cover the costs of the requirements.

Based on similar reasoning, amending 16 CFR part 1112 to include the NOR for the infant bouncer seats standard will not have a significant adverse impact on small test laboratories. Moreover, based upon the number of test laboratories in the United States that have applied for CPSC acceptance of accreditation to test for conformance to other mandatory juvenile product standards, we expect that only a few test laboratories will seek CPSC acceptance of their accreditation to test for conformance with the infant bouncer seats standard. Most of these test laboratories will have already been accredited to test for conformity to other mandatory juvenile product standards, and the only costs to them would be the cost of adding the infant bouncer seats standard to their scope of accreditation. For these reasons, the Commission certifies that the NOR amending 16 CFR part 1112 to include the infant bouncer seats 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, Incorporation by Reference, Reporting and recordkeeping requirements, Third party conformity assessment body.

16 CFR Part 1229

Bouncer seats, Chairs, Consumer protection, Imports, Incorporation by reference, Infants and children, Labeling, Law enforcement, Seats, and Toys.

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

PART 1112—REQUIREMENTS PERTAINING TO THIRD PARTY CONFORMITY ASSESSMENT BODIES

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

Authority: Pub. L. 110-314, section 3, 122 Stat. 3016, 3017 (2008); 15 U.S.C. 2063.

2. Amend § 1112.15 by adding paragraph (b)(42) 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) * * *

(42) 16 CFR part 1229, Safety Standard for Infant Bouncer Seats.

* * * * *

3. Add part 1229 to read as follows:

PART 1229-SAFETY STANDARD FOR INFANT BOUNCER SEATS

Sec.

1229.1 Scope.

1229.2 Requirements for infant bouncer seats.

Authority: Sec. 104, Public Law 110-314, 122 Stat. 3016.

§ 1229.1 Scope.

This part establishes a consumer product safety standard for infant bouncer seats.

§ 1229.2 Requirements for infant bouncer seats.

(a) Except as provided in paragraph (b) of this section, each infant bouncer seat must comply with all applicable provisions of ASTM F2167-17, Standard Consumer Safety Specification for Infant Bouncer Seats, approved on June 1, 2017. 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

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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:

http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(b) Comply with ASTM F2167-17 with the following additions or exclusions:

(1) Instead of complying with section 7.11.3.1 of ASTM F2167-17, comply with the following:

(i) 7.11.3.1 *Visibility With CAMI Dummy Restrained in Seat*— While standing in front of the product with the Newborn CAMI dummy installed, verify that the required warnings are visible and placed above an imaginary horizontal line that crosses through the junctions of under arm and side of the torso armpits on both left and right and not obscured by any part of the dummy (Figure 10).



Fig 10. Allowable area for warning label placement starts from the dotted line that crosses the junctions of underarm and both sides of the torso.

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(ii) [Reserved]

(2) Instead of complying with section 8.5.1.1 of ASTM F2167-17, comply with the following:

(i) 8.5.1.1 The fall hazard warning statements shall address the following:

Fall Hazard: Babies have suffered skull fractures falling while in and from bouncers.

- Use bouncer **ONLY** on floor.
- **ALWAYS** use restraints and adjust to fit snugly, even if baby falls asleep.
- **NEVER** lift or carry baby in bouncer. [NOTE: Bouncer seats with a handle(s)

intended for use to lift and carry a child are exempt from including this warning statement.]

NOTE 12 – “Address” means that verbiage other than what is shown can be used as long as the meaning is the same or information that is product-specific is presented.

(ii) [Reserved]

(3) Instead of complying with sections 8.5.2.1 through 8.5.3 of ASTM F2167-17, comply with the following:

(i) 8.5.2.1. The suffocation hazard warning statements shall address the following:

Suffocation Hazard: Babies have suffocated when bouncers tipped over on soft surfaces.

- **NEVER** use on a bed, sofa, cushion, or other soft surface.
- **NEVER** leave baby unattended.

To prevent falls and suffocation:

- **ALWAYS** use restraints and adjust to fit snugly, even if baby falls asleep.
- **STOP** using bouncer when baby starts trying to sit up or has reached [insert manufacturer’s recommended maximum weight, not to exceed 20 lb], whichever comes first.

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NOTE 13 – “Address” means that verbiage other than what is shown can be used as long as the meaning is the same or information that is product-specific is presented.

(ii) 8.5.3 Example warnings in the format described in this section are shown in Fig 11-12 warning formats below are presented as EXAMPLES ONLY for the display of the required warnings. The safety alert symbol “▲” and the signal word “**WARNING**” shall be as specified above. The warning statements’ wording content, as well as the use of any underlining, capital lettering, or bold typeface, or a combination thereof, is at the discretion of the manufacturer.

(4) Instead of complying with sections 9.2.1 and 9.2.2 of ASTM F2167-17, comply with the following:

(i) 9.2.1 The instructions shall include all warnings specified in 8.4.5, 8.5.1 and 8.5.2, except warning statement may be in one group. An example warning that meets the requirements is shown in Figure 13. The warning statements’ wording content, as well as the use of any underlining, capital lettering, or bold typeface, or combination thereof, is at the discretion of the manufacturer.

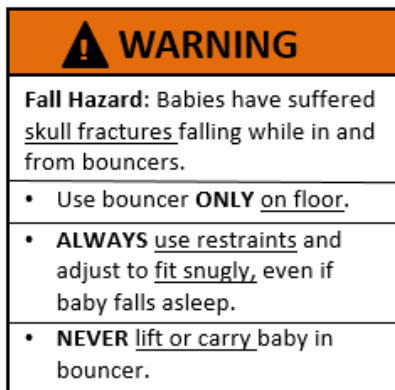


Fig. 11 Fall Hazard Warning

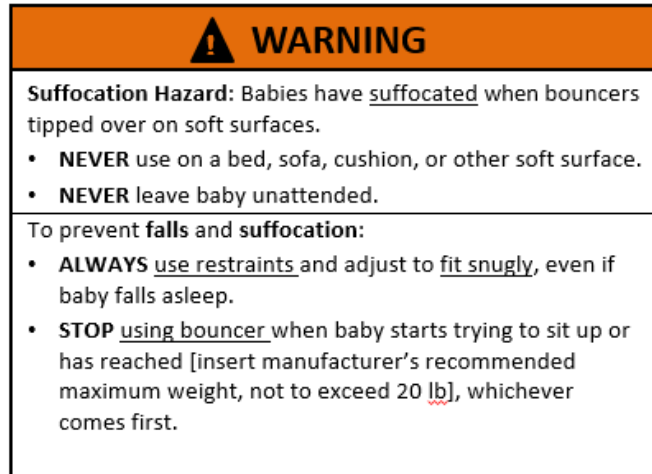


Fig. 12 Suffocation Hazard Warning

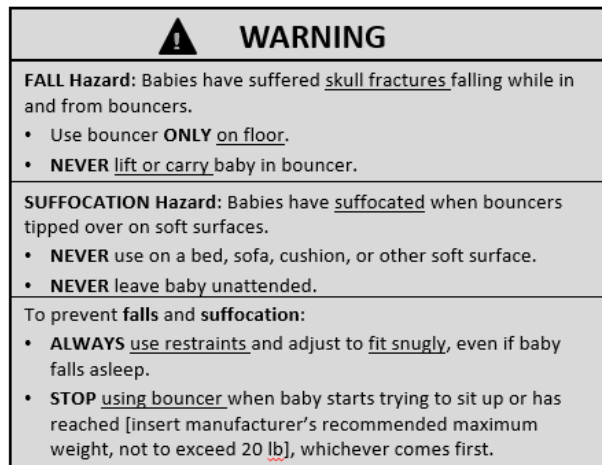


Fig. 13 Instruction Warning Statements

(ii) 9.2.2 Warning statements in instructional literature shall meet the format requirements specified in 8.4.4, 8.4.5, and 8.4.6 with the following two exceptions: the background of the Signal Word panel need not be in color, and clause 6.4 of ANSI Z535.4 need not be applied. An example warning that meets the requirements is shown in Figure 13. The warning statements' wording content, as well as the use of underlining, capital lettering, italics, or bold typeface, or combination thereof, are at the discretion of the manufacturer.

NOTE 14— For additional guidance on the design of warnings for instructional literature, please refer to ANSI Z535.6, American National Standard: Product Safety Information in Product Manuals, Instructions, and Other Collateral Materials.

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Dated: _____

Todd A. Stevenson,
Secretary, Consumer Product Safety Commission



Draft Final Rule for Infant Bouncer Seats Under the Danny Keysar Child Product Safety Notification Act

August 23, 2017

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Briefing Memorandum



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

This document has been electronically
approved and signed.

Memorandum

Date: August 23, 2017

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Mary T. Boyle, General Counsel
Patricia H. Adkins, Executive Director
DeWane Ray, Deputy Executive Director for Safety Operations

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

Suad Wanna-Nakamura, Ph.D., Infant Bouncer Seats Project Manager
Division of Pharmacology and Physiology Assessment
Directorate for Health Sciences

SUBJECT: Staff's Draft Final Rule for Infant Bouncer Seats under the Danny Keysar
Child Product Safety Notification Act

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.

This briefing package includes staff's responses to comments received in response to the infant bouncer seat notice of proposed rulemaking (NPR).¹ This package also assesses the current voluntary standard for infant bouncer seats, discusses the potential impact of the draft final rule on small business, and provides staff's recommendations for a draft final rule to

¹ Briefing package is located at: https://www.cpsc.gov/s3fs-public/pdfs/blk_media_ProposedRuleSafetyStandardforInfantBouncerSeatSeptember302.pdf.

address the hazards associated with this product. CPSC staff recommends incorporating by reference ASTM F2167-17², with two modifications to the warning and labeling requirements.

Section 104(f)(1) of the CPSIA defines “durable infant or toddler products” as “a durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years,” and provides a non-exclusive list of product categories. Although infant bouncer seats are not listed, the Commission has specifically identified infant bouncer seats as a category of “durable infant or toddler product” in the Commission’s product registration card rule under section 104(d).³ Additionally, section 104(b)(1)(A) of the CPSIA requires the Commission to consult with “representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts” to develop rules for durable infant or toddler products. Staff began the consultation process for bouncer seats through the standard development procedures of ASTM International⁴ in January 2013.

II. BACKGROUND

A. *Product Review:*

An “infant bouncer seat” is defined in the scope section of 1.2 of ASTM F2167-17, *Standard Consumer Safety Specification for Infant Bouncer Seats*, as “a freestanding product intended to support an occupant in a reclined position to facilitate bouncing by the occupant, with the aid of a caregiver or by other means” and “whose intended occupants are infants who have not developed the ability to sit up unassisted (approximately 0 to 6 months of age).” Bouncer seats vary in design, from a wire frame construction model with a fabric cover, a toy bar and a three-point restraint, to more complex designs with additional features, such as battery-powered devices that vibrate and play melodies and nature sounds (Figure 1).



Figure 1: Examples of Bouncer Seats

² Current edition approved on June 1, 2017. Published June 2017. Originally approved in 2001. Last previous edition approved in 2016 as F2167 – 16. DOI:10.1520/F2167-17.

³ 74 *Fed. Reg.* 68,668 (December 29, 2009), codified at 16 C.F.R. § 1130.2(a)(16), available at: <http://www.cpsc.gov/PageFiles/124299/durable.pdf>.

⁴ ASTM International website: www.astm.org.

B. ASTM Voluntary Standard Overview

ASTM F2167, *Standard Consumer Safety Specification for Infant Bouncer Seats*, is the voluntary standard developed to address the identified hazard patterns associated with the use of infant bouncer seats. The standard is intended to minimize the risk of injury or death to infants in bouncer seats associated with falls from elevated surfaces, product disassembly/collapse, stability, and suffocation. The voluntary standard for infant bouncer seats was first approved in December 2001, and published in January 2002, as ASTM F2167-01, *Standard Consumer Safety Specification for Infant Bouncer Seats*. The NPR referenced the ASTM F2167-15 version of the standard.

Since the NPR was published in the Federal Register on October 19, 2015, CPSC staff continued to work with the ASTM subcommittee on addressing the four additional warning requirements that were part of the proposed rule. ASTM held three subcommittee meetings and two task group meetings. On November 22, 2016 staff sent a letter to ASTM⁵ supporting the balloted changes intended to align the warning design in bouncer seats with the Ad Hoc Task Group recommendations. In addition, staff voted affirmative and sent a letter to ASTM⁶ on February 28, 2017 supporting a ballot to include a maximum weight limit regarding when to stop using a bouncer. The balloted changes were incorporated into the F2167-17 version of the standard.

On January 4, 2017, staff sent a letter to ASTM⁷ urging the subcommittee to publish a standard expeditiously that incorporates Ad Hoc Task group recommendations. Staff also suggested several clarifications to the standard to improve the effectiveness of warning labels in the areas of warning label placement and wording. These improvements addressed two outstanding issues related to fall hazard warning label text and placement that were in the NPR but had not yet been addressed by the subcommittee. The letter was discussed at the January 18, 2017 subcommittee meeting, and as a result of the discussion the subcommittee declined to ballot staff's proposed changes due to expected negatives, and the subcommittee did not have any further discussions on staff's proposed changes.

Since the NPR, ASTM has published two new versions of the standard, ASTM F2167-16 and ASTM F2167-17. Changes to each of the two successive versions were:

ASTM F2167-16 (approved on May 1, 2016) version:

- Added specific developmental guidance for caregivers on when to stop using the bouncer.

⁵ https://www.cpsc.gov/s3fs-public/LetterToASTMInfantBouncers112216.pdf?E4zpD3gtiFB39IHULY_AJq98DcCv3IOW

⁶ <https://www.cpsc.gov/s3fs-public/LetterToASTMInfantBouncers%20022817.pdf?.eowcSVEVmRCYgQSuwA0BFoD5O00lp11>

⁷ https://www.cpsc.gov/s3fs-public/LetterToASTMInfantBouncers010417.pdf?H3_SFNIHHQeNpsYysiT1bp1zIRumd0X

- Removed from the standard general requirements for banned toys or other articles because those requirements do not apply to infant bouncer seats.

ASTM F2167-17 (approved June 1, 2017) version:

- Incorporated ad hoc approved wording to warning label formatting requirements.⁸
- Added wording to limit the maximum weight of an occupant in an infant bouncer seat.

C. The Proposed and Final Rules

The Commission issued an NPR⁹ for a safety standard for infant bouncer seats in the *Federal Register* (80 *Fed. Reg.* 63168, (Oct. 19, 2015)) based on the voluntary standard, ASTM F2167-15, “Standard Consumer Safety Specification for Infant Bouncer Seats.” The Commission proposed to incorporate by reference ASTM F2167-15, with the following modifications, to improve and strengthen the content, format, and placement of warning labels and instructions to further reduce the risk of injury to infants associated with falls from bouncer seats:

1. Add a requirement that the fall hazard label be located on the front surface of the bouncer seat adjacent to the area where the child’s head would rest, and modify the current visibility test to reflect this requirement;
2. Add text to the warnings that states: use the restraints, “. . . even if baby is sleeping . . .”;
3. Change the text in the warnings to advise caregivers to: “stop using when baby starts trying to sit up”;
4. Specify a standard format (including black text on a white background, table design, bullet points, and black border) for the warnings on the product and in the instructions.

ASTM has incorporated into the voluntary standard two of the modifications proposed in the NPR. The ASTM subcommittee on Infant Bouncer Seats reviewed and agreed with the language that the Commission proposed on developmental guidance, stated in number 3 above (Change the text in the warnings advising caregivers to “stop using when baby starts trying to sit up”). The proposed language was added to ASTM F2167-16. ASTM also specified a standard format for the warnings, stated in number 4 above, through adoption of the Ad Hoc Task Group’s recommendations in the ASTM bouncer, standard starting from the 2017 version.

However, staff recommends that the draft final rule incorporate by reference ASTM F2167-17, with two modifications to address remaining two safety issues, as reflected in numbers 1 and 2 above to further reduce the risk of injury associated with falls. We discuss staff’s

⁸ The Ad Hoc Task Group was formed by ASTM and consists of members of the various voluntary standards groups whose standards are affected by the durable nursery products rules. The purpose of the Ad Hoc Task Group is to harmonize the wording and warning label format of durable infant and toddler products. Ad Hoc Task Group recommendations for warning statements were originally published as a reference document titled, “Ad Hoc Wording – May 4, 2016,” as part of the F15 Committee Documents, and subsequently, the recommendations were revised and published in October 2016, with the title, “Ad Hoc Approved Wording, Revision A – October 17, 2016” (Ad Hoc Approved Wording).

⁹ Available at: <https://www.gpo.gov/fdsys/pkg/FR-2015-10-19/pdf/2015-26386.pdf>.

recommendations for the final rule on these two safety objectives in staff's response to comments, as well as in section III.C. below. An Appendix summarizing the requirements in ASTM F2167-17, the recommendations in the NPR, and staff's recommended modifications in the draft final rule is attached as Tab B.

III. DISCUSSION

A. *Overview of New Incident Data*¹⁰ (Tab A)

In the Infant Bouncer Seats NPR briefing package, CPSC staff from the Directorate for Epidemiology identified a total of 277 incidents in CPSC's Consumer Product Safety Risk Management System (CPSRMS), including 51 reported injuries and 11 fatalities from January 1, 2006 through February 2, 2015. Since February 2, 2015, CPSC staff received reports of 70 additional incidents in CPSRMS associated with infant bouncer seats, including one fatality. The fatality occurred when a bouncer fell from a table and the infant suffered a fractured skull. Of the 70 additional incident reports, 51 were associated with the structural integrity of the product.

For the NPR briefing package, CPSC staff retrieved 672 NEISS records describing infant bouncer seat incidents between January 1, 2006 and December 31, 2013. Staff found that 385 cases, or an estimated 9,200 injuries, occurred in hazardous environments (counters, tables, and other elevated surfaces). From January 1, 2014 through December 31, 2015, staff found 202 additional NEISS records describing infant bouncer incidents. Staff's inspection of the updated NEISS data revealed that 100 cases, or an estimated 2,800 injuries, took place in hazardous environments. Staff found no additional fatalities in the NEISS data. Staff estimates that 4,700 (85%) bouncer injuries involved the head and face. Based on the annual injury estimates, staff found a statistically significant upward trend in the estimated emergency department-treated injuries involving bouncers from 2006 to 2015, for victims under 1 year old.

Staff did not identify any new hazards in the updated incident data, beyond the hazard patterns already identified in the NPR briefing package, related to product design, structural integrity, toy bars, stability, chemical/electric hazards, restraints, and hazardous environments.

B. *Staff Responses to NPR Comments*

The CPSC received six comments¹¹ in response to the NPR; three commenters supported the NPR and the proposed changes. Most of the comments centered on the proposed changes to

¹⁰ The CPSC databases searched were the National Electronic Injury Surveillance System (NEISS) and the Consumer Product Safety Risk Management System (CPSRMS). CPSRMS combines data stored in the In-Depth Investigation (INDP) file, the Injury or Potential Injury Incident (IPII) file, and the Death Certificate (DTHS) file. The date of extraction was 7/6/16. The reported 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 infant bouncer seats.

warning labels and instructional manuals, including the proposed placement of the fall warning label in an area adjacent to the infant's head. Several commenters stated that limited space would not accommodate warnings in multiple languages, noting the desire to use the same product and label for foreign markets. Several commenters objected to formatting requirements and recommended labeling requirements, despite them being consistent with the recommendations of the Ad Hoc Task Group. Two commenters objected to adding the language, "even if sleeping," to cautionary statements about using restraints, arguing that such language might encourage a caregiver to use the product for extended infant sleep. One commenter recommended that the ASTM subcommittee reach a consensus on the need for the additional proposed language: "Stop using bouncer when baby starts trying to sit up." Two commenters recommended that the warning label be affixed to the product using embroidery or stamping to increase its permanency. Another commenter stated that the fall hazard label visibility test procedure is not specific and can be misinterpreted. This commenter suggested using the test protocol in the current ASTM standard that uses the CAMI newborn dummy.

Staff's responses to those comments that resulted in changes in the draft final rule are explained below:

1. Acceptable area for the warning label on the bouncer seat back and the corresponding visibility test proposed in the NPR

ASTM F2167 requires that the fall hazard label be placed on the front surface of the bouncer seat back, so that it is visible when a newborn CAMI dummy is placed in the bouncer seat. In the NPR, the Commission assessed this provision of the voluntary standard and found that it did not adequately address the risk of injury to infants falling from and with bouncer seats placed on elevated surfaces, a foreseeable misuse related to infant bouncer seats. To strengthen the standard and further reduce the risk of injury, the NPR proposed that the fall hazard warning label be on the front surface of the bouncer seat, adjacent to where the child's head would rest, and the NPR also modified the visibility test.

Some commenters were concerned that for some products, the area adjacent to the child's head was insufficient to accommodate the necessary warning labels. Commenters were also concerned about the repeatability of the visibility test proposed in the NPR. Staff's research on the seat back space, including models with narrow seat backs, did not corroborate the commenters' concerns. Nevertheless, to enhance test repeatability and to increase allowable space for warning labels, staff has clarified and enlarged the acceptable area for warning label placement in the draft final rule, as well as the corresponding visibility test (Figure 2). The visibility test is based on ASTM F2167-17, and adds an observable line using the CAMI dummy, to determine whether the warning labels are located per the requirements, which allows additional seat back space for warning labels and clarifies the precision of the visibility test, both of which should address commenters' concerns.

¹¹ <http://www.regulations.gov/docket?D=CPSC-2015-0028>.



Fig 2. Allowable area for warning label placement starts from the dotted line that crosses the junctions of underarm and both sides of the torso (Tab B).

2. *Addition of wording “. . . even if baby is sleeping” to the warning label language*

ASTM F2167-17 does not require a warning stating that caregivers should use the restraints, even if an infant is asleep. The current language states: “Always use restraints. Adjust to fit snugly.” Based on the incident data that relate deaths to suffocation among unrestrained infants while they slept, and relate serious head injuries to unrestrained infants due to falls from bouncer seats that are placed on elevated surfaces and falls from bouncer seats that are being carried, the Commission stated in the NPR that the voluntary standard was inadequate to address the risk of injury to infants from falls out of bouncer seats, or the risk of suffocation among unrestrained infants who are sleeping. Accordingly, in the NPR, the Commission proposed warning language stating: “Adjust to fit snugly, *even if baby is sleeping.*”

Some commenters were concerned by the addition of the word “sleeping” to the product warnings because the word may suggest that bouncer seats are intended to be used for long-term, unattended, sleep. Use of the word “sleeping” reflects the fact that infants sleep in bouncer seats, and based on the injury data, staff continues to be concerned about seating infants in bouncers without the use of restraints. Incident data show that unrestrained infants suffer serious head injuries due to falls from bouncer seats, or they get into compromised positions that may result in suffocation. Furthermore, some bouncers on the market indicate short periods of sleep as a proper use scenario. For these reasons, staff advises that caregivers be instructed to use the restraints even for a sleeping baby.

However, staff recommends that the draft final rule use the phrase, “falls asleep,” instead of the phrase, “is sleeping” that the Commission proposed in the NPR. The recommended change aligns with wording approved by the Ad Hoc Task Group. The Ad Hoc Task Group approved a warning to “*Never leave child unattended, even if child falls asleep.*” This warning is intended for products (*i.e.*, bouncers, swings, infant rockers, hand-held carriers) to be used for infants who are likely to fall asleep in the product, but that are not intended for periods of unattended sleep. During the ASTM meetings in April 2017, several manufacturers in the Ad Hoc Task Group requested removal of this recommendation from the Ad Hoc Task Group’s recommendations, given that no subcommittee adopted the sentence. ASTM balloted the removal of the sentence in June 2017; the ballot item received multiple negative votes and did not pass. During the Ad Hoc Task Group discussions, some manufacturers expressed concern that this sentence may imply that caregivers can safely use such products for unattended sleep, even though manufacturers have provided no evidence to demonstrate this. Incident data for products such as bouncers and handheld carriers demonstrate that babies do “fall asleep” in these products. Incident data on bouncers and Health Sciences staff’s assessment demonstrate that being unrestrained increases the severity of injury from a fall. Thus, staff advises that the statement, “even if baby falls asleep,” be on the warning label for bouncer seats. This statement does not preclude manufacturers who believe that their bouncers should not be used for sleep from adding language alerting caregivers that bouncers are not designed for safe sleeping. The Ad Hoc Task Group is continuing to work on the recommended wording to reach a consensus, and CPSC staff is participating in the discussions.

3. *Addition of wording associated with when to stop using bouncer*

One commenter was concerned about replacing the wording, “Never use for a child able to sit up unassisted,” with the language, “Stop using bouncer when baby starts trying to sit up.” The commenter suggested using the existing statement until it can be determined through the ASTM consensus process that the proposed wording is needed. Since the NPR was issued, ASTM has revised the voluntary standard, beginning with ASTM F2167-16, to require that the warning label state: “stop using when baby starts trying to sit up,” which was the language that the Commission proposed. In addition, ASTM F2167-16 requires that instructional literature include the developmental guidance that must be on warning labels.

Staff agrees with the language adopted in the ASTM F2167 standard, starting from the 2016 version, and staff no longer recommends this wording as a change in the draft final rule.

4. *Changes to the warning label format*

Some commenters stated that, in general, ASTM standards provide flexibility to manufacturers to pick colors and formatting features that are most appropriate for the product. One commenter recommended delaying publication of the final rule for any and all warning requirements until the warning format and content revisions proposed in the NPR can be reviewed by the ASTM Ad Hoc Task Group, balloted through the ASTM process, and incorporated into F2167.

The Ad Hoc Wording Task Group, in which CPSC staff participated, developed a set of recommendations to harmonize the warning format. Staff believes that adopting the Ad Hoc Wording reference document recommendations provides noticeable and consistent warning labels on infant bouncer seats and across juvenile products. These recommendations have been incorporated into multiple ASTM juvenile product standards and have been balloted and approved by ASTM F15.21. These formatting changes have now been incorporated into ASTM F2167-17. Accordingly, the draft final rule adopts F2167-17, without modification, regarding the format of the warning label.

C. Differences Between the Voluntary Standard, NPR, and Draft Final Rule

As described in section II.C above, the NPR proposed to modify the voluntary standard regarding four issues with the warning label. ASTM has addressed two of these issues in the voluntary standard, and two issues, including warning label placement and content, remain. Based on the comments received, staff recommends making several clarifications to the two remaining modifications in the draft final rule. Below we describe the differences between the voluntary standard, the proposed language in the NPR, and we provide staff's recommended language in the draft final rule.

1. Placement of fall hazard warning label:

- ASTM F2167-17 requires that the fall hazard label be placed on the front surface of the bouncer seat back, so that it is visible when a newborn CAMI dummy is placed in the bouncer seat.
- The NPR proposed to add a requirement that the fall hazard label be located on the front surface of the bouncer adjacent to the area where the child's head would rest and modifies the visibility test to reflect this requirement.
- The draft final rule expands the area that the NPR proposed to allow for the fall hazard warning label and clarifies the visibility test procedure to be more repeatable. Staff recommends that the warning label be placed around the area where the infant's head would rest to increase the likelihood that the label gets the attention of the caregiver and facilitate the perception of the hazard via an emotional connection by having the label close to the baby's face. In addition, the visibility test procedure is based on the current ASTM standard and ensures test repeatability. The expanded area addresses staff's concern about visibility of the fall hazard warning label and the clarified test procedure provides repeatable testing to confirm the visibility of the warning label as well as commenters' concerns about available seat back space.

2. Fall hazard warning label text modification:

- ASTM F2167-17 does not require a warning stating that caregivers should use the restraints, even if an infant is asleep. The current language states: "Always use restraints. Adjust to fit snugly."

- The NPR proposed to add text to the warnings stating: use the restraints “. . . even if baby is sleeping.”
- The draft final rule changes the wording from “. . . even if baby is sleeping” to “. . . even if baby falls asleep.” The wording in the draft final rule addresses staff’s concern that caregivers must be warned to use restraints, even if the child is asleep, and aligns with the Ad Hoc Task Group’s recommended language for products in which infants are likely to fall asleep. Staff recommends that to prevent injuries from falls, this additional warning language is needed for a product like a bouncer seat in which babies are likely to sleep. The language is intended to improve the likelihood that caregivers will use the restraints and be less inclined to loosen or remove the restraints.

In addition, staff agrees with the following three changes to the ASTM standard since the 2015 version:

- Starting from the 2016 version of the ASTM standard, the general requirement for banned toys or other articles has been removed from the standard because it does not apply to infant bouncer seats. Specifically, the following sections have been removed (removed text is shown with a strikethrough):

2.2 Federal Regulations:

~~16 CFR 1500.18(a)(6) Banned Toys and Other Banned Articles Intended for Use by Children~~

~~CFR 1500.86(a)(4) Exemptions from Classification as a Banned Article for Use by Children~~

~~5.4 Banned Articles—There shall be no banned toys or other banned articles as defined by 16 CFR 1500.18(a)(6) and 16 CFR.86(a)(4).~~

Staff agrees with this change because it does not impact the safety of infant bouncer seats.

- The 2017 version of the ASTM standard includes additional text in the suffocation hazard warning label to limit the maximum weight for an occupant in an infant bouncer seat. The rationale for this change was based on surveillance of the marketplace, which demonstrated that some manufacturers have weight limits that do not correlate to the developmental milestones contemplated in the current warnings. Specifically, the text that is shown below with an underline has been added to Section 8.5.2.1:

STOP using bouncer when baby starts trying to sit up or has reached [insert manufacturer’s recommended maximum weight, not to exceed 20 lb], whichever comes first.

Staff agrees with this change because it does not impact the safe use of a bouncer. Caregivers are advised to stop using the bouncer when baby starts trying to sit up or reaches a certain weight, whichever comes first. Babies, on average, begin trying to sit up at 4.8 months,

whereas the age range for this activity is typically between 3 months and 8 months old.¹² If a child is on the higher end of this developmental range, but reaches the weight limit (either the maximum recommended weight or 20 lbs, which is approximately the 95th percentile weight for a 6-month-old¹³), parents are advised to stop using the bouncer. If a child reaches this developmental milestone early, parents are advised to stop using the bouncer, even though the child's weight may be lower than the recommended weight limit or 20 lbs.

- Starting from the 2017 version of the ASTM standard, the requirement to change the model number whenever the infant bouncer seat undergoes a significant structural or design modification has been removed as such a requirement does not relate to safety. Most of the ASTM juvenile product standards do not include this requirement and the requirement is being deleted from the standards that include it. According to the ASTM member manufacturers, changing the model number is a good manufacturing practice but does not impact the safety of the product thus is not appropriate to include it in an ASTM safety standard. Specifically the following text has been removed:

~~8.2 The manufacturer shall change the model number whenever the infant bouncer seat undergoes a significant structural or design modification or a change that affects its conformance to this consumer safety specification.~~

Staff agrees with this change because changing the model number has no effect on the safety of the product as the product has to comply with the standard regardless of the model number.

D. Impact on Small Business

Staff identified 23 firms supplying infant bouncers to the U.S. market. These firms primarily specialize in the manufacture and/or distribution of children's products, including durable nursery products. Based on U.S. Small Business Administration guidelines, 11 of the 23 firms are small domestic businesses, including five domestic manufacturers and six domestic importers.

As described in Tab C, staff finds that there could be a significant economic impact for four of the 11 (36%) known small suppliers of infant bouncers to the U.S. market. Accordingly, staff prepared a Final Regulatory Flexibility Analysis.

The economic impact of complying with the draft final rule is expected to be small for all five domestic manufacturers. Of the six small importers, a significant economic impact cannot be ruled out for four of the importers, either because of the staff-recommended requirements, or the resulting third party testing costs.

¹² Bayley, N. (1969). Manual for the Bayley Scales of Infant Development. New York, NY" The Psychological Corporation.

¹³ Kuczmarski, R. J., Ogden, C. L., Guo, S. S., et al. (2002). 2000 CDC Growth Charts for the United States: Methods and Development. National Center for Health Statistics. *Vital Health Statistics*, 11(246)

D. Effective Date of Final Rule

The Administrative Procedure Act (APA) requires that the effective date of a rule be at least 30 days following publication of the final rule (5 U.S.C. § 553(d)). In the NPR, the Commission proposed a 6-month effective date to allow infant bouncer seat manufacturers time to bring their products into compliance after a final rule is issued. Staff is recommending that the Commission provide an effective date of 6 months after publication of the final rule.

E. Compliance Recall Information

Staff found no additional recalls involving infant bouncer seats since the last two recalls by Compliance staff on April 18, 2007, and July 28, 2009.

IV. STAFF RECOMMENDATIONS

CPSC staff recommends incorporating by reference ASTM F2167-17, with two modifications to the warning and labeling requirements in the standard, as detailed in Tab B:

1. Revise content of the warnings, markings, and instructions to include a warning to use the restraints “. . . even if baby falls asleep.”
2. Clarify the acceptable area for the warning label placement on the bouncer seat back and the corresponding visibility test.

CPSC staff concludes that ASTM F2167-17, with the added modifications, will further reduce the number of deaths and injuries to infants associated with falls from infant bouncer seats. Therefore, staff recommends that the Commission adopt staff’s draft final rule for infant bouncer seats, with an effective date of 6 months after publication of the final rule, applicable to products manufactured or imported on or after that date.

TAB A: Infant Bouncer Seats-Related Deaths, Injuries and Potential Injuries, and NEISS Injury Estimates January 1, 2014 to July 6, 2016

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

Memorandum

Date: August 23, 2017

TO : Suad C. Wanna-Nakamura, Ph.D.
Infant Bouncer Seats Project Manager
Division of Pharmacology and Physiology Assessment
Directorate for Health Sciences

THROUGH: Kathleen Stralka
Associate Executive Director, Epidemiology, EP
Directorate for Epidemiology

Stephen Hanway
Division Director, Hazard Analysis, EPHA
Directorate for Epidemiology

FROM : Ted Yang
Division of Hazard Analysis
Directorate for Epidemiology

SUBJECT : Infant Bouncer Seats-Related Deaths, Injuries, and Potential Injuries; January 1,
2014 to July 6, 2016

Introduction

This memorandum updates data for infant bouncer seats received by the U.S. Consumer Product Safety Commission (Commission or CPSC) since the notice of proposed rulemaking (NPR) briefing package was presented to the Commission in September 2015. The time frame covered in the previous data extraction was January 1, 2006 to December 31, 2013, for injury characterizations based on National Electronic Injury Surveillance System (NEISS) records and January 1, 2006 to February 2, 2015, for incident reports in the Injury or Potential Injury Incident (IPII), In-Depth Investigation (INDP), and Death Certificates (DTHS) databases managed by CPSC's Consumer Product Safety Risk Management System (CPSRMS). This memorandum summarizes infant bouncer-related NEISS records from January 1, 2014 through December 31,

2015, and infant bouncer seat incident data from CPSRMS since February 2, 2015 through July 6, 2016.¹⁴

Infant bouncer seats are categorized within CPSC data under the product code 1558 (baby bouncer seats, excluding jumpers). However, not all incidents involving infant bouncer seats are covered by product code 1558. As a secondary measure, CPSC staff also searched for keywords suggestive of infant bouncer seats from product codes 1549 (other baby carriers), 1520 (baby exercisers), 1553 (portable baby swings, for home use), 1807 (floors or flooring materials), and 4074 (chairs, other or not specified). Staff reviewed these additional incidents to determine if indeed they involved an infant bouncer seat.

I. Incident Data¹⁵

a. CPSRMS Data

At the time of the NPR briefing package, CPSC staff was aware of a total of 277 incidents, including 11 fatalities and 51 reported injuries, involving infant bouncer seats occurring between January 1, 2006 and February 2, 2015.

Since the extraction of those data, CPSC staff has received 70 incident reports involving infant bouncer seats from CPSRMS, including one fatality and three injuries. A 4-month-old female child died after suffering a fractured skull when the infant bouncer seat fell from a table. Two additional incident reports described head contusions resulting from a bouncer tipping over on the floor and a bouncer cover coming off. In another incident report, the victim suffered minor leg burns from a hot metal bar under a bouncer cover.

b. NEISS Data

For the NPR briefing package, CPSC staff retrieved 672 NEISS records describing infant bouncer incidents between January 1, 2006 and December 31, 2013. Staff found that 385 cases, or an estimated 9,200 injuries, occurred in hazardous environments (counters, tables, and other elevated surfaces).

¹⁴ 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.

¹⁵ The CPSC databases searched were the National Electronic Injury Surveillance System (NEISS) and the Consumer Product Safety Risk Management System (CPSRMS). CPSRMS combines data stored in the In-Depth Investigation (INDP) file, the Injury or Potential Injury Incident (IPII) file, and the Death Certificate (DTHS) file. The date of extraction was 7/6/16. The reported 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 infant bouncer seats.

From January 1, 2014 through December 31, 2015, staff found 202 additional NEISS records describing infant bouncer incidents. Staff's inspection of the updated NEISS data revealed that 100 cases, or an estimated 2,800 injuries, took place in hazardous environments. The remaining 102 cases, or an estimated 2,800 injuries, took place on the floor or at an unknown location. Staff found no additional fatalities in the NEISS data. Staff estimates that 4,700 (85%) bouncer injuries involved the head and face.

Estimated NEISS Bouncer Injuries, 2006-2015 (age 0-1)

Year	Cases	Estimated Injuries
2006	67	1,400
2007	66	1,700
2008	74	1,600
2009	86	2,200
2010	94	2,300
2011	121	3,400
2012	90	2,500
2013	74	2,100
2014	98	2,900
2015	104	2,700
2006-2015	877	22,800

Based on the annual estimates provided in the table, staff found a statistically significant upward trend (p-value of 0.006) in the estimated emergency department-treated injuries involving bouncers for victims under 1-year-old from 2006 to 2015.

II. Hazard Pattern Identification

Staff did not identify any new hazards in the updated incident data beyond the hazard patterns already mentioned in the NPR briefing package (product design, structural integrity, toy bar-related, stability, chemical/electric hazards, restraints, hazardous environment), which specifically identified *product design* and *structural integrity* as the top two product-related hazards (in terms of frequency of occurrence). Similarly, staff found that product design and structural integrity were also the top two product-related hazards (in terms of frequency) for the updated CPSRMS data. Of the 70 incident reports involving infant bouncers, 51 incident reports described issues with product design, while 13 incident reports described issues with structural integrity. Staff determined that almost all of the issues with product design were related to lopsided or low-riding bouncer frames.

TAB B: Infant Bouncer Seats: Human Factors Staff Responses to NPR Comments

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

Memorandum

Date: August 23, 2017

TO: Suad Wanna-Nakamura, Ph.D.
Project Manager, Infant Bouncer Seats Rulemaking
Division of Pharmacology and Physiology Assessment
Directorate for Health Sciences

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

FROM : Rana Balci-Sinha, Ph.D.
Division Director of Human Factors
Directorate for Engineering Sciences

SUBJECT: Infant Bouncers: Human Factors Staff Responses to Comments

I. Introduction

The Commission issued a notice of proposed rulemaking (NPR) for a safety standard for infant bouncer seats in the *Federal Register* (80 *Fed. Reg.* 63168, (Oct. 19, 2015)). The NPR proposed to incorporate by reference the voluntary standard, ASTM F2167-15 *Standard Consumer Safety Specification for Infant Bouncer Seat* (ASTM F2167-15), with the following proposed modifications:

1. Revise content of the warnings, markings, and instructions:
 - (a) modify text in the warnings stating to use the restraints “. . . even if baby is sleeping”;
 - (b) change the text in the warnings to read: “stop using when baby starts trying to sit up”;
 - and
 - (c) change the developmental guidance in the instructions, if stated, to read: “from birth (or “0”) until baby starts trying to sit up.”
2. Require the fall hazard label on the front surface of the bouncer to be adjacent to the area where the child’s head would rest, and modify the visibility test to reflect this requirement.
3. Specify a standard format (including black text on a white background, table design, bullet points, and black border) for the warnings on the product and in the instructions.

This memorandum summarizes warning label-related clarifications made in the draft final rule and provides responses to the major human factors issues raised in the comments submitted in response to the NPR.

II. Summary of Warnings Requirements in the Draft Final Rule

1. Clarify the acceptable area for the warning label on the bouncer seat back and the corresponding visibility test proposed in the NPR.

ASTM F2167 requires that the fall hazard label be placed on the front surface of the bouncer seat back so that it is visible when a newborn CAMI dummy is placed in the bouncer seat. In the NPR, the Commission assessed this provision of the voluntary standard and found that it did not adequately address the risk of injury to infants falling from and with bouncer seats placed on elevated surfaces, a foreseeable misuse related to infant bouncer seats¹. To strengthen the standard and further reduce the risk of injury, the NPR proposed that the fall hazard warning label be on the front surface of the bouncer seat, adjacent to where the child's head would rest, and the NPR also modified the visibility test.

In the draft final rule, staff recommends clarifying the area of the seat back that is considered "adjacent to the area where a child's head would rest" and the associated visibility test. Commenters were concerned that for some products, the area adjacent to the child's head was insufficient to accommodate the necessary warning labels. Commenters were also concerned about the repeatability of the visibility test in the NPR. Staff's research on the seat back space, including models with narrow seat backs, did not corroborate the commenters' concerns. Nevertheless, to enhance test repeatability and to address the comments to increase allowable space for warning labels, staff has clarified and enlarged the acceptable area for warning label placement in the NPR, as well as clarified the corresponding visibility test. The visibility test is based on ASTM F2167-17 and adds an observable line using the CAMI dummy to determine whether the warning labels are located per the requirements. This allows additional seat back space for warning labels and clarifies the precision of the visibility test, both of which should address commenters' concerns.

2. Revise content of the warnings, markings, and instructions proposed in the NPR to modify text in the warnings stating to use the restraints "... even if baby falls asleep."

ASTM F2167-17 does not require a warning stating that caregivers should use the restraints, even if an infant is asleep. The current language states: "Always use restraints. Adjust to fit snugly." Based on the incident data relating deaths from suffocation among unrestrained infants while they slept, as well as serious head injuries to unrestrained infants due to falls from bouncer seats when they are placed on elevated surfaces, and falls from bouncer seats being carried, the Commission stated in the NPR that the voluntary standard was inadequate to address the risk of injury to infants from falls out of bouncer seats, or the risk of suffocation among unrestrained infants who are sleeping. Accordingly, in the NPR, the Commission proposed warning language stating: "Adjust to fit snugly, *even if baby is sleeping.*"

¹ <http://www.cpsc.gov/Global/Newsroom/FOIA/CommissionBriefingPackages/2015/ProposedRuleSafetyStandardforInfantBouncerSeatSeptember302.pdf>. (Tab D)

Some commenters expressed concern about the addition of language to the product warnings regarding sleep, asserting that the language may suggest that bouncer seats are intended to be used for long-term, unattended, sleep. Infants sleep in bouncer seats, and based on the injury data, staff continues to be concerned about seating infants in bouncers without the use of restraints. Incident data show that unrestrained infants suffer serious head injuries due to falls from or with the bouncer seats or getting into compromised positions that may result in suffocation. Furthermore, some bouncers on the market indicate short periods of sleep as a proper use scenario. For these reasons, staff advises that caregivers be instructed to use the restraints, even when a baby is sleeping.

Staff recommends substituting the words, “falls asleep,” for “is sleeping,” in the draft final rule. The recommended change aligns with the wording approved by the Ad Hoc Task Group for products like bouncers. The Ad Hoc Task Group wording, which is: “*Never leave child unattended, even if child falls asleep,*” is intended for products likely to be used for infants who are sleeping but that are not intended for periods of unattended sleep (*i.e.*, bouncers, swings, infant rockers, and handheld carriers). During the April 2017 ASTM meetings, several Ad Hoc Task Group members requested the removal of this sentence from the Ad Hoc recommendations because no subcommittee adopted the sentence. In the discussions, some manufacturers stated that these products are not appropriate for sleep, stating that the language “even if baby falls asleep,” may mislead caregivers. The Ad Hoc Group balloted the removal of the sentence in June 2017; however, the ballot received multiple negative votes and did not pass. Based on the incident data and traditional use pattern of bouncers, infants sleep or doze off while in bouncers. Incident data and Health Sciences’ assessment demonstrate that being unrestrained increases the severity of injury from a fall. Thus, staff still advises that the statement, “even if baby falls asleep,” be on the warning label for bouncer seats. This statement does not preclude manufacturers who believe that their bouncers should not be used for sleep from adding language to alert caregivers that bouncers are not designed for safe sleeping.

In conclusion, staff’s recommendation for the final rule differs from the warning label text in the NPR, as shown below:

For fall hazard warning label:

- Always use restraints and adjust to fit snugly, even if baby is sleeping falls asleep.

For suffocation hazard warning label:

To prevent falls and suffocation:

- Always use restraints and adjust to fit snugly, even if baby is sleeping falls asleep.

3. Other changes that were recommended in the NPR:

The following two changes that were recommended in the NPR were incorporated into the ASTM standard in a format that is either exactly or substantially the same as the NPR language. Thus, staff no longer recommends these changes:

- (a) After the NPR was issued, ASTM revised the voluntary standard to require that the warning label state: “stop using when baby starts trying to sit up.” ASTM made this revision in ASTM F2167-16 and the language remains in the 2017 version. This language

aligns with text the Commission proposed in the NPR, and thus, staff recommends removing this change.

- (b) The warning label format in the NPR is now consistent with ASTM F2167-17. Human Factors staff regularly cites the ANSI Z535.4 *American National Standard for Product Safety Signs and Labels* as a baseline in developing warning materials. Proposed changes on the formatting of warning labels in the NPR are consistent with the ANSI Z535.4 language. Since the NPR was issued, the Ad Hoc Task Group convened and made recommendations for warnings across juvenile products that are based on ANSI Z535.4 and included more stringent requirements.² The Ad Hoc Group's recommendations were originally published as a reference document titled, "Ad Hoc Wording – May 4, 2016," as part of the F15 Committee Documents, which subsequently was revised and published in October 2016 with the title, "Ad Hoc Approved Wording, Revision A – October 17, 2016" (Ad Hoc Approved Wording). Following publication of the Ad Hoc Approved Wording, the ASTM F15.21 Subcommittee for Infant Bouncers balloted changes in the ASTM F2167-16 to align with Ad Hoc Approved Wording recommendations. The ballot passed, and the ASTM F2167-17 version of the standard incorporating these changes was published in June 2017. Adopting the Ad Hoc Wording reference document recommendations provides noticeable and consistent warning labels on infant bouncer seats and across juvenile products.

III. Public Comments

CPSC received six comments in response to the NPR, one of which is a joint letter submitted by four consumer advocacy groups. Three commenters support the changes proposed by the CPSC. Staff's responses to the remaining three commenters are provided below.

1. Warning Label Location

Comment 1: One commenter stated that the proposed requirement for the fall hazard warning label to be adjacent to the infant's head would necessitate a wider seat back. The same commenter also stated that the requirement would not allow a warning label in multiple languages to be presented in this location, which is desirable for international sales. According to the same commenter, the ASTM F15.21 Subcommittee had already evaluated this location and concluded that other locations above and below the infant's head were considered to be just as visible as the locations adjacent to an infant's head. A second commenter stated that the proposed fall hazard label visibility test procedure is not specific and can be misinterpreted by test labs. This commenter suggested using the test protocol in the current ASTM standard that uses the CAMI newborn dummy.

Response 1: Based on the incident data and research, CPSC staff continues to recommend placing the fall hazard warning label near the child's face. This location allows caregivers to

² Ad Hoc Task Group consists of members of the various voluntary standards affected by the durable nursery products rules and was formed to harmonize the wording as well as warning format in durable infant and toddler products.

notice the label while making eye contact with the infant, and potentially creates mental images of the consequence (“skull fracture”) of not complying with the instructions because the warning label would be placed next to the body part at risk.³ Commenters claim that the area adjacent to an infant’s head could be severely limited in some cases, due to the design of the seat back and allowance needed for stitching tolerances. CPSC staff’s research did not corroborate this claim. *Ibid.* Accordingly, the NPR, 80 *Fed. Reg.* 63168, 63179-80 (Oct. 19, 2015), invited commenters to provide information on costs and design changes that would be required if the label were required to be next to an infant’s head. Commenters provided neither cost estimates, nor specific comments, other than stating that the location would require a wider seat back and would limit representing multiple languages. During the ASTM Ad Hoc Task Group meetings held in January and February 2016, manufacturers provided several examples of juvenile products, including infant bouncer seats, to demonstrate difficulties associated with warning label placement in proposed locations.

To resolve commenters’ concerns and address staff’s concern about an effective warning label, staff recommends that the allowable area for the fall hazard warning label and test procedure be clarified in the draft final rule. A warning label located at or around the infant’s shoulders can address the visibility and caregiver motivational concerns expressed in the Human Factors staff memorandum for the NPR (Tab B), and meanwhile, provide additional surface area to accommodate the recommended warning label.

The recommended changes in the draft final rule outlined below relate to sections 7.11 and 8.3.3.1 of the ASTM standard (additions to the ASTM standard are shown as underlined text; deletions are shown as strike-through) and provide clarity and visual guidance to determine appropriate placement of the warning label:

7.11 Fall Hazard Label Visibility Test:

7.11.1 Place infant bouncer seat on the floor.

7.11.2 Place and secure the Newborn CAMI dummy (Fig. 2) in the infant bouncer seat.

7.11.3 *Visibility Tests With and Without Accessories and Toy Bars:*

7.11.3.1 *Visibility With CAMI Dummy Restrained in Seat*— While standing in front of the product with the Newborn CAMI dummy installed, verify that the required warnings are visible and placed above an imaginary horizontal line that crosses through the junctions of underarm and side of the torso (armpits) on both left and right and not obscured by any part of the dummy (Figure 10).

³ <http://www.cpsc.gov/Global/Newsroom/FOIA/CommissionBriefingPackages/2015/ProposedRuleSafetyStandardforInfantBouncerSeatSeptember302.pdf>. (Tab D)

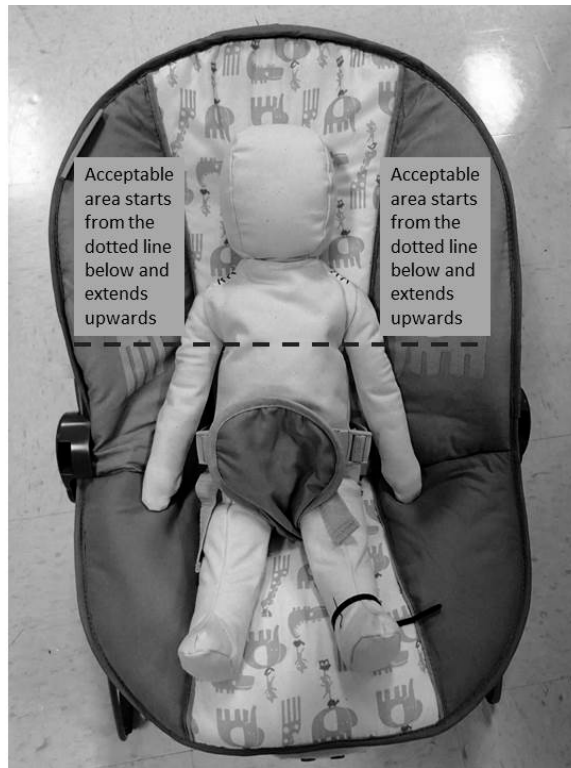


Fig 10. Allowable area for warning label placement starts from the dotted line that crosses the junctions of underarm and both sides of the torso.

2. Warning Label Format

Comment 2: Two commenters recommended against the proposed formatting requirements. Commenters specifically highlighted the following proposed warning formatting requirements:

- A heavy black border around the label,
- Delineating message panels with solid lines,
- Black text on white message panel,
- Bullet points preceding precautionary statements,
- Choosing a background color for the signal word panel based on a best contrast against the product material, and
- Using non-condensed style font.

Commenters stated that, in general, ASTM standards provide flexibility to manufacturers to pick colors and formatting features that are most appropriate for the product. One commenter recommended delaying publication of the final rule for any and all warning requirements until the warning format and content revisions proposed in the NPR can be reviewed with respect to the ASTM Ad Hoc Task Group, balloted through the ASTM process, and thereafter implemented into F2167. The same commenter also indicated that the formatting requirements in the bouncer NPR and several other NPRs are inconsistent with each other.

Response 2: As stated in staff's NPR Briefing Package, Human Factors staff at CPSC employs ANSI Z535.4, *American National Standard for Product Safety Signs and Labels*, as a baseline to develop warning materials. The standard, which is one of the ANSI Z535 series of standards, establishes performance requirements for the design, application, use, and placement of safety signs and labels on a wide variety of products. As previously noted, the ASTM Ad Hoc Task Group recommendations are based on, but are more stringent than, the ANSI Z535 series.

ESHF staff supports the changes in the ASTM F2167-17 that meet the recommendations developed by the Ad Hoc Task Group. Ad Hoc recommendations address the public comments specific to the bouncer seat warning label formatting requirements, as follows:

- Heavy black border around the label: Ad Hoc-Approved Wording has a distinctiveness requirement for the label, which may be achieved by a contrasting border, as well as white space or a line.
- Delineating message panels with solid lines: Ad Hoc-Approved Wording includes a requirement to allow sufficient space between multiple messages.
- Black text on white message panel: Ad Hoc-Approved Wording requires that the message panel have either black lettering on a white background, or white lettering on a black background.
- Bullet points preceding precautionary statements: Ad Hoc-Approved Wording advises that the text in each column is to be arranged in list or outline format, with precautionary (hazard avoidance) statements preceded by bullet points.
- Choosing a background color for the signal word panel, based on a best contrast against the product material: Ad Hoc-Approved Wording requires that the word WARNING be in black letters on an orange background.
- Non-condensed-style font: Ad Hoc-Approved Wording states that for improved warning readability, use of typefaces with large height-to-width ratios, which are commonly identified as "condensed," "compressed," "narrow," or similar, should be avoided.

Accordingly, for the draft final rule, staff recommends adopting, without modification, ASTM F2167-17 for the format of the warning label.

3. Warning Label Language with Reference to Sleeping

Comment 3: Two commenters recommended against the proposed addition of "even if baby is sleeping" to the end of the precautionary statement: "Always use restraints. Adjust to fit snugly." One commenter expressed the belief that this statement implies that sleeping in a bouncer is acceptable and may encourage caregivers to use the product for extended periods of sleep. The second commenter stated the belief that this statement contradicts the warning to never leave children unattended in a bouncer.

Response 3: Incident data associated with bouncers show that unrestrained infants suffer serious head injuries from falls and get into compromised positions that may result in suffocation.⁴

⁴ <http://www.cpsc.gov/Global/Newsroom/FOIA/CommissionBriefingPackages/2015/ProposedRuleSafetyStandardforInfantBouncerSeatSeptember302.pdf>. (Tab A)

Young infants will sleep in bouncers because they spend more time asleep than awake.⁵ Some bouncers in the market advertise calming and soothing features of a bouncer, as well as appropriateness for short periods of sleep in a bouncer, such as: “Your child can also sleep for short periods of time in the bouncer if he or she is content doing so.” During the discussions with ASTM bouncer subcommittee members, manufacturers identified the hazard as infants sleeping in the bouncers.

In addition, the ASTM Ad Hoc Task Group approved recommending a warning on this issue in October 2016. The recommended wording: “Products likely to be used for infants who are sleeping (*i.e.*, bouncers, swings, infant rockers, handheld carriers) that are not intended for periods of unattended sleep, would benefit from this warning about unattended use.”

“Never leave child unattended, even if child falls asleep.”

Although staff agrees with the Ad Hoc Task Group’s language, during the April 2017 ASTM meetings, several Ad Hoc Group members stated that referencing sleep on a warning label is not appropriate and requested removal of this sentence from Ad Hoc recommendations. The removal of the sentence was balloted in June 2017; the ballot received multiple negative votes and did not pass. Because infants fall asleep in bouncers, and due to associated hazards demonstrated in the incident data, staff advises that reference to sleep on the bouncer seat warning label is paramount. This does not preclude manufacturers who produce certain bouncers in which infants should not be allowed to sleep to add a language alerting the caregivers to this issue. The Ad Hoc Task Group is continuing to work on the recommended wording to reach a consensus, and CPSC staff is participating in the discussions.

4. Warning Label Language Related to Developmental Guidance

Comment 4: One commenter recommended that the ASTM subcommittee reach a consensus on the need for the additional proposed language: “Stop using bouncer when baby starts trying to sit up.”

Response 4: At the ASTM meeting of January 12, 2016, the F15.18 subcommittee on Infant Bouncer Seats reviewed and agreed with the Commission’s proposed language on developmental guidance. ASTM balloted and approved the proposed language and it is included starting from the ASTM F2167-16 version of the standard.

5. Warning Label Attachment Method

Comment 5: Two commenters recommended attaching the warning label to the product using embroidery or stamping to increase its permanency.

⁵ <http://www.cpsc.gov/Global/Newsroom/FOIA/CommissionBriefingPackages/2015/ProposedRuleSafetyStandardforInfantBouncerSeatSeptember302.pdf>. (Tab D)

Response 5: The ASTM standard does not require a certain type of attachment for labels but requires the labels to be tested per section 7.8 to determine the labels' permanency. A similar permanency test procedure is used in other ASTM standards. No data were provided by the commenter, and staff has no information suggesting that the ASTM requirements are ineffective. Accordingly, staff recommends adopting section 7.8 of ASTM F2167-17 without modification.

6. Pictorial Symbols

Comment 6: Three commenters recommended using pictures to clarify the warning messages.

Response 6: Staff acknowledges that well-designed graphics can be useful to increase the noticeability of the warnings because they help capture a user's attention. Pictograms are also helpful for users with limited or no English literacy. However, the design of effective graphics can be difficult. To avoid confusion, a warning pictogram should be developed with an empirical study and be well-tested on the target audience. Although staff could recommend that the Commission take action in the future if staff believes graphic symbols are needed to reduce the risk of injury associated with these products, the rule permits, but does not mandate, such supporting graphics.

III. Conclusion

ESHF staff suggests two clarifications to ASTM F2167-17, one associated with the warning requirements in the draft final rule to address public comments received in response to the NPR for infant bouncer seats, and another regarding changes to the voluntary standard made after publication of the NPR. Staff recommends that (1) warnings advise caregivers to use the restraints "even if baby falls asleep," and (2) visibility test and location requirements be clarified. Staff's recommended revisions to ASTM F2167-17 are detailed in the Appendix of this memorandum. Staff believes that these changes will further reduce the risk of injury by informing caregivers on the proper use of restraints in foreseeable scenarios and improve the noticeability and compliance with the warning language stated in the fall hazard warning label.

APPENDIX

CPSC Staff-Recommended Changes to the Proposed Rule for Infant Bouncer Seats

ASTM F2167-17 Section #	NPR Language (Additions to the ASTM F2167-15 are shown as underlined text, deletions are shown with strikethroughs)	Draft Final Language (carryover NPR language have no lines underneath; additions to the NPR language that are identical to ASTM F2167-17 are shown with dashed underline; additions to the NPR language that are not present in ASTM F2167-17 are shown as double underlined text, NPR additions to the ASTM F2167-15 are shown as underlined text; deletions are shown with strikethroughs)
<p>7.11 <i>Fall Hazard Label Visibility Test:</i></p> <p>7.11.1 Place infant bouncer seat on the floor.</p> <p>7.11.2 Place and secure the Newborn CAMI dummy (Fig. 2) in the infant bouncer seat.</p> <p>7.11.3 <i>Visibility Tests With and Without Accessories and Toy Bars:</i></p> <p>7.11.3.1 <i>Visibility With CAMI Dummy Restrained in Seat—</i></p> <p>While standing in front of the product with the Newborn CAMI dummy installed, verify that the required warnings are visible and not obscured by any part of the dummy.</p> <p>7.11.3.2 <i>Visibility with Accessories (Excluding Toy Bars)—</i></p> <p>Infant bouncer seats that include any accessory (ies) that could potentially obscure the fall hazard warning shall</p>	<p>7.11 <i>Fall Hazard Label Visibility Test:</i></p> <p>7.11.1 Place infant bouncer seat on the floor.</p> <p>7.11.2 Place and secure the Newborn CAMI dummy (Fig. 2) in the infant bouncer seat.</p> <p>7.11.3 <i>Visibility Tests With and Without Accessories and Toy Bars:</i></p> <p>7.11.3.1 <i>Visibility With CAMI Dummy Restrained in Seat—</i></p> <p>While standing in front of the product with the Newborn CAMI dummy installed, verify that the required warnings are visible and not obscured by any part of the dummy.</p> <p>7.11.3.2 <i>Visibility with Accessories (Excluding Toy</i></p>	<p>7.11 <i>Fall Hazard Label Visibility Test:</i></p> <p><u>7.11.1 Place infant bouncer seat on the floor.</u></p> <p><u>7.11.2 Place and secure the Newborn CAMI dummy (Fig. 2) in the infant bouncer seat.</u></p> <p><u>7.11.3 <i>Visibility Tests With and Without Accessories and Toy Bars:</i></u></p> <p><u>7.11.3.1 <i>Visibility With CAMI Dummy Restrained in Seat—</i></u></p> <p><u>While standing in front of the product with the Newborn CAMI dummy installed, verify that the required warnings are visible and placed above an imaginary horizontal line that crosses through the junctions of under arm and side of the torso armpits on both left and right and not obscured by any part of the dummy (Figure 10).</u></p>

comply with visibility requirements of 7.11 both with such accessory (ies) in place (in all configurations and combinations) and with the accessory (ies) removed.

7.11.3.3 Visibility With Toy Bar—If any part of the required warnings is obscured by a toy bar or its attached toys, but is visible with a shift of the observer's head position, then this is considered acceptable.

~~**Bars**—Infant bouncer seats that include any accessory (ies) that could potentially obscure the fall hazard warning shall comply with visibility requirements of 7.11 both with such accessory(ies) in place (in all configurations and combinations) and with the accessory(ies) removed.~~

7.11.1 Visibility with Accessories Excluding Toy Bar Identify and install each accessory unrelated to the toy bar that could obscure the warning label during a caregiver's interaction with the occupant.

Place the bouncer on the floor.

7.11.2 Face the front of the bouncer from a distance of 1.0 ft (0.3 m and verify that all warning text is visible and not obscured by the accessory (ies).

7.11.2.3 A label on the bouncer seat back surface that is obscured by an accessory such as an infant insert would meet the visibility requirement if the label is plainly visible and easily readable on the accessory.

7.11.3 Visibility with Toy Bar and Related Accessories Identify and install the toy bar and related accessory (ies) that could obscure the warning label during a



Fig 10. Allowable area for warning label placement starts from the dotted line that crosses the junctions of underarm and both sides of the torso.


7.11.3.2 Visibility with Accessories (Excluding Toy Bars)—Infant bouncer seats that include any accessory(ies) that could potentially obscure the fall hazard warning shall comply with visibility requirements of 7.11 both with such accessory(ies) in place (in all configurations and combinations) and with the accessory(ies) removed.

7.11.3.3 Visibility With Toy Bar—If any part of the required warnings is partly obscured by a toy bar or its attached toys related accessories, but is visible with a shift of the observer's head position would meet the visibility requirement, then this is considered acceptable.

7.11.1 Visibility with Accessories Excluding Toy Bar Identify and install each accessory unrelated to

	<p><u>caregiver's interaction with the occupant. Place the bouncer on the floor.</u></p> <p><u>7.11.3.1 Face the front of the bouncer from a distance of 1.0 ft (0.3 m and verify that all warning text is visible and not obscured by the toy bar and related accessory (ies).</u></p> <p><u>7.11.3.32 Visibility With Toy Bar</u>—If any part of the required warnings <u>A fall hazard label that is partly obscured by a toy bar or its attached toys related accessories, but is visible with a shift of the observer's head position would meet the visibility requirement,</u> then this is considered acceptable.</p>	<p><u>the toy bar that could obscure the warning label during a caregiver's interaction with the occupant. Place the bouncer on the floor.</u></p> <p><u>7.11.2 Face the front of the bouncer from a distance of 1.0 ft (0.3 m and verify that all warning text is visible and not obscured by the accessory (ies).</u></p> <p><u>7.11.2.3 A label on the bouncer seat back surface that is obscured by an accessory such as an infant insert would meet the visibility requirement if the label is plainly visible and easily readable on the accessory.</u></p> <p><u>7.11.3 Visibility with Toy Bar and Related Accessories Identify and install the toy bar and related accessory (ies) that could obscure the warning label during a caregiver's interaction with the occupant. Place the bouncer on the floor.</u></p> <p><u>7.11.3.1 Face the front of the bouncer from a distance of 1.0 ft (0.3 m and verify that all warning text is visible and not obscured by the toy bar and related accessory (ies).</u></p>
<p>8.1 Each product and its retail package shall be marked or labeled clearly, and legibly to indicate the following:</p> <p>8.1.1 The name, place of business (city, state, and mailing address, including zip code), and telephone number of the manufacturer, distributor, or seller.</p> <p>8.1.2 A code mark or other means that identifies the date (month and year as a minimum) of manufacture.</p>	<p>8.1 Each product and its retail package shall be marked or labeled clearly, and legibly, and permanently to indicate the following (note that an upholstery label required by law shall not be used to meet the requirements of 8.1):</p> <p>8.1.1 The name of the manufacturer, distributor, or seller, and either the place of business (city, state, and mailing</p>	<p>Same as ASTM F2167-17</p>

	address, including zip code), or telephone number, or both. 8.1.2 A code mark or other means that identifies the date (month and year as a minimum) of manufacture.	
8.2 The manufacturer shall change the model number whenever the infant bouncer seat undergoes a significant structural or design modification or a change that affects its conformance to this consumer safety specification.	8.2 The manufacturer shall change the model number whenever the infant bouncer seat undergoes a significant structural or design modification or a change that affects its conformance to this consumer safety specification.	8.2 The manufacturer shall change the model number whenever the infant bouncer seat undergoes a significant structural or design modification or a change that affects its conformance to this consumer safety specification.
8.2 The marking and labeling on the product shall be permanent.		Same as ASTM F2167-17
8.3 Any upholstery labeling required by law shall not be used to meet the requirements of this section.		Same as ASTM F2167-17
8.3.1 Warning Groups and Headers—Each infant bouncer seat shall be labeled with two groups of warning statements: a fall hazard warning and a suffocation warning. Both warning statement groups shall be preceded by a header consisting of the safety alert symbol and the signal word “WARNING”.	8.3.1 Warning Groups and Headers—Each infant bouncer seat shall be labeled with two groups of warning statements: a fall hazard warning and a suffocation warning. Both <u>Each</u> warning statement groups shall be preceded by a header consisting of the safety alert symbol “▲” and the signal word “WARNING.”	Same as ASTM F2167-17
8.4 Warning Design for Product		Same as ASTM F2167-17
8.4.1 The warning shall be easy to read and understand and be in the English language		Same as ASTM F2167-17

at a minimum.		
8.4.2 Any marking or labeling provided in addition to those required by this section shall not contradict or confuse the meaning of the required information, or be otherwise misleading to the consumer.		Same as ASTM F2167-17
8.4.3 The warnings shall be conspicuous and permanent.		Same as ASTM F2167-17
8.4.4 The warnings shall conform to ANSI Z535.4 – 2011, American National Standard for Product Safety Signs and Labels, sections 6.1-6.4, 7.2-7.6.3, and 8.1, with the following changes.		Same as ASTM F2167-17
8.4.4.1 In sections 6.2.2, 7.3, 7.5, and 8.1.2, replace “should” with “shall.”		Same as ASTM F2167-17
8.4.4.2 In section 7.6.3, replace “should (when feasible)” with “shall.”		Same as ASTM F2167-17
8.4.4.3 Strike the word “safety” when used immediately before a color (e.g., replace “safety white” and “white”).		Same as ASTM F2167-17
8.4.5 Warning Groups—Each infant bouncer seat shall include two separate groups of warning statements: a fall hazard warning and a suffocation warning. The safety alert symbol “  ” and the signal word “WARNING” shall be at least 0.2 in. (5 mm) high and in bold capital letters. The remainder of the text shall be in characters whose upper case shall be at		Same as ASTM F2167-17

<p>least 0.1 in. (2.5 mm), except where otherwise specified.</p> <p>NOTE: For improved warning readability, typefaces with large height-to-width ratios, which are commonly identified as “condensed,” “compressed,” “narrow,” or similar should be avoided.</p>		
8.4.6 Message Panel Text Layout		Same as ASTM F2167-17
<p>8.4.6.1 The text shall be left aligned, ragged right for all but one-line text messages, which can be left aligned or centered.</p> <p>NOTE 2: Left aligned means that the text is aligned along the left margin, and, in the case of multiple columns of text, along the left side of each individual column. Please see Figure A.1 located in Appendix for examples of left aligned text.</p>		Same as ASTM F2167-17
<p>8.4.6.2 The text in each column should be arranged in list or outline format, with precautionary (hazard avoidance) statements proceeded by bullet points. Multiple precautionary statements shall be separated by bullet points if paragraph formatting is used.</p>		Same as ASTM F2167-17
<p>8.4.7 Fall Hazard Warning Location:</p> <p>8.4.7.1 The fall hazard warnings in 8.5.1.1 shall be on the front surface of the infant bouncer seat back so as to comply with the</p>	<p>8.3.3 Warning Locations:</p> <p>8.3.3.1 The fall hazard warnings <u>label</u> in 8.3.4.1 shall be on the front surface of the infant bouncer</p>	Same as ASTM F2167-17

visibility requirements in 7.11.	seat back so as to comply with the visibility requirements in <u>adjacent to the area where a child's head would rest, so that the label is plainly visible and easily readable. If one or more accessories are provided with the bouncer that could obscure the warning label during use, the visibility of the label shall be verified in accordance with 7.11.</u>	
8.5 Each product shall be marked or labeled with warning as follows:		Same as ASTM F2167-17
8.5.1 Fall Hazard Warnings		Same as ASTM F2167-17
8.5.1.1 The fall hazard warning statements shall address the following: Fall Hazard: Babies have suffered skull fractures falling while in and from bouncers. • Use bouncer ONLY on floor. • Always use restraints. Adjust to fit snugly. • Never lift or carry baby in bouncer. [NOTE: Bouncer seats with a handle(s) intended for use to lift and carry a child are exempt from including this warning statement.]	8.3.4.1 <i>Fall Hazard:</i> Fall Hazard: Babies have suffered skull fractures falling while in and from bouncers. • Use bouncer ONLY on floor. • Always use restraints. Adjust to fit snugly, <u>even if baby is sleeping.</u> • Never lift or carry baby in bouncer. [NOTE: Bouncer seats with a handle(s) intended for use to lift and carry a child are exempt from including this warning statement.]	8.5.1.1 The fall hazard warning statements shall address the following: Fall Hazard: Babies have suffered skull fractures falling while in and from bouncers. • Use bouncer ONLY on floor. • ALWAYS use restraints, <u>and adjust to fit snugly, even if baby is sleeping falls asleep.</u> • NEVER lift or carry baby in bouncer. [NOTE: Bouncer seats with a handle(s) intended for use to lift and carry a child are exempt from including this warning statement.]
Note 3: "Address" means that verbiage other than what is shown can be used as long as the meaning is the same or information that is product-specific is		

presented.		
<p>8.5.2 Suffocation Hazard:</p> <p>8.5.2.1. The suffocation hazard warning statements shall address the following: Suffocation Hazard: Babies have suffocated when bouncers tipped over on soft surfaces.</p> <ul style="list-style-type: none"> • Never use on a bed, sofa, cushion, or other soft surface. • Never leave baby unattended. <p>To prevent falls and suffocation:</p> <ul style="list-style-type: none"> • Always use restraints. Adjust to fit snugly. • Stop using bouncer when baby starts trying to sit up or has reached [insert manufacturer's recommended maximum weight, not to exceed 20 lb], whichever comes first.. 	<p>8.3.4.2 <i>Suffocation Hazard:</i> Suffocation Hazard: Babies have suffocated when bouncers tipped over on soft surfaces.</p> <ul style="list-style-type: none"> • Never use on a bed, sofa, cushion, or other soft surface. • Never leave baby unattended. <p>To prevent falls and suffocation:</p> <ul style="list-style-type: none"> • Always use restraints. Adjust to fit snugly, <u>even if baby is sleeping.</u> • Stop <u>using bouncer when baby starts trying to sit up.</u> Never use for a child able to sit up unassisted. 	<p>8.5.2 Suffocation Hazard:</p> <p>8.5.2.1. The suffocation hazard warning statements shall address the following: Suffocation Hazard: Babies have suffocated when bouncers tipped over on soft surfaces.</p> <ul style="list-style-type: none"> • NEVER use on a bed, sofa, cushion, or other soft surface. • NEVER leave baby unattended. <p>To prevent falls and suffocation:</p> <ul style="list-style-type: none"> • ALWAYS use restraints, <u>and a</u> Adjust to fit snugly, <u>even if baby is sleeping falls asleep.</u> • Stop using bouncer when baby starts trying to sit up <u>or has reached [insert manufacturer's recommended maximum weight, not to exceed 20 lb], whichever comes first.</u>
Note 4: "Address" means that verbiage other than what is shown can be used as long as the meaning is the same or information that is product-specific is presented.		Same as ASTM F2167-17
8.5.3 Example warnings in the format described in this section are shown in Figs. 10 and 11 warning formats below are presented as EXAMPLES ONLY for the display of the required warnings. The safety alert symbol "▲" and the signal word " WARNING " shall be as specified above. The warning statements' wording content, as well as the use of any underlining,	8.3.5 Figs. 10-12 label formats below are presented as EXAMPLES ONLY for the display of the required warnings. The safety alert symbol "▲" and the signal word " WARNING " shall be as specified above, but with the option of background colors as described above. The	8.5.3 <u>Example warnings in the format described in this section are shown in Figs. 10-11 and 12</u> warning formats below are presented as EXAMPLES ONLY for the display of the required warnings. The safety alert symbol "▲" and the signal word " WARNING " shall be as specified above. The warning statements' wording content, as well as the use of any underlining, capital lettering, or bold typeface, or a combination thereof, is at the

capital lettering, or bold typeface, or a combination thereof, is at the discretion of the manufacturer.	warning statements' wording content, as well as the use of any underlining, capital lettering, or bold typeface, or a combination thereof, are at the discretion of the manufacturer.	discretion of the manufacturer.
9.1.1.5 Instructions must indicate the manufacturer's recommended maximum weight, height, age, developmental level, or combination thereof of the occupant for which the infant bouncer seat is intended. If the infant bouncer seat is not intended for use by a child for a specific reason (insert reason), the instructions shall so state this limitation.	9.1.1.5 Instructions must indicate the manufacturer's recommended maximum weight, height, age, developmental level, <u>consistent with the warning statement in 8.3.4.2</u> , or combination thereof of the occupant for which the infant bouncer seat is intended. If the infant bouncer seat is not intended for use by a child for a specific reason (insert reason), the instructions shall so state this limitation.	Same as ASTM F2167-17
9.2.1 The instructions shall include all warnings specified in 8.4.5, 8.5.1 and 8.5.2, except warning statement may be in one group. An example warning that meets the requirements is shown in Figure 12. The warning statements' wording content, as well as the use of any underlining, capital lettering, or bold typeface, or combination thereof, is at the discretion of the manufacturer.	9.2.1 The instructions shall contain the warning statements as defined in 8.3.4 and these warnings shall use the format specified in 8.3.1 and 8.3.2, excluding the background color requirements for the header.	9.2.1 <u>The instructions shall include all warnings specified in 8.4.5, 8.5.1 and 8.5.2, except warning statement may be in one group. An example warning that meets the requirements is shown in Figure 12. The warning statements' wording content, as well as the use of any underlining, capital lettering, or bold typeface, or combination thereof, is at the discretion of the manufacturer.</u>

 WARNING
Fall Hazard: Babies have suffered <u>skull fractures</u> falling while in and from bouncers.
<ul style="list-style-type: none"> • Use bouncer ONLY on floor. • ALWAYS use restraints. Adjust to <u>fit snugly</u>. • NEVER <u>lift or carry</u> baby in bouncer.

Fig. 10 Fall Hazard Warning


 WARNING
Suffocation Hazard: Babies have <u>suffocated</u> when bouncers tipped over on soft surfaces.
<ul style="list-style-type: none"> • NEVER use on a bed, sofa, cushion, or other soft surface. • NEVER leave baby unattended.
To prevent falls and suffocation :
<ul style="list-style-type: none"> • ALWAYS use restraints. Adjust to <u>fit snugly</u>. • STOP <u>using bouncer</u> when baby starts trying to sit up

Fig. 11 Suffocation Hazard Warning

 WARNING
FALL Hazard: Babies have suffered <u>skull fractures</u> falling while in and from bouncers.
<ul style="list-style-type: none"> • Use bouncer ONLY on floor. • NEVER <u>lift or carry</u> baby in bouncer.
SUFFOCATION Hazard: Babies have <u>suffocated</u> when bouncers tipped over on soft surfaces.
<ul style="list-style-type: none"> • NEVER use on a bed, sofa, cushion, or other soft surface. • NEVER leave baby unattended.
To prevent falls and suffocation :
<ul style="list-style-type: none"> • ALWAYS use restraints. Adjust to <u>fit snugly</u>. • STOP <u>using bouncer</u> when baby starts trying to sit up.

Fig. 12 Instruction Warning Statements


 WARNING
Fall Hazard: Babies have suffered <u>skull fractures</u> falling while in and from bouncers.
<ul style="list-style-type: none"> • Use bouncer ONLY on floor. • ALWAYS use restraints and adjust to <u>fit snugly</u>, even if baby falls asleep. • NEVER <u>lift or carry</u> baby in bouncer.

Fig 10 11 Fall Hazard Warning


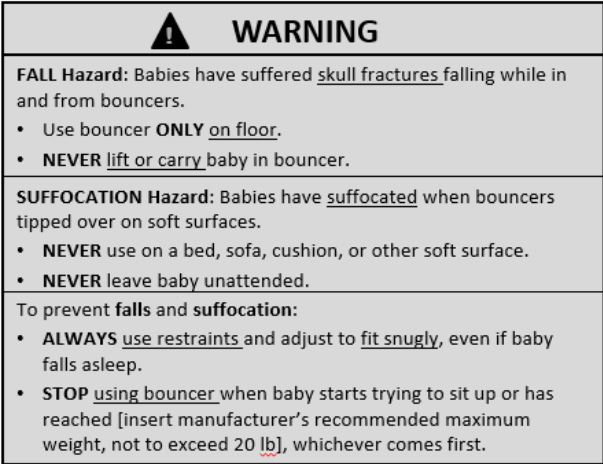
 WARNING
Suffocation Hazard: Babies have <u>suffocated</u> when bouncers tipped over on soft surfaces.
<ul style="list-style-type: none"> • NEVER use on a bed, sofa, cushion, or other soft surface. • NEVER leave baby unattended.
To prevent falls and suffocation :
<ul style="list-style-type: none"> • ALWAYS use restraints and adjust to <u>fit snugly</u>, even if baby falls asleep. • STOP <u>using bouncer</u> when baby starts trying to sit up or has reached [insert manufacturer's recommended maximum weight, not to exceed 20 <u>lb</u>], whichever comes first.

Fig 11 12 Suffocation Hazard Warning

		 <p>Fig. 12. Instruction Warning Statements</p>
<p>9.2.2 Warning statements in instructional literature shall meet the format requirements specified in 8.4.4, 8.4.5, and 8.4.6 with the following two exceptions: the background of the Signal Word panel need not be in color, and clause 6.4 of ANSI Z535.4 need not be applied. An example warning that meets the requirements is shown in Figure 12. The warning statements' wording content, as well as the use of underlining, capital lettering, italics, or bold typeface, or combination thereof, are at the discretion of the manufacturer.</p> <p>Note 14- For additional guidance on the design of warnings for instructional literature, please refer to ANSI Z535.6, American National Standard: Product Safety Information in Product Manuals, Instructions, and Other Collateral Materials.</p>		<p>9.2.2 Warning statements in instructional literature shall meet the format requirements specified in 8.4.4, 8.4.5, and 8.4.6 with the following two exceptions: the background of the Signal Word panel need not be in color, and clause 6.4 of ANSI Z535.4 need not be applied. An example warning that meets the requirements is shown in Figure 12. The warning statements' wording content, as well as the use of underlining, capital lettering, italics, or bold typeface, or combination thereof, are at the discretion of the manufacturer.</p> <p>Note 14- For additional guidance on the design of warnings for instructional literature, please refer to ANSI Z535.6, American National Standard: Product Safety Information in Product Manuals, Instructions, and Other Collateral Materials.</p>

TAB C: Final Regulatory Flexibility Analysis of Staff-Recommended Proposed Standard for Infant Bouncer Seats and Regulatory Flexibility Analysis of the Accreditation Requirements for Conformity Assessment Bodies for Testing Conformance to the Infant Bouncer Seats Standard

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

Memorandum

DATE: August 23, 2017

TO: Suad C. Wanna-Nakamura, Ph.D.
Project Manager, Infant Bouncer Seats
Division of Pharmacology and Physiology Assessment
Directorate for Health Sciences

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

Robert L. Franklin
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
Infant Bouncer Seats and the Accreditation Requirements for Conformity
Assessment Bodies for Testing Conformance to the Infant Bouncer Seats Standard

I. Introduction

On October 19, 2015, the CPSC published a notice of proposed rulemaking (NPR) in the *Federal Register* (FR) (80 FR 63168). The NPR proposed to incorporate by reference the then current voluntary ASTM International (ASTM) standard for infant bouncer seats (F2167-15), with several modifications to the on-product warning labels and instructional literature. Since the NPR, ASTM has published F2167-17,²¹ which includes one of the warning label changes proposed by the Commission. Based on a review of the public comments received in response to the NPR, Division of Human Factors (HF) staff altered its recommendations regarding on-product warning labels and instructional literature. These recommendations and their impact on infant bouncer seat suppliers are discussed in Section VI.

This memorandum evaluates the potential economic impact of the staff-recommended final infant bouncer seat (bouncer or infant bouncer) standard on small entities, including small

²¹ ASTM also published an earlier update, F2167-16.

businesses, as required by the Regulatory Flexibility Act (RFA).²² 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. As explained below, staff finds that the staff-recommended final rule could have a significant economic impact for four of the eleven (36 percent) known small suppliers of infant bouncers to the U.S. market. Accordingly, we have prepared a FRFA.

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 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 requirement and the type of professional skills necessary for preparation of the report or record;
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 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.

II. The Product

An infant bouncer seat is defined in ASTM F2167-17, *Standard Consumer Safety Specification for Infant Bouncer Seats*, as “a freestanding product intended to support an occupant in a reclined position to facilitate bouncing by the occupant, with the aid of a caregiver or by other means.” It is intended for “infants who have not developed the ability to sit up unassisted approximately 0 to 6 months of age).” These products vary widely in price; they can be purchased for as little as \$20, but can also cost more than \$200.

The standard does not cover infant rockers, which is subject to a voluntary ASTM standard (F3084), or infant swings which is covered by both a voluntary ASTM standard (F2088) and a

²² 5 U.S.C. §§ 601-612.

mandatory standard (16 CFR part 1223). Some infant bouncer seats fall into more than one product category and are covered by more than one standard. For example, several firms produce infant rockers that become bouncers with the use of a stop. Also, a few firms produce infant swings that, given the design, can act (and are marketed) as bouncers when the power is turned off.

III. The Market for Infant Bouncer Seats

For the FRFA, staff identified 23 firms supplying infant bouncer seats to the U.S. market, with several firms moving into or out of the market since the NPR. As before, these firms primarily specialize in the manufacture and/or distribution of children's products, including durable nursery products. Eight of the 23 known firms are domestic manufacturers and 8 are domestic importers. The remaining seven firms are foreign (4 manufacturers, 2 importers, and 1 retailer).²³

Staff expects that the infant bouncer seats of 14 of these firms are already compliant with ASTM F2167 because the firms either: (1) have their bouncers certified by the Juvenile Products Manufacturers Association (JPMA) (five firms); (2) claim compliance with the voluntary standard (eight firms); or (3) have been tested to the ASTM standard by CPSC staff (one firm).²⁴

IV. Objectives of the Final Rule

Section 104 of the CPSIA requires the CPSC to promulgate a mandatory standard for infant bouncer seats that is substantially the same as, or more stringent than, the voluntary standard if the Commission determines that a more stringent standard would further reduce the risk of injury associated with such products. The risk associated with infant bouncer use was calculated as part of the initial regulatory flexibility analysis (IRFA) and found to be approximately 10 emergency department-treated injuries per 10,000 infant bouncers in use annually.²⁵

CPSC staff worked closely with ASTM to develop the revised requirements, test procedures, and warning labels that have been incorporated into ASTM F2167 since the rulemaking process started in January 2013 in an effort to reduce this risk. Based on recommendations from the ASTM's Ad Hoc Wording Task Group (ad hoc task group)²⁶ (which CPSC staff actively

²³ Determinations were made using information from Dun & Bradstreet and ReferenceUSAGov, as well as firm websites.

²⁴ JPMA typically allows six months for products in their certification program to shift to a new standard once it is published. Therefore, firms are likely already complying with ASTM F2167-16, which was published in May 2016. They are not expected to comply with the recently published ASTM F2167-17 until December 2017.

²⁵ Memorandum from Jill L. Jenkins, Ph.D., Directorate for Economic Analysis, dated August 3, 2015, Subject: Initial Regulatory Flexibility Analysis of the Staff-Recommended Proposed Standard for Infant Bouncer Seats and the Accreditation Requirements for Conformity Assessment Bodies for Testing Conformance to the Infant Bouncer Seats Standard.

²⁶ The ad hoc task group's purpose is to develop recommended wording for sections common to multiple ASTM standards.

participated in developing), as well as public comments received in response to the October 2015 NPR, staff has modified some of the warning label and instruction manual requirements, which will harmonize with the warning labels of other products.²⁷

V. Issues Raised by Public Comments

There were no comments submitted in response to the NPR that specifically addressed the IRFA. However, several comments focused on the staff-recommended changes to the warning label and instructional manual requirements. Several of those comments resulted in changes to the staff-recommended final standard. The comments and their responses can be found in the Division of Human Factors (HF) memorandum (Tab B). The impact of these recommendations on suppliers, particularly relative to the proposed requirements in the NPR, is discussed below.

VI. Requirements of the Staff-Recommended Final Rule

The staff-recommended final rule would incorporate by reference the voluntary standard for infant bouncer seats (ASTM F2167-17) with modifications to the warning label and instruction manual requirements, making it a mandatory product safety rule under the Consumer Product Safety Act (CPSA). Firms whose bouncers 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 staff-recommended final standard.

A. ASTM F2167-17

The requirements from ASTM F2167-17 remain fundamentally the same as those in ASTM F2167-15²⁸ with the exception of warning label and instruction manual requirements. The latest version of the voluntary standard has incorporated the recommendations of the Ad Hoc Task Group, as was proposed in the NPR. Additionally, ASTM reworded the warning “NEVER use for a child able to sit up unassisted.” to say “STOP using bouncer when baby starts trying to sit up.” This was also one of the proposed changes to the warning label language proposed in the NPR.

B. Staff-Recommended Warning Label Changes

As discussed in the HF memorandum (Tab B), staff recommends two modifications to ASTM F2167-17 for the final rule: (1) change the warning, marking, and instruction language to state that restraints should be used “...even if baby falls asleep;” and (2) a clarification to the on-product warning label location requirement.

²⁷ Memorandum from Rana Balci-Sinha, Ph.D., Director, Division of Human Factors, dated August 23, 2017, Subject: Infant Bouncers: Human Factors Staff Responses to Comments.

²⁸ See Jenkins, 2015 for a complete list of the requirements.

Wording changes, such as (1) are generally straightforward and not expected to generate costs that would be considered significant relative to any of the infant bouncer firm's revenues. To assist in the evaluation of the economic impact of the NPR, Directorate for Economics (EC) staff contacted several ASTM members and supplier representatives. We contacted nine firms (four of which responded) and had informal discussions with approximately five other firm representatives at the ASTM meetings. Four firms provided estimates of the cost to modify the wording of warning labels (at the time, those changes included other formatting modifications as well). These ranged from 8 cents to 50 cents per bouncer unit, depending on the types of changes needed. If several changes to materials, dyes, and/or application processes are needed, costs would tend toward the higher end of the range. Given the more limited changes now recommended by staff, costs are likely to be closer to the low estimate.

As noted in the IRFA, the economic significance of staff's warning label recommendations hinges on the location requirement for the on-product warning labels. The majority of the firm representatives contacted in preparation for the proposed rule (seven of nine) were concerned that insufficient room exists on some bouncer models to accommodate a fall hazard warning adjacent to the infant's head, particularly if the warning is presented in multiple languages. This concern was also reflected in the public comments. As a result, HF staff reviewed the location recommendation and determined that including additional space on the front of the bouncer, down to "an imaginary horizontal line that crosses through the junctions of under arm and side of the torso (armpits) on both left and right," would retain the benefits of the original proposal, while addressing supplier concerns. The modified location requirement nearly doubles the space available for warning labels under the NPR recommendation. As a result, it now appears that up to eight warning labels could be accommodated on bouncers in the U.S. market, although some of the smaller models might still appear cluttered.

Staff still cannot rule out the possibility that a small number of firms operating in several foreign markets with differing warning label requirements might need to develop a unique product to meet U.S. requirements or, alternatively, redesign the product (by increasing the size of the seat back primarily) to accommodate warning labels in multiple languages if they choose to produce a single product that simultaneously conforms to U.S. and all other trading partners' requirements. However, it is unlikely that this would be a widespread problem, as staff has not seen any bouncers with eight languages on a warning label, and staff does not believe that many bouncers supplied to the U.S. include warnings in more than eight languages.²⁹

VII. Impact on Small Businesses

CPSC staff is aware of approximately 23 firms currently marketing infant bouncer seats in the United States, 16 of which are domestic. Under U.S. Small Business Administration (SBA)

²⁹ More than eight warning labels in multiple languages on a bouncer tends to look cluttered regardless of the location. Therefore, although there are three firms that use more than eight languages in their instructional materials (including one firm selling in countries encompassing 34 distinct languages), staff does not believe that it is likely that these firms would find it beneficial to segment their markets in a manner that would require more than eight languages.

guidelines, a manufacturer of infant bouncer seats is categorized as small if it 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 23 firms are small—five domestic manufacturers and six domestic importers. Additional unknown small domestic infant bouncer seat suppliers may be operating in the U.S. market.

Table 1. Firms in the U.S. Infant Bouncers Market

CATEGORY	NUMBER OF FIRMS
Total Firms	23
Domestic	16
Small	11
Manufacturers	5
Compliant with ASTM Voluntary Standard	5
Not Compliant with ASTM Voluntary Standard	0
Importers or Wholesalers	6
Compliant with ASTM Voluntary Standard	3
Not Compliant with ASTM Voluntary Standard	3
Large	5
Foreign	7
Highlighted categories are the focus of this analysis.	

A. Small Manufacturers

The economic impact of the staff-recommended final bouncer standard should be small for the five small domestic manufacturers. Each has an established history of compliance with the ASTM standard for infant bouncers and is therefore expected to be compliant with ASTM F2167-17, the version of the voluntary standard upon which the staff-recommended mandatory standard is based, by the time the mandatory standard becomes final.

None of these firms includes more than four languages in their warnings and redesign is not expected. Based upon inspection of their products, there should be more than sufficient space for their warning labels without the products seeming cluttered under the modified recommendation for the final rule.

Under section 14 of the CPSA, once the new infant bouncer seat requirements become effective, all manufacturers will be subject to the third party testing and certification requirements under the CPSA and the Testing and Labeling Pertaining to Product Certification rule (16 C.F.R. part 1107) (1107 rule). Third party testing will include any physical and mechanical test requirements specified in the final infant bouncer seats rule. Manufacturers and importers should already be conducting required lead testing for bouncers.

Third party testing costs are in addition to the direct costs of meeting the infant bouncer seats standard. The IRFA concluded that we could not rule out a significant economic impact, given that we do not know specifically how much the third party requirement adds to testing costs or precisely how many models are needed to meet the “high degree of assurance,” but that it was unlikely to be economically significant for most small manufacturers (*i.e.*, testing costs would be less than 1 percent of gross revenue). Given that these firms are already testing to the voluntary standard and that staff received no public comments about third party testing, staff believes that it is unlikely that third party testing would have a significant economic impact on any of the five small manufacturers.

B. Small Importers

1. Small Importers with Compliant Infant Bouncer Seats

As noted in the IRFA, imported bouncers tend to be produced to meet the requirements for several trading partners simultaneously, including their different labeling requirements. Producers for international markets typically address labeling requirements for their various trading partners by simply providing a warning that covers all required safety issues in multiple languages. Specificity regarding warning label location impacts the practicability of replicating the warning label in multiple languages. This could mean that foreign producers will need to design a product for the U.S. market or reduce the number of languages used for warnings on U.S.-bound bouncer seats. Because staff has modified the recommended warning label location requirement to allow more space, firms would not need to reduce the number of languages for their on-product warnings for the final rule as drastically as the NPR required.

There are three small importers of infant bouncer seats currently in compliance with the voluntary standard; these firms would likely continue compliance as new versions of the voluntary standard are published. Staff believes that one importer would not likely experience a significant economic impact, even if the importer opted to redesign its bouncers to accommodate more than eight warning label languages. The cost estimate to redesign an infant bouncer (based on information from several firms) is between \$200,000 and \$300,000, which is less than 1 percent of this firm’s . The other two small importers of compliant bouncer seats might experience significant economic costs, based on the same comparison (*i.e.*, \$200,000 to \$300,000 could represent more than 1 percent of their annual revenue). While it is not expected that these firms would require space for warning labels in more than eight languages, staff cannot rule out a significant economic impact for one of these two firms, given an extremely low revenue level compared to estimated costs for redesign. The second firm appears to have the option of exiting the bouncer market without experiencing a significant impact.

2. Small Importers with Noncompliant Infant Bouncer Seats

Three firms import bouncers that do not comply with the voluntary standard. The bouncers for these firms will require changes to come into compliance with the voluntary standard as well as modifications to meet the staff-recommended warning label requirements. In the absence of information on precisely what changes would be required to bring the bouncer seats supplied by all three firms into compliance with the staff-recommended final rule (as well as information on sales revenue for all three firms), staff cannot rule out a significant economic impact for any of these firms.

The magnitude of the economic impact on the three firms with noncompliant infant bouncer seats will depend upon the cost of the changes required and the degree to which their supplying firms pass on any increases in production costs associated with changes to the product needed to meet the mandatory standard (a redesign is estimated to cost between \$200,000 to \$300,000). Two of the firms are directly tied to their foreign suppliers and therefore, finding an alternate supply source would not be a viable alternative. However, given this close relationship, it seems likely that their foreign suppliers would have an incentive to work with their U.S. subsidiaries to maintain an American market presence. However, one of those two firms would likely only avoid a significant economic impact if their supplier absorbed 100 percent of the cost of a redesign. The third firm imports and wholesales a wide variety of children's products. However, we do not know how much of the firm's revenue is due to bouncer sales and cannot determine what impact discontinuing bouncer sales might have on the third firm should the firm be unable to find a supplier of bouncers that comply with the standard.

We can say, however, that the additional space associated with the modified warning label location requirement in the draft final rule means that two of these firms should not require modifications to meet that portion of the staff-recommended standard (although they would have required modifications under the NPR).

3. Third Party Testing Costs for Small Importers

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. Half of the bouncer importers (3 of 6) are already testing their products to verify compliance with the ASTM standard, and any costs would be limited to the incremental costs associated with third party testing over the current testing regime.

We were able to obtain revenue data for one of the small importers with noncompliant bouncers. For that importer, third party testing costs, considered alone and apart from any additional performance requirements due to the draft proposed rule, would not exceed one percent of gross revenue unless around 12 units per model required testing to provide a "high degree of assurance." We had no basis for estimating the size of the impact for the remaining two importers of noncompliant bouncers.

C. Summary of Impacts

CPSC staff is aware of 11 small firms, five domestic manufacturers and six domestic importers, currently marketing infant bouncer seats in the United States. With regards to the five domestic manufacturers, EC staff considers it unlikely that testing costs would have a significant impact on any of these firms. Of the six small importers, a significant economic impact cannot be ruled out for four of the importers either as a result of the staff-recommended requirements or the resulting third party testing costs. Therefore, we cannot rule out a significant economic impact for four of the 11 firms (36 percent) operating in the U.S. market for bouncers.

VIII. Steps the Agency Has Taken to Minimize the Significant Economic Impact on Small Entities

One of the alternatives to reduce the impact on small entities discussed in the NPR was to adopt the voluntary standard with all of the staff-recommended modifications to the on-product warning labels, except for the location specificity (*i.e.*, next to the child's head). Based on comments received, the requirements regarding on-product warning label placement have been modified in the draft final rule (*i.e.*, up from the child's armpits on either side). This provides additional room and EC staff believes that it will reduce the economic impact of the warning label location specificity on small suppliers. The Commission could further reduce the economic impact on small entities by eliminating the location requirement entirely. However, this would reduce the effectiveness of the fall hazard warning label. The staff-recommended location "allows caregivers to notice the label while making eye contact with the infant, and potentially creates mental images of the consequence ("skull fracture") of not complying with the instructions..."³⁰

Two additional alternatives available to the Commission were discussed in the NPR that might minimize the economic impact on small entities: (1) adopt ASTM F2167-17 with no modifications;³¹ and (2) allow a later effective date.

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, adopting ASTM F2167-17 with no modifications is the least stringent rule allowed by law. This alternative would reduce the impact on all of the known small businesses supplying infant bouncers to the U.S. market. If it were adopted, it should eliminate any economic impact related to warning label changes, but firms would continue to be affected by third party testing requirements.

Finally, the Commission could reduce the staff-recommended final rule's impact on small businesses by setting a later effective date. A later effective date would reduce the economic impact on firms in two ways. 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

³⁰ Balci-Sinha, 2017.

³¹ Adopting the voluntary standard with no modifications is an option if the Commission determines that a more stringent standard would not further reduce the risk of injury associated with infant bouncers.

within the required timeframe. Also, firms could spread costs over a longer time period, thereby reducing their annual costs, as well as the present value of their total costs. However, staff received no comments asserting that firms would not have sufficient time to comply with the proposed 6 month effective date.

IX. 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 propose an amendment to 16 C.F.R. part 1112 that would establish the NOR for those testing laboratories that want to test for compliance with the bouncers final rule. This section assesses the impact of the amendment on small laboratories.

A 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 the rule to include the NOR for the bouncer 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 infant bouncer seat 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 bouncer standard to their scope of accreditation, a cost that test laboratories have indicated is extremely low when they are already accredited for other section 104 rules. As a consequence, the Commission could certify that the NOR for the infant bouncer seat standard will not have a significant impact on a substantial number of small entities.