

persons to submit comments on any aspect of the proposed rule. Comments should be submitted in accordance with the instructions in the **ADDRESSES** section at the beginning of this notice.

### List of Subjects

#### 16 CFR Part 1112

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

#### 16 CFR Part 1222

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

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 Part 1112.15 by adding paragraph (b)(34) 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) The CPSC has published previously, or in the cases of 16 CFR parts 1221, 1223, and 1224, and ASTM F 963–11 for the first time, the requirements for accreditation for third party conformity assessment bodies to assess conformity with the following CPSC rules and/or test methods:

\* \* \* \* \*

(34) 16 CFR part 1222, Safety Standard for Bedside Sleepers.

3. Add part 1222 to read as follows:

### PART 1222—SAFETY STANDARD FOR BEDSIDE SLEEPERS

Sec.

1222.1 Scope.

1222.2 Requirements for Bedside Sleepers.

**Authority:** The Consumer Product Safety Improvement Act of 2008, Pub. L. 110–314, § 104, 122 Stat. 3016 (August 14, 2008); Pub. L. 112–28, 125 Stat. 273 (August 12, 2011).

#### § 1222.1 Scope.

This part establishes a consumer product safety standard for bedside sleepers.

#### § 1222.2 Requirements for Bedside Sleepers.

(a) Except as provided in paragraph (b) of this section, each bedside sleeper must comply with all applicable provisions of ASTM F2906–12, Standard Consumer Safety Specification for Bedside Sleepers, approved on June 1, 2012. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from ASTM International, 100 Bar Harbor Drive, P.O. Box 0700, West Conshohocken, PA 19428; <http://www.astm.org/cpsc.htm>. You may inspect a copy at the Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone 301–504–7923, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federalregulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federalregulations/ibr_locations.html).

(b) Comply with the ASTM F2906–12 standard with the following additions:

(1) In addition to complying with section 3.1.7 of ASTM F2906–12, comply with the following:

(i) 3.1.8 “*bedside sleeper accessory*, n—an elevated sleep surface that attaches to a non-full-size crib or play yard, designed to convert the product into a bedside sleeper intended to have a horizontal sleep surface while in a rest (non-rocking) position.”

(ii) [Reserved]

(2) In addition to complying with section 5.6 of ASTM F2906–12, comply with the following:

(i) 5.7 *Bedside Sleeper Accessory Fabric-Sided Enclosed Openings*—A bedside sleeper accessory shall meet the F2194 performance requirement, “*Fabric-Sided Enclosed Openings*.”

(A) 5.7.1 Bedside sleeper accessories are exempt from this requirement if either of the following two conditions is met after disengaging all fasteners between the accessory and the non-full-size crib or play yard base to which it is assembled:

(B) 5.7.1.1 The bedside sleeper accessory collapses under its own weight, such that any part of the mattress pad contacts the bottom floor of the non-full-size crib or play yard.

(C) 5.7.1.2 The bedside sleeper accessory’s sleep surface tilts by more than 30 degrees.

(ii) 5.8 *Bedside Sleeper Play Yard Accessories Missing Key Structural Elements*: A bedside sleeper accessory shall meet the F406 general requirement

“Bassinet/Cradle Accessories Missing Key Structural Elements.”

Dated: December 3, 2012.

**Todd A. Stevenson,**

*Secretary, Consumer Product Safety Commission.*

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### CONSUMER PRODUCT SAFETY COMMISSION

#### 16 CFR Parts 1112 and 1225

[CPSC Docket No. CPSC–2012–0068]

**RIN 3041–AD16**

#### Safety Standard for Hand-Held Infant Carriers

**AGENCY:** Consumer Product Safety Commission.

**ACTION:** Notice of Proposed Rulemaking.

**SUMMARY:** The Danny Keysar Child Product Safety Notification Act, Section 104(b) of the Consumer Product Safety Improvement Act of 2008 (CPSIA) requires the United States Consumer Product Safety Commission (Commission, CPSC, or we) 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 concludes that more stringent requirements would further reduce the risk of injury associated with the product. The Commission is proposing a safety standard for handheld infant carriers in response to the direction under Section 104(b) of the CPSIA. The proposed rule would incorporate ASTM F2050–12 by reference, with two modifications.

**DATES:** Submit comments by February 25, 2013.

**ADDRESSES:** Comments related to the Paperwork Reduction Act aspects of the marking, labeling, and instructional literature of the proposed rule should be directed to the Office of Information and Regulatory Affairs, OMB, Attn: CPSC Desk Officer, Fax: 202–395–6974, or emailed to mailed to: [oira\\_submission@omb.eop.gov](mailto:oira_submission@omb.eop.gov).

Other comments, identified by Docket No. CPSC–2012–0068, may be submitted electronically or in writing:

**Electronic Submissions:** Submit electronic comments to the Federal eRulemaking Portal at: <http://www.regulations.gov>. Follow the instructions for submitting comments. To ensure timely processing of comments, the Commission is no longer

directly accepting comments submitted by electronic mail (email), except through [www.regulations.gov](http://www.regulations.gov). The Commission encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

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

**Instructions:** All submissions received must include the agency name and docket number for this rulemaking. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to: <http://www.regulations.gov>. Do not submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If furnished at all, such information should be submitted in writing.

**Docket:** For access to the docket to read background documents or comments received, go to: <http://www.regulations.gov>, and insert the docket number, CPSC 2012-0068, into the "Search" box, and follow the prompts.

#### FOR FURTHER INFORMATION CONTACT:

Patricia L. Edwards, Project Manager, Directorate for Engineering Sciences, U.S. Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; email: [pedwards@cpsc.gov](mailto:pedwards@cpsc.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background and Statutory Authority

The CPSIA was enacted on August 14, 2008. Section 104(b) of the CPSIA, part of the Danny Keats Child Product Safety Notification Act, requires the Commission 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 concludes 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. Infant carriers are one of the

products specifically identified in section 104(f)(2)(F) as a durable infant or toddler product. At this time, the Commission has identified four types of products that could fall within the infant carrier product category, including: Frame backpack carriers, soft infant and toddler carriers, slings, and handheld infant carriers. This rule addresses hazards associated only with hand held infant carriers. Hazards associated with other types of carriers would be addressed in separate rulemaking proceedings.

In this document, the Commission proposes a safety standard for hand held infant carriers. The proposed standard is based on the voluntary standard developed by ASTM International (formerly the American Society for Testing and Materials), ASTM F2050-12, "Standard Consumer Safety Specification for Hand-Held Infant Carriers." The ASTM standard is copyrighted. However, by permission of ASTM, the standard can be viewed as a read-only document during the comment period on this proposal, at: <http://www.astm.org>.

## II. The Product

### A. Definition

ASTM F2050-12 defines a "hand held infant carrier" as a "freestanding, rigid-sided product intended to carry an occupant whose torso is completely supported by the product to facilitate transportation by a caregiver by means of hand-holds or handles." The current ASTM voluntary standard references two types of hand held infant carriers: hand-held bassinets/cribbs that incline 10 degrees or less from horizontal and sit directly on the floor, and hand-held carrier seats that incline more than 10 degrees from horizontal and are often also used as attachments to serve as infant car seats, strollers, or high chairs. The current ASTM voluntary standard defines "hand-held carrier seat" as a "hand-held infant carrier having a seat back that is intended to be in a reclined position (more than 10° from horizontal)," and "hand-held bassinet/crib" is defined as "freestanding product, with a rest/support surface to facilitate sleep (intended to be flat or up to 10° from horizontal), that sits directly on the floor, without legs or a stand, and has hand-holds or handle(s) intended to allow carrying an occupant whose torso is completely supported by the product." Some of the requirements in F2050-12 are different for hand-held bassinets/cribbs and hand-held infant carriers because the intended position of the occupant (lying supine vs. sitting reclined) and the product designs used

to accommodate the occupant can create different hazards. A Moses basket is considered to be a freestanding product with a rest/support surface to facilitate sleep and typically has hand-holds or handle(s) intended to allow carrying an occupant. Moses baskets typically have semi-rigid sides. The Commission seeks comments on whether Moses baskets are or should be covered by this safety standard. The Commission specifically seeks comments on (1) whether the definition of "hand-held bassinet/crib" in ASTM F2050-12 includes Moses baskets, and (2) if Moses baskets are not covered by the safety standard but should be, how the present definition should be amended to more clearly cover Moses baskets.

### B. The Market

Based on the 2005 survey conducted by American Baby Group titled, "2006 Baby Products Tracking Study," and annual birth data from the Centers for Disease Control and Prevention (CDC), we estimate that approximately 2.1 million infant car seats are sold in the United States each year. We do not know how many hand-held bassinets/cribbs are sold annually. Hand-held carrier seats and hand-held bassinets/cribbs are typically produced and/or marketed by juvenile product manufacturers and distributors, except for Moses baskets, a unique type of hand-held bassinet/crib that is often marketed by bedding manufacturers and distributors. We estimate there are currently at least 43 suppliers of both types of hand-held infant carriers to the U.S. market, 11 of which are domestic manufacturers and 10 of which are domestic importers. We estimate that 20 firms supply Moses basket-style hand-held bassinets/cribbs only, but the source of these carriers is unknown. There are also two foreign firms—a foreign manufacturer and an importer that import products from foreign companies and distributes them in the United States.

The products of 13 of the 43 hand-held infant carrier suppliers will likely be compliant with ASTM F2050-12 (6 are Juvenile Products Manufacturers Association (JPMA) certified to F2050-09; 3 claim compliance with F2050; and 4 have JPMA-certified strollers with hand-held infant carrier attachments).<sup>1</sup>

<sup>1</sup>JPMA typically allows 6 months for products in their certification program to shift to a new standard once it is published. ASTM F2050-12, The voluntary standard upon which the proposed standard is based, will become effective for JPMA certification purposes in approximately March 2013. Firms that supply JPMA-certified strollers are expected to ensure that all of their attachments,

Of the remaining 30 firms supplying noncompliant hand-held infant carriers, the majority (25 firms) supply products that are newly covered due to the expanded scope of ASTM F2050–12 (20 supply Moses baskets; 3 supply bassinet attachments for strollers; and 2 supply other types of bassinet-style carriers) to include hand-held bassinets/crib cradles.

### III. Incident Data

The CPSC's Directorate for Epidemiology notes that there have been 242 incidents, occurring between January 1, 2007 and June 7, 2012, reported to the Commission regarding hand-held infant carriers. Of the 242 incidents, there were 36 fatalities, 60 nonfatal injuries, and 146 incidents where no injury occurred or was reported.

#### A. Fatalities

From January 1, 2007 through early June, 2012, there were 36 fatalities associated with hand-held infant carriers. The majority of the fatalities are attributed to the improper use or non-use of the carrier's restraint system.

Five of the fatalities were caused by the infant carrier being placed in a hazardous environment, and therefore, these fatalities are considered to be non-product related. Two of these fatalities occurred when the infant carrier was placed atop a stove, which subsequently was ignited accidentally. Another fatality was attributed to hyperthermia after an infant was left unattended in a carrier for an extended period of time, wrapped in multiple blankets, and left in a room with temperatures exceeding 90 degrees. In another of these five deaths, an infant in a carrier that was placed cross-wise inside a bassinet was able to tip the carrier into a reclined position, resulting in an asphyxiation death. The last of these five fatalities was the result of an infant suffocating on a blanket that was placed over his head while in the carrier. For an additional two fatalities, the evidence is insufficient to determine if there was any product involvement or the presence of any hazardous external circumstances.

The remainder of the fatal incidents includes:

- Nine children were strangled by the carrier's harness chest clips or strap. In most of these incidents the infant was partially restrained in the seat with only the shoulder straps in place, with the crotch strap left unsecured, which allowed the infant to slide forward in the seat far enough to get caught at the

throat by the chest clip that connects the two shoulder straps.

- In one incident, the restraint straps were too tight and impaired the infant's breathing, although no information regarding the placement of the straps was provided.
- Seven children were left unrestrained in the carrier and found in a prone position, face down on the seat, or on a blanket, covers, and/or pillow.
- Two children who had been left unrestrained in the carrier were found prone on the seat of the carrier, which had also tipped over.
- Three children were reported to have been trapped in an overturned seat, although no information was provided about the use of the restraints or how the seat overturned in these incidents.
- One fatality resulted from a fall from a carrier that was on a shopping cart but not equipped to attach to the cart.
- Six additional deaths were associated with hand-held carriers, but there was insufficient information to determine the circumstances.

#### B. Nonfatal Injuries

From January 1, 2007 through early June 2012, 206 nonfatal incidents were reported. Of those, 60 incidents involved an injury, and 2 of those required hospitalization due to serious head injuries suffered from a fall from a carrier that was on top of a shopping cart. Bumps, bruises, abrasions, lacerations, allergic reactions and near-choking episodes are the most common injuries reported in the remaining 58 injury reports. No age was reported for 28 percent of the injury incidents. For incidents where the age was reported, 1 child was reported to be 13 months old, 1 was reported to be 23 months old, and the rest were 12 months or younger. The remaining 146 incident reports indicate that no injury occurred or they fail to provide any information regarding injuries to the carrier occupant. However, many of the descriptions of the incidents suggest the potential for serious injury or death.

#### C. Recalls

There have been a total of three consumer-level recalls involving hand-held carriers from January 1, 2007 through June 7, 2012.

One recall, involving 450,000 car seats/carriers manufactured from December 2004 through September 2006, pertained to the carrier seat handle. The carrier handle could release unexpectedly, causing the seat to rotate forward in a manner that could result in the occupant of the carrier falling to the

ground and suffering serious injuries. There were 679 incidents of the handle releasing unexpectedly, resulting in 160 injuries reported to the CPSC and the manufacturer. The recall notice instructed consumers not to use the seat as a carrier until the repair kit offered by the manufacturer had been obtained and installed. (The modifications to the handle auto-lock test discussed in Section VI would address this hazard.)

Another recall, conducted on December 18, 2009, involving 447,000 infant car seat/carriers manufactured from January 6, 2008 to April 6, 2009, also pertained to the carrier handle. The seat handle could loosen and fall off, posing a fall hazard to the infant occupant of the seat. There were 77 incidents of the child restraint handle fully or partially detaching from the car seat/carrier, resulting in three injuries, reported to the CPSC and the manufacturer. Consumers were instructed not to use the seat as a carrier until they had obtained and installed the repair kit offered by the manufacturer. (The carrying handle integrity test included in ASTM F2050–12, addresses this hazard.)

The third recall was conducted on November 4, 2010, and it involved 23,000 infant car seats/carriers manufactured between April 2009 and May 2010. The harness chest clips could break, posing a fall hazard, and the broken pieces were small enough for an infant to swallow, which posed a choking hazard. There were four incidents of the chest clip breaking, resulting in three injuries reported to the CPSC and the manufacturer. The injuries that resulted from the clip breaking were minor lacerations and scratches to arms and a finger, and one report involved an infant placing the broken clip in his mouth. The recall notice instructed consumers to contact the manufacturer to request a free repair kit. (The restraint system test included in ASTM F2050–12 addresses this hazard.)

### IV. Hand-Held Carrier International Standards and the ASTM Voluntary Standard

Section 104(b)(1)(A) of the CPSIA requires the Commission to consult representatives of "consumer groups, juvenile product manufacturers, and independent child product engineers and experts" to "examine and assess the effectiveness of any voluntary consumer product safety standards for durable infant or toddler products." As a result of incidents and recalls of hand-held infant carriers in the 1990s, CPSC staff requested ASTM to develop voluntary requirements to address the hazards

including hand-held infant carriers, comply with all applicable ASTM standards as well.

related to handle breakage and handle lock failures. Through the ASTM process, we consulted with manufacturers, retailers, trade organizations, laboratories, consumer advocacy groups, consultants, and members of the public. The voluntary standard for hand-held infant carriers was first approved and published in August 2000, as ASTM F2050–00, *Standard Consumer Safety Performance Specification for Hand-Held Infant Carriers*. It has been revised five times since then. The current version, ASTM F2050–12, was approved on July 1, 2012.

In addition to reviewing the ASTM standard, we reviewed several international standards.

#### A. International Standards

We identified one international standard, EN 12790, *European/British Standard for Child Care Articles—Reclined Cradles*, which addresses hand-held infant carriers in a manner similar to ASTM F2050–12. However, reclined cradles are designed and intended for unattended sleep, and the European standard includes requirements that also pertain to that use pattern. One difference between EN 12790 and ASTM F2050–12 is entrapment dimensions for holes and slot openings. The European standard permits dimensions for slot openings to be between 7 mm and 12 mm, while ASTM F–2050–12 allows dimensions of 5 mm to 9.5 mm. We have concluded that the existing dimensions in the ASTM standard are anthropometrically appropriate and that there are no hazard patterns that would warrant modification of these dimensions. In addition, we concluded that the hazard patterns noted in the incidents do not warrant modification of the ASTM standard to address the requirements for flammability, surface chemicals, cords/ribbons, cradle angles, and cradle strength/durability that appear in EN 12790. Finally, we note that EN 12790 includes requirements for folding cradles, which is a use pattern outside the scope of ASTM F2050–12.

We reviewed several other international standards and a National Highway Safety Transportation Administration (NHTSA) standard that address requirements for restraint systems of products when used in motor vehicles, and we concluded that these standards do not address the incident hazard patterns associated with hand-held infant carriers. These standards are: ECE 44 (European Provision for Restraining Devices for Child Occupants of Power-Driven Vehicles, JIS D 0401 (Japanese Standard for Automotive

Accessories—Child Restraints), AS/NZS 1754:2010 (Australian/New Zealand Standard for Child Restraint Systems for Use in Motor Vehicles), and FMVSS No. 213 (NHSTA Requirements for Child Restraint Systems Used in Motor Vehicles and Aircraft).

#### B. The ASTM Voluntary Standard

In response to incidents and recalls of hand-held infant carriers in the 1990s related to handle breakage and handle lock failures, CPSC requested ASTM to develop voluntary requirements to address the hazards. CPSC staff participated in ASTM subcommittee meetings and testing protocols in developing draft requirements. ASTM F 2050, *Standard Consumer Safety Performance Specification for Hand-Held Infant Carriers* was first approved and published in August 2000. ASTM has revised the standard four times since then, with the most current version ASTM F 2050–12, approved on July 1, 2012. Details regarding the changes in the voluntary standard through revisions in October, 2001, November, 2003, December, 2008, and October 2009, are provided at pages 30 and 31 of the November 7, 2012, Staff Briefing Package.

ASTM F2050–12 addresses many of the general hazards associated with durable nursery products, such as lead in paints, sharp edges/sharp points, small parts, wood part splinters, scissoring/shearing/pinching, openings/entrapments, and toys. Specific requirements for labeling, handle integrity, handle auto-locking, and restraint systems are also included.

The key provisions of the current ASTM hand-held infant carrier standard include: Definitions; general requirements; performance requirements; specific test methods; and requirements for marking, labeling, and instructional literature.

**Definitions.** ASTM F2050–12 defines “hand-held infant carrier” as a “free standing, rigid-sided product intended to carry an occupant whose torso is completely supported by the product to facilitate transportation by a caregiver by means of hand-holds or handles.” The definition of “hand-held infant carrier seat” is “a hand-held infant carrier having a seat back that is intended to be in a reclined position (more than 10° from horizontal).” The definition of “hand-held bassinet/cradle” is a “freestanding product, with a horizontal rest/support surface to facilitate sleep (intended to be flat or up to 10° from horizontal), which sits directly on the floor, without legs or a stand, and has hand-holds or handle(s) intended to allow carrying an occupant

whose torso is completely supported by the product.”

**General Requirements.** ASTM F2050–12 contains general requirements that the product must meet, as well as mandated test methods that must be used to ensure that the product meets those requirements, including:

- Restrictions on sharp points, small parts, lead paint, and wood parts;
- Specifications to prevent scissoring, shearing, and pinching;
- Requirements for toy accessory items, and the non-removal of protective components;
- Specifications on openings (intended to prevent finger and toe entrapment), labeling (intended to prevent labels from being removed and ingested or aspirated on), and coil springs; and
- Torque and tension tests for protective components.

**Performance Requirements and Specific Test Methods.** ASTM F2050–12 provides performance requirements that the product must meet, as well as mandated test methods that must be used to ensure that the product meets the performance requirement, including:

- A carry handle auto-locking requirement (the carry handle must move unaided into the designated carry position or move unaided into a position that is obvious to the caregiver that the carry handle is not in the designated carry position);
- A carry handle integrity requirement (a rigid carry handle that rotates in head-to-foot and foot-to-head directions must not break or unlatch on either or both sides when subject to the handle endurance test);
- A restraint system requirement (hand held carrier seats not intended for use in motor vehicles must have a waist and crotch restraint while hand-held bassinets/cradles may not contain a restraint system);
- Slip-resistance requirements;

**Marking, Labeling, and Instructional Literature.** ASTM F2050–12 sets forth requirements for marking, labeling, and instructions that must accompany a hand-held carrier, including warnings regarding proper use of restraint straps, placement of the carrier on soft or elevated surfaces, and suffocation and strangulation hazards that may arise if restraint straps are not used properly and suffocation hazards that can arise when the carrier is placed on a soft surface. The warning label also advises caregivers never to leave a child unattended in the carrier. The standard also includes requirements and tests for the permanency of labels and warnings.

## V. Assessment of Voluntary Standard ASTM F2050–12

We considered the fatalities, injuries, and noninjury incidents associated with hand-held carriers, and we evaluated the voluntary standard to determine whether ASTM F2050–12 addresses the incidents or whether more stringent standards are required that would further reduce the risk of injury associated with these products. We discuss our assessment in this section, but our assessment does not include deaths and injuries associated with hand-held carriers where there was insufficient evidence to determine the circumstances.

### 1. Hazardous Surroundings

Five of the 36 fatalities reported, and 12 of the 242 incidents reported involving a hand-held carrier were attributable to unsafe environments around the carrier. Two of the five fatalities resulted when the carrier was placed on top of a stove that later was ignited. In another of the fatalities, the infant died from hyperthermia after being left unattended in a carrier, wrapped in blankets, in a room where temperatures exceeded 90 degrees. In another fatality, the infant was placed in the carrier cross-wise inside a bassinet and asphyxiated when the carrier was tipped into a reclined position trapping the infant between the carrier and the interior of the bassinet. The fifth fatality was attributable to a suffocation in which a blanket was placed over the infant's head while in the carrier. Risks due to hazardous surroundings are not attributable to the design or construction of the hand-held carriers. ASTM F 2050–12 includes product warnings that address the dangers of placing the product near the edges of counter tops or on elevated surfaces, and the warnings direct caregivers never to leave a child unattended in a carrier. We do not believe there are additional requirements that can be put into place in the standard to address this issue.

### 2. Hazards Related to Accessories

Issues related to accessories, such as toys, canopies, carrier seat covers, and head and body support devices were reported in 28 of the 242 (12 percent) reported incidents. In 27 of these incidents, the accessory was not supplied with the carrier, but was purchased separately by a caregiver. In the remaining incident, the accessory was an attached canopy. While there were no fatalities involving accessories, the incidents reported included: Choking on a device designed to attach a toy to the carrier handle; jamming an

arm into the side of toy; breathing obstruction from canopy drooping onto child's face; and breaking and detaching small pieces from a pacifier and a pacifier holder. The current standard precludes hazardous sharp edges or points, as defined in 16 CFR 1500.48 and 1500.49 before and after testing to the standard, and prohibits small parts, as defined in 16 CFR part 1501, before testing or liberated as a result of testing to the standard. The standard also requires that any toy accessories attached to, removable from, or sold with, an infant carrier, as well as their means of attachment must meet the applicable requirements of ASTM Consumer Safety Specification F963 (now CPSC's mandatory toy standard). We believe that these requirements are sufficient to address these hazards, and therefore we are not proposing any additional requirements at this time.

### 3. Design Issues

Twenty-eight of the 242 incident reports (12 percent) are attributed to the design of the carrier. Three of the incidents reported in this category were fatalities. Design issues are related to instability, sharp surfaces, unsafe infant posture when seated, and structural integrity. Although the three reported fatalities involve a child becoming trapped under an overturned seat, insufficient information was provided in these reports to determine what caused the seat to overturn. It is possible these tip overs could be related to the stability of the carrier when placed on tables, sofas, or chairs. However, there is insufficient incident data to support a conclusion that design issues were the cause of the fatalities or other incidents. Additionally, many carriers are designed to meet NHTSA requirements for occupant crashworthiness, and modification of the carrier to improve stability when used outside the vehicle might affect how the carrier integrates into the carrier base in the vehicle. For these reasons, we are not proposing any changes to address stability-related design issues at this time.

In addition to stability, this hazard pattern includes occupant-positioning incidents. Six consumer complaints involve infant head slumping. However, we received no reports of fatalities or injuries resulting from infant head slumping. Because we are aware of no injuries resulting from this hazard, and because a revision of the standard to address angle of seat incline may implicate issues within NHTSA's jurisdiction, we are not proposing any changes to address angle of seat incline at this time.

Three consumer complaints state that mothers do not always pay appropriate attention to the way they swing carriers while an infant is in the seat. The complaints suggest that this movement may place the infant at risk for shaken baby syndrome. Because there are no injuries reported in connection with this scenario, and because no revision of the standard would likely address any potential risk of injury arising from the way a caregiver swings the carrier, we are not proposing any changes to address this issue at this time.

### 4. Falls From Shopping Carts

Incidents included one reported fatality and two reported injuries involving children who fell from shopping carts on which the carriers had been placed. The two injured children required hospitalization for serious head injuries suffered when they fell to the floor from a carrier that had been placed on a shopping cart. The risk associated with placing a child in a hand-held carrier on a shopping cart is addressed by ASTM 2372–11a, *Standard for Consumer Safety Performance Specification for Shopping Carts*, which was developed to address injuries to children associated with falls from shopping carts. This standard requires each shopping cart to have warning statements instructing the user not to use a personal infant carrier but instead to use the seat in the cart and to fasten the child securely into the seat. In addition, the standard requires retailers to provide additional safety information in the form of warning posters at the point of use. The warning label pertaining to safe use recently was revised and includes a pictogram concerning the use of hand-held carriers in the cart. This new label is included in this latest version, which was approved in January 2012. We do not believe that there are additional requirements that can be put in place in either ASTM 2372–11a or ASTM F2050–12 to address this issue.

### 5. Fabric Issues

In 15 of the 242 (6 percent) reported incidents, the injury related to the carrier fabric or padding. Incidents related to fabric include: allergic reactions to padding or items attached to padding; bruising from fabric stitching; and ingesting padding foam. This hazard pattern is not specific to this product. Because similar incidents occur with other durable products and are expected with any product with fabric or padding, we are not proposing any additional requirements to address fabric issues at this time.

## 6. Other Product-Related Concerns

In 10 of the 242 (4 percent) reported incidents, we were unable to identify a specific hazard pattern because insufficient information regarding the circumstances of the incident was provided. Six of these incidents resulted in fatalities. Most of these reports indicate possible improper use of the carrier or another contributing factor, such as soft bedding. For example, one case involves an infant sleeping in the carrier with a blanket or covering that may have resulted in suffocation. However, because we are unable to identify a specific hazard pattern in incidents with insufficient information, we are not proposing additional requirements at this time.

## 7. Other Unknown Issues

Two fatalities could not be attributed to design or performance of the hand-held carrier. We are in the process of investigating both deaths, and once these investigations are complete, further review by CPSC staff will be warranted to determine if the design or construction of the hand-held carrier contributed to the deaths. If we conclude that the design or construction of the hand-held carrier contributed to either of these deaths, we will determine whether additional requirements are necessary. Because the involvement of the product in these incidents is unclear, we cannot propose additional requirements in the absence of information supporting the conclusion that these two incidents were attributed to the design or performance of the hand-held carrier.

## VI. Description of Proposed Changes to ASTM Standard

The proposed rule would create a new part 1225 titled, "Safety Standard for Hand Held Carriers." The proposed rule would establish ASTM F2050–12, "Standard Consumer Safety Specification for Hand-Held Infant Carriers," as a consumer product safety standard, but with certain changes. We are proposing two changes to ASTM F2050–12. One change would add a strangulation warning label to be affixed to the outer surface of the cushion or padding of a hand-held carrier seat in or adjacent to the area where the child's head would rest. The warning label for hand-held carrier seats that are intended to be used as restraints in motor vehicles would include a pictogram, while the warning label for hand-held carrier seats not intended to be used as restraints in motor vehicles would not include the pictogram because these

seats do not have the chest clips depicted in the pictogram.

The other change would affect the test method for ensuring that the carrier will not rotate and spill an unrestrained infant when a caregiver picks up the carrier and the handle is not locked in the carry position. The test method in ASTM F2050–12 requires the tester to use a standard CAMI, Mark II 6-month infant dummy as an infant surrogate. The proposed change would require the tester to use an aluminum cylinder designed as a surrogate for a 6-month old infant, in lieu of the CAMI dummy, because the CAMI dummy could be wedged into the seat padding or otherwise manipulated, such that it does not fall out during the lift test when it otherwise should fall. Further, the ability to pass or fail the test based on friction or placement of the CAMI affects the consistency and repeatability of the test results.

We describe these proposed changes in the following section.

### A. Improper Restraint Usage

Incorrect use or nonuse of the harness straps were involved in 81 of the 242 reported incidents and resulted in 19 of the 36 fatalities related to hand-held carriers from January 1, 2007 to early June 2012. Among these 19 fatalities, nine strangulation incidents occurred due to loose or partially buckled harness straps. In six of the fatalities involving nonuse or improper use of harness straps, the child strangled on the chest clips, while in two incidents children strangled on loose straps. In seven incidents, children who were not restrained in the carrier moved themselves into a compromising position, resulting in asphyxia. Two fatalities occurred when unrestrained infants became trapped under an overturned carrier. In one fatality, straps that were too tight impaired the child's breathing while in the other, it is unclear how the harness strap contributed to the child's death.

ASTM F2050–12 includes product warnings that address the dangers of leaving a child unattended in the carrier, leaving a child in a carrier with loose or unfastened harness straps, and putting the carrier on a soft surface where it can roll over and suffocate a child. The warnings are required to be 'conspicuous,' i.e., visible when the carrier is in the recommended use position to a person standing near the infant carrier in any one position around the carrier but not necessarily visible from all positions. This warning statement attempts to address suffocation, strangulation, and fall hazards. However, a caregiver may not

encounter the label during regular use of the carrier.

We propose a new strangulation warning label, placed where a caregiver is expected to notice it during regular interaction with the carrier and the infant, which includes a pictogram depicting proper and improper harness use and that states: 'WARNING—Children have STRANGLED in loose or partially buckled harness straps. Fully restrain the child even when carrier is used outside the vehicle.' An ASTM task group, with the assistance of CPSC staff, developed several different pictorial symbols that were presented to an audience of 159 people. More than 95 percent of the participants who reviewed the recommended pictogram interpreted it correctly. We believe the warning label with the pictogram will improve noticeability and comprehension of the risk.

### B. Handle Issues

Handles breaking, detaching, or failing to lock in the carry position were reported in 55 of the 242 incidents. Some of these incidents resulted in injuries, such as a lacerated lip, bruises, and a cranial hemorrhage, when the carrier and/or the child fell to the ground. We believe that many of the incidents attributable to the failure of the handle to lock are the result of the handle appearing to be in a locked position when the caregiver lifts the carrier. We believe that the incidents in which the handle itself breaks or detaches from the carrier are attributable to manufacturing or assembly errors.

The current voluntary standard contains a handle preconditioning cycle test, followed by a static hang test, to assess handle lock stability and integrity. The handle lock impact test is designed to test the handle and handle lock integrity to reduce the number of fall injuries. This test is conducted at the conclusion of the static hang test and consists of dropping a hanging weight at the end of the carrier. The hanging weight simulates dynamic loads placed on the handle and handle lock while a caregiver walks with an infant in the carrier.

The handle auto-lock test helps ensure that when a caregiver picks up the carrier with the handle out of the locked position, the carrier will not rotate and spill an unrestrained infant. This is accomplished by requiring the carrier handle to have an auto-lock feature, or, when not locked in the carry position, to fall to a position so it is obvious to the caregiver that the handle is not in the carry position. If neither condition is met, then the handle must lock into the carry position or another

position, such that when the carrier is lifted by the handle, the infant will not fall out.

The existing handle auto-lock test uses a standard CAMI, Mark II 6-month infant dummy during the lift test. When we tested one carrier, the CAMI became wedged into the seat padding in such a way that the CAMI did not fall out during the lift test when an unrestrained infant in this position likely would fall from the carrier. We also found that CAMI placement in the carrier could be manipulated to achieve the desired results. For example, placing a CAMI with its back high in the seat makes the carrier more likely to pass the test, while placing a CAMI lower in the seat may make the carrier more likely to fail. Thus, friction or the placement of the CAMI affects the consistency and repeatability of the test.

To resolve these CAMI-related test issues, we conducted the auto-lock test using an aluminum cylinder designed as a surrogate for a 6-month-old infant in lieu of the CAMI dummy. This change resulted in consistent test results because the cylinder does not wedge into the carrier padding like the CAMI dummy, and placement of the cylinder is less likely to affect the outcome of the test.

We propose modifying ASTM F2050 to require conducting the auto-lock test with the surrogate cylinder instead of the infant CAMI dummy. The surrogate cylinder is modeled from the torso of a 6-month-old child, and it is also used in the bassinet segmented mattress test we recently proposed in the NPR for bassinets and cradles. 77 FR 64055. Further, EN 12790 *European/British Standard for Child Care Articles—Reclined Cradles*, uses a similar cylinder to conduct their tip test for the same products.

## VII. Effective Date

The Administrative Procedure Act (APA) generally requires that the effective date of a rule be at least 30 days after publication of the final rule. 5 U.S.C. 553(d). To allow time for hand-held carriers to come into compliance, we propose that the standard become effective 6 months after publication of the final rule in the Federal Register. We invite comment on how long it will take manufacturers to come into compliance.

## VIII. Regulatory Flexibility Act

### A. Introduction

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601-612, requires agencies to consider the impact of proposed rules on small entities, including small businesses. Section 603 of the RFA

requires that the Commission prepare an initial regulatory flexibility analysis and make it available to the public for comment when the notice of proposed rulemaking is published. The initial regulatory flexibility analysis (IRFA) must describe the impact of the proposed rule on small entities and identify any alternatives that may reduce the impact. Specifically, the IRFA must contain:

- A description of, and where feasible, an estimate of the number of small entities to which the proposed rule will apply;
- A description of the reasons why action by the agency is being considered;
- A succinct statement of the objectives of, and legal basis for, the proposed rule;
- A description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities subject to the requirements, and the type of professional skills necessary for the preparation of reports or records; and
- An identification, to the extent possible, of all relevant federal rules that may duplicate, overlap, or conflict with the proposed rule.

### B. The Market

The majority of hand-held infant carriers are produced and/or marketed by juvenile product manufacturers and distributors. A potential exception is the Moses basket (whose inclusion in the scope as a type of hand-held bassinet or cradle is under consideration by the Commission), which are often marketed by bedding manufacturers and distributors. The Commission estimates that currently, there are at least 43 suppliers of hand-held infant carriers to the U.S. market. Eleven are domestic manufacturers, and 10 are domestic importers. There are also two foreign firms—a foreign manufacturer and an importer that imports products from foreign companies and distributes them from outside of the United States. An additional 20 domestic firms supply Moses basket bedding, along with Moses baskets, whose source is unknown.

Hand-held infant carriers from six of the 43 firms have been certified as compliant with ASTM F2050 by the JPMA, the major U.S. trade association that represents juvenile product manufacturers and importers. Three firms claim compliance with F2050; and four have JPMA-certified strollers with hand-held infant carrier attachments. It is assumed that the hand-held infant carriers supplied by all 13 of these firms will be in compliance with the

voluntary standard. Of the remaining 30 firms supplying noncompliant hand-held infant carriers, the majority (25 firms) supply products that are newly covered due to the expanded scope of ASTM F2050-12 (20 supply Moses baskets, 3 supply bassinet attachments for strollers, and 2 supply other types of bassinet-style carriers).

The market data available is limited to infant car seats, which represented nearly the entire hand-held infant carrier market under prior versions of ASTM F2050. According to a 2005 survey conducted by the American Baby Group (2006 Baby Products Tracking Study), 68 percent of new mothers own infant car seats. Approximately 25 percent of infant car seats were handed down or purchased secondhand. Thus, about 75 percent of infant car seats were acquired new. This suggests annual sales of about 2.1 million infant car seats ( $.68 \times .75 \times 4.1$  million births per year).<sup>2</sup> These 2.1 million infant car seats represent the minimum number of units sold per year that might be affected by the proposed handheld infant carrier standard. It is unknown how many Moses baskets and other bassinet/cradle-style carriers are sold annually.

### C. Reason for Agency Action and Legal Basis for Proposed Rule

The Danny Keysar Child Product Safety Notification Act, section 104 of the CPSCIA, requires the CPSC to promulgate a mandatory standard for hand-held infant carriers that is substantially the same as, or more stringent than, the voluntary standard. CPSC worked closely with ASTM to develop the new requirements and test procedures that have been added to the voluntary standard since 2010. These new requirements address several known hazard patterns and will help to reduce injuries and deaths in hand-held carriers, and they have resulted in the current voluntary standard, F2050-12, upon which the proposed rule is based.

However, the Commission proposes adding one new requirement to F2050-12, as well as modifying the methodology for the existing handle auto-lock test. The new requirement would mandate a new warning label, as described in Section VI (A), which addresses strangulation and suffocation hazards that have occurred as a result of incorrect or nonuse of harness straps. The modification proposed by the

<sup>2</sup> U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), National Center for Health Statistics, National Vital Statistics System, "Births: Final Data for 2009," *National Vital Statistics Reports* Volume 60, Number 1 (November 2011): Table I. Number of births in 2009 is rounded from 4,130,665.

Commission is that an aluminum cylinder, designed as a surrogate for a 6-month old infant, be used in lieu of the CAMI dummy in the handle auto-lock test. This proposed change would result in consistent test results because the cylinder does not wedge into the carrier padding like the CAMI dummy, and placement of the cylinder is less likely to affect the outcome of the test.

#### *D. Requirements of the Proposed Rule*

The Commission proposes adopting the voluntary ASTM standard for hand-held infant carriers (F2050-12), with a new warning label requirement, and a modification of the handle auto-lock test. Some of the more significant requirements of the current voluntary standard for hand-held infant carriers (ASTM F2050-12) are listed below:

- Carry handle integrity—a series of endurance and durability tests are intended to ensure that rigid, adjustable handles do not break or unlock during use.
- Carry handle auto-locking—intended to address incidents that have occurred when the rigid, adjustable handles switched positions unexpectedly.
- Restraints—intended to minimize the fall hazard associated with inclined hand-held carriers while simultaneously minimizing the potential for injury or death in flat bassinet/cradle products where restraints can pose a strangulation hazard.
- Slip resistance—intended to prevent slipping when the hand-held infant carrier is placed on a slightly inclined surface (10 degrees).

The voluntary standard also includes: (1) Torque and tension tests to ensure that components cannot be removed; (2) requirements for several hand-held infant carrier features to prevent entrapment and cuts (minimum and maximum opening size, coverage of exposed coil springs, small parts, hazardous sharp edges or points, smoothness of wood parts, and edges that can scissor, shear, or pinch); (3) marking and labeling requirements; (4) requirements for the permanency and adhesion of labels; (5) requirements for instructional literature; and (6) toy accessory requirements. ASTM F2050-12 includes no reporting or recordkeeping requirements. The Commission proposes adding a new warning label content and placement requirement and using the more appropriate cylinder surrogate for the handle auto-lock testing.

The carry handle auto-locking requirement applies only to hand-held infant carriers that are rigid, adjustable, rotate about a singular axis, and lock

into the manufacturer's designated carry position; therefore, many suppliers, most notably Moses basket suppliers, would not be affected. Several models of hand-held infant carriers with these types of handles would be able to pass the revised test without modifying their product(s). The simplest and most effective way to meet the requirement is to add auto-lock positions close to the one intended for use. This would prevent the handle from moving so far out of position and spilling the child from the carrier. While redesign would probably not be necessary, the hard tools used to manufacture the handle's lock positions would need to be modified. These hard tools are usually modified by an outside firm, which means that production would cease and, unless the firm maintains an alternating production schedule, could result in significant downtime for the firm's production process.

The revised warning would change the size, location, wording, and presentation to highlight better the dangers associated with only partially buckling children into hand-held carriers. A pictogram is included as part of the modified warning for hand-held carrier seats intended to be used as restraints in motor vehicles. The warning would be required on the product itself, as well as within the product's instructional literature. Changes to warning labels are not expected to have a significant impact on suppliers. Typically, warning labels that are placed on fabric, such as the revised strangulation warning, are less costly than those used on plastic or metal.

#### *E. Other Federal or State Rules*

The Commission is in the process of implementing sections 14(a)(2) and 14(i)(2) of the Consumer Product Safety Act (CPSA), as amended by the CPSIA. Section 14(a)(2) of the CPSA requires every manufacturer of a children's product that is subject to a children's product safety rule to certify, based on third party testing, that the product complies with all applicable safety rules. Section 14(i)(2) of the CPSA requires the Commission to establish protocols and standards (i) for ensuring that a children's product is tested periodically and when there has been a material change in the product, (ii) for the testing of representative samples to ensure continued compliance, (iii) for verifying that a product tested by a conformity assessment body complies with applicable safety rules, and (iv) for safeguarding against the exercise of undue influence on a conformity assessment body by a manufacturer or private labeler.

Because hand-held infant carriers will be subject to a mandatory standard, they will also be subject to the third party testing requirements of section 14(a)(2) of the CPSA when the mandatory standard and the notice of requirements become effective.

#### *F. Impact of the Proposal on Small Business*

There are approximately 43 firms currently known to be marketing hand-held infant carriers in the United States. Under U.S. Small Business Administration (SBA) guidelines, a manufacturer of hand-held infant carriers is small if it has 500 or fewer employees, and importers and wholesalers are considered small if they have 100 or fewer employees. Based on these guidelines, 29 are small firms—6 domestic manufacturers, 4 domestic importers, and 19 firms supplying Moses baskets whose supply source is unknown. The remaining firms are five large domestic manufacturers, six large domestic importers, one foreign manufacturer, one foreign importer, and one large firm supplying Moses baskets from an unknown source. There may be additional unknown small hand-held infant carrier suppliers operating in the U.S. market.

*Small Manufacturers.* The expected impact on small manufacturers of the proposed standard will differ based on whether their hand-held infant carriers are already compliant with F2050-09. Firms whose hand-held infant carriers meet the requirements of F2050-09 are likely to continue to comply with the voluntary standard as new versions are published. In addition, they are likely to meet any new standard within 6 months of approval because this is the amount of time JPMA allows for products in their certification program to shift to a new standard. Many of these firms are active in the ASTM standard development process, and compliance with the voluntary standard is part of an established business practice. Therefore, it is likely that firms supplying hand-held infant carriers that comply with ASTM F2050-09 (which went into effect for JPMA certification purposes in April 2010) would also likely comply with F2050-12 by March 2013, even in the absence of a mandatory standard. It should be noted, however, that because the scope of F2050-09 is more limited than the scope of F2050-12, only firms supplying infant car seats would be expected to have developed a pattern of compliance. However, staff believes that firms that manufacture JPMA-certified strollers with attachments that can be used separately as hand-held carriers will also meet ASTM F2050-12 by

March 2013; having developed a pattern of compliance for strollers, they would likely choose to meet any related ASTM standards as well.

Given these considerations, it is unlikely that the direct impact on manufacturers whose products are likely to meet the requirements of ASTM F2050–12 (four of six small domestic manufacturers) will be significant. Modifying warning labels and updating instructional literature is a small cost for most firms. It is possible that one or more firms might have to modify their carry handles to continue to pass the auto-locking test, but this would most likely result in modifying their hard tools to add locking positions, rather than a complete product redesign.

Meeting ASTM F2050–12's requirements could necessitate product redesign for at least some hand-held infant carriers not believed to be compliant with F2050–09 (two of six small domestic manufacturers), regardless of the proposed modifications. A redesign would be minor if most of the changes involve adding straps and fasteners or using different mesh or fabric, but the costs could be more significant if changes to the frame are required, including changes to the handles. Some firms have estimated product redesigns, including engineering time, prototype development, tooling, and other incidental costs to reach approximately \$500,000. Consequently, the proposed rule could potentially have a significant direct impact on small manufacturers whose products do not conform to F2050–09. However, because most products would probably not need to be completely redesigned, actual costs are likely to be lower than the \$500,000 level, and any direct impact may be mitigated if costs are treated as new product expenses that can be amortized.

It is possible that one or both of the firms whose hand-held infant carriers are neither certified as compliant, nor claim compliance with F2050–09, in fact, are compliant with the standard. The Commission has identified many such cases with other products. To the extent that some of these firms may supply compliant hand-held infant carriers and have developed a pattern of compliance with the voluntary standard, the direct impact of the proposed standard will be less significant than described above.

In addition to the direct impact of the proposed standard described above, there are indirect impacts. These impacts are considered indirect because they do not arise directly as a consequence of the hand-held infant carrier rule's requirements. Nonetheless,

they could be significant. Once the rule becomes final and the notice of requirements is in effect, all manufacturers will be subject to the additional costs associated with the third party testing and certification requirements. This will include any physical and mechanical test requirements specified in the final rule; lead and phthalates testing is already required, and hence, it is not included here.<sup>3</sup>

Based on durable nursery product industry input and confidential business information supplied for the development of the third party testing rule, testing to the ASTM voluntary standard could cost \$500–\$1,000 per model sample. Testing overseas could potentially reduce some testing costs, but that may not always be practical.

On average, each small domestic manufacturer supplies two different models of hand-held infant carriers to the U.S. market annually. Therefore, if third party testing were conducted every year on a single sample for each model, third party testing costs for each manufacturer would be about \$1,000–\$2,000 annually. Based on a review of firm revenues, the impact of third party testing to ASTM F2050–12 is unlikely to be significant if only one hand-held infant carrier sample per model is required. However, if more than one sample would be needed to meet the testing requirements, it is possible that third party testing costs could have a significant impact on one or more of the small manufacturers.

*Small Importers.* Importers of hand-held infant carriers would need to find an alternate source if their existing supplier does not come into compliance with the requirements of the proposed rule, which may be the case with all four small importers of hand-held infant carriers, none of which is believed to be in compliance with F2050–09. Some could respond to the rule by discontinuing the import of their noncomplying hand-held infant carriers, possibly discontinuing the product line altogether. However, the impact of such a decision could be mitigated by replacing the noncompliant hand-held infant carriers with a compliant alternative. Deciding to import an alternative product would be a reasonable and realistic way to offset any lost revenue.

As is the case with manufacturers, all importers will be subject to third party testing and certification requirements,

and consequently, will experience costs similar to those for manufacturers if their supplying foreign firm(s) does not perform third party testing. The resulting costs could have a significant impact on a few small importers that must perform the testing themselves if more than one sample per model is required.

*Moses Basket Suppliers.* There are 19 small firms supplying Moses baskets to the U.S. market. Most of these firms also supply bedding; some of them manufacture the bedding, while others act as importers. The Commission has been unable to determine the source of the Moses baskets themselves, although it is likely that most sellers purchase them from other suppliers, either foreign or domestic. Because these products are recent potential additions to the scope of ASTM F2050, it is unlikely that any of them has been designed to comply with this standard. However, it is possible that many might be able to comply with the standard with minimal modifications. Moses baskets generally do not use restraints, so the biggest changes might be the addition of warnings and instructional literature. Alternatively, Moses basket suppliers could remove themselves from the scope of the proposed rule by removing the handles from their products. Because most Moses baskets come with warnings against carrying an infant in the basket, this would be a reasonable change for suppliers to make.

As with manufacturers and importers, all Moses basket suppliers within the scope of the proposed rule will be subject to third party testing and certification requirements, and consequently, they could experience testing costs if their supplying firm(s) does not perform third party testing. Because Moses baskets would not be subject to most of the mechanical tests in the proposed standard, it is expected that third party testing costs, at most, will be half that of other types of hand-held infant carriers, or approximately \$250–\$500 per model sample. The resulting costs could have a significant impact on a few small firms that must perform the testing themselves, even if only one sample per model is required.

#### G. Alternatives

Under the Danny Keysar Child Product Safety Notification Act, one alternative that would reduce the impact on small entities is to make the voluntary standard mandatory with no modifications. Doing so would eliminate the impact on the four small manufacturers with compliant products. However, because of the number and severity of the incidents associated with

<sup>3</sup> Hand-held infant carrier suppliers already must third party test their products to the lead and phthalate requirements. Therefore, these costs are left out of the analysis above.

falls and restraints, staff does not recommend this alternative.

A second alternative would be to set an effective date later than the proposed 6 months, which is generally considered sufficient time for suppliers to come into compliance with a proposed rule. Setting a later effective date would allow suppliers additional time to modify and/or develop compliant hand-held infant carriers and spread the associated costs over a longer period of time.

The Commission invites comments describing the possible impact of this rule on manufacturers and importers, as well as comments containing other information describing how this rule will affect small businesses.

## IX. Environmental Considerations

The Commission's regulations address whether we are required to prepare an environmental assessment or an environmental impact statement. These regulations provide a categorical

exclusion for certain CPSC actions that normally have "little or no potential for affecting the human environment." Among those actions are rules or safety standards for consumer products. 16 CFR 1021.5(c)(1). The proposed rule falls within the categorical exclusion.

## X. Paperwork Reduction Act

This proposed rule contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). In this document, pursuant to 44 U.S.C. 3507(a)(1)(D), we set forth:

- A title for the collection of information;
- A summary of the collection of information;
- A brief description of the need for the information and the proposed use of the information;
- A description of the likely respondents and proposed frequency of

response to the collection of information;

- An estimate of the burden that shall result from the collection of information; and

- Notice that comments may be submitted to the OMB.

*Title:* Safety Standard for Hand-Held Infant Carriers.

*Description:* The proposed rule would require each hand-held infant carrier to comply with ASTM F2050–12, Standard Consumer Safety Specification for Hand-Held Infant Carriers. Sections of ASTM F2050–12 contain requirements for marking, labeling, and instructional literature. These requirements fall within the definition of "collection of information," as defined in 44 U.S.C. 3502(3).

*Description of Respondents:* Persons who manufacture or import hand-held infant carriers.

*Estimated Burden:* We estimate the burden of this collection of information 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
1221 .....	43	4	172	1	172

*Our estimates are based on the following:*

Section 8.1 of ASTM F 2050–12 requires that the name of the manufacturer, distributor, or seller, and either the place of business (city, state, and mailing address, including zip code) or telephone number, or both, to be marked clearly and legibly on each product and its retail package. Section 8.2 of ASTM F 2050–12 requires a code mark or other means that identifies the date (month and year, as a minimum) of manufacture.

There are 43 known entities supplying hand-held infant carriers to the U.S. market. All 43 firms are assumed to use labels already on both their products and their packaging, but they might need to make some modifications to their existing labels. The estimated time required to make these modifications is about 1 hour per model. Each entity supplies an average of four different models of hand-held infant carriers; therefore, the estimated burden associated with labels is 1 hour per model × 43 entities × 4 models per entity = 172 hours. We estimate the hourly compensation for the time required to create and update labels is \$27.55 (U.S. Bureau of Labor Statistics, "Employer Costs for Employee Compensation," March 2012, Table 9,

total compensation for all sales and office workers in goods-producing private industries: <http://www.bls.gov/ncs/>). Therefore, the estimated annual cost to industry associated with the labeling requirements is \$4,738.60 (\$27.55 per hour × 172 hours = \$4,738.60). There are no operating, maintenance, or capital costs associated with the collection.

Section 9.1 of ASTM F2050–12 requires instructions to be supplied with the product. Hand-held infant carriers are products that generally require installation or assembly, and products sold without such information would not be able to compete successfully with products supplying this information. Under the OMB's regulations (5 CFR 1320.3(b)(2)), the time, effort, and financial resources necessary to comply with a collection of information that would be incurred by persons in the "normal course of their activities" are excluded from a burden estimate, where an agency demonstrates that the disclosure activities required to comply are "usual and customary." Therefore, because we are unaware of hand-held infant carriers that generally require installation or some assembly but lack any instructions to the user about such installation or assembly, we estimate tentatively that there are no

burden hours associated with section 9.1 of ASTM F 2050–12 because any burden associated with supplying instructions with hand-held infant carriers would be "usual and customary" and not within the definition of "burden" under the OMB's regulations.

Based on this analysis, the proposed standard for hand-held infant carriers would impose a burden to industry of 172 hours at a cost of \$4,728.60 annually.

In compliance with the PRA (44 U.S.C. 3507(d)), we have submitted the information collection requirements of this rule to the OMB for review. Interested persons are requested to submit comments regarding information collection by January 9, 2013, to the Office of Information and Regulatory Affairs, OMB (see the **ADDRESSES** section at the beginning of this notice).

Pursuant to 44 U.S.C. 3506(c)(2)(A), we invite comments on:

- Whether the collection of information is necessary for the proper performance of the CPSC's functions, including whether the information will have practical utility;
- The accuracy of the CPSC's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

- Ways to enhance the quality, utility, and clarity of the information to be collected;

- Ways to reduce the burden of the collection of information on respondents, including the use of automated collection techniques, when appropriate, and other forms of information technology; and

- The estimated burden hours associated with label modification, including any alternative estimates.

## XI. Preemption

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

## XII. Certification and Notice of Requirements (NOR)

Section 14(a)(2) of the CPSA imposes the requirement that children’s products subject to a children’s 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)(2). For children’s products, such certification must be based on tests on a sufficient number of samples by a third party conformity assessment body accredited by the Commission to test according to the applicable requirements. As discussed in section I of this preamble, section 104(b)(1)(B) of the CPSIA refers to standards issued under this section as “consumer product safety standards.” Accordingly, a safety standard for hand-held infant carriers issued under section 104 of the CPSA is a consumer product safety rule that is subject to the testing and certification requirements of section 14 of the CPSA. Because hand-held infant carriers are children’s products, they must be tested by a third party conformity assessment body whose

accreditation has been accepted by the CPSC. Notices of requirements (NORs) provide the criteria and process for our acceptance of accreditation of third party conformity assessment bodies.

On May 24, 2012, the Commission published in the Federal Register the proposed rule, *Requirements Pertaining to Third Party Conformity Assessment Bodies*, 77 FR 331086, which, when finalized, would establish the general requirements and criteria concerning testing laboratories. These include the requirements and procedures for CPSC acceptance of the accreditation of a laboratory to test children’s products in support of the certification required by section 14(a)(2) of the CPSA. The proposed rule, at 16 CFR part 1112, *Requirements Pertaining to Third Party Conformity Assessment Bodies*, lists the children’s product safety rules for which the CPSC has published NORs for laboratories. In this document, the Commission is proposing to amend the list in 16 CFR part 1112, once that rule becomes final, to include the hand-held infant carrier standard, once finalized, along with the 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 hand-held infant carriers would be required to meet the third party conformity assessment body accreditation requirements in 16 CFR part 1112, *Requirements Pertaining to Third Party Conformity Assessment Bodies*, once that rule becomes final. When a laboratory meets the requirements as a CPSC-accepted third party conformity assessment body, it can apply to the CPSC to have 16 CFR part 1225, *Safety Standard for Hand-Held Infant Carriers* included in its scope of accreditation of CPSC safety rules listed for the laboratory on the CPSC Web site at: <http://www.cpsc.gov/labsearch>.

The final NOR will base the CPSC laboratory accreditation requirements on the performance standard set forth in the final rule for the safety standard for hand-held infant carriers and the test methods incorporated within that standard. The Commission may recognize limited circumstances in which the Commission will accept certification based on product testing conducted before the Commission’s acceptance of accreditation of laboratories for testing hand-held infant carriers (also known as retrospective testing) in the final NOR. The Commission seeks comments on any issues regarding the testing requirements of the proposed rule for

hand-held infant carriers and the accompanying proposed NOR.

## XIII. Request for Comments

This proposed rule begins a rulemaking proceeding under section 104(b) of the CPSIA to issue a consumer product safety standard for hand-held carriers. We invite all interested persons to submit comments on any aspect of the proposed rule. Comments should be submitted in accordance with the instructions in the **ADDRESSES** section at the beginning of this notice.

We specifically seek comments from the public on whether Moses baskets should be included in this safety standard. If Moses baskets should be included in this safety standard, does the present definition cover Moses baskets? And if the present definition does not cover Moses baskets, how should it be amended to cover them?

We also seek comment concerning the surrogate used in the handle auto-locking test. Specifically, the Commission asks if the test cylinder described in this preamble and in the proposed rule is an appropriate surrogate for a six-month old infant. Is there another surrogate—in particular, the infant hinge gauge—that is as likely or more likely to identify those hand-held infant carriers that pose the hazards identified in the handle lock test?

## List of Subjects

### 16 CFR Part 1112

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

### 16 CFR Part 1225

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

Therefore, the Commission proposes to amend Title 16 of the Code of Federal Regulations to read as follows:

## PART 1112—REQUIREMENTS PERTAINING TO THIRD PARTY CONFORMITY ASSESSMENT BODIES

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)(35) 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)

(35) 16 CFR part 1225, Safety Standard for Hand-Held Infant Carriers.  
3. Add part 1225 to read as follows:

**PART 1225—SAFETY STANDARD FOR HAND-HELD INFANT CARRIERS**

Sec.

1225.1 Scope.

1225.2 Requirements for hand-held infant carriers.

**Authority:** The Consumer Product Safety Improvement Act of 2008, Pub. L. 110-314, § 104, 122 Stat. 3016 (August 14, 2008).

**§ 1225.1 Scope.**

This part establishes a consumer product safety standard for hand-held infant carriers.

**§ 1225.2 Requirements for hand-held infant carriers.**

(a) Except as provided in paragraph (b) of this section, each hand-held infant carrier must comply with all applicable provisions of ASTM F 2050-12, Standard Consumer Safety Specification for Hand-Held Infant Carriers, approved on July 1, 2012. 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>. You may inspect a copy at the Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone 301-504-7923, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: [http://www.archives.gov/federal-register/code-of-federal-regulations/ibr\\_locations.html](http://www.archives.gov/federal-register/code-of-federal-regulations/ibr_locations.html).

(b) Comply with the ASTM F2050-12 standard with the following additions or exclusions:

(1) In addition to complying with section 2.3 *Other References*, comply with the following:

(i) 2.3 *Other References*: Test Cylinder A (see Fig. X)

(ii) [Reserved]

(2) Instead of complying with section 6.1.3 of ASTM F2050-12, comply with the following:

(i) 6.1.3 The carry handle shall lock in a position forward or rearward of the manufacturer's designated carry position such that an unrestrained Test Cylinder A (see Figure X) does not fall

out of the carrier when tested in accordance with 7.1.2 through 7.1.4.

(ii) [Reserved]

(3) Instead of complying with section 7.1.1 of ASTM F2050-12, comply with the following:

(i) 7.1.1 Without a dummy in the carrier, secure the harness according to the manufacturer's instructions, and adjusting so that the harness along its entire exposed length contacts the seating surface. Position Test Cylinder A centrally against the backrest of the carrier in such a way that the bottom edge is in contact with the seat/back junction line (see Figure Y).

(ii) [Reserved]

(4) Instead of complying with Section 8.3.2 of ASTM F2050-12, comply with the following:

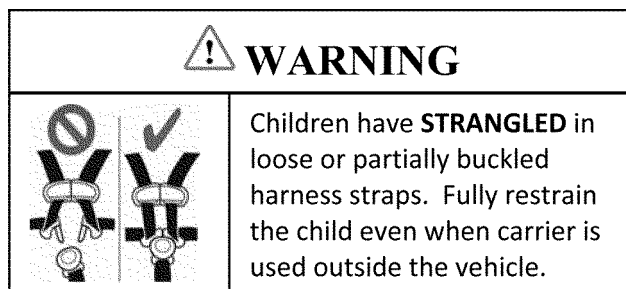
(i) 8.3.2 The warning statements shall address the following except as otherwise noted.

(ii) [Reserved]

(5) Instead of complying with section 8.3.2.3 of ASTM F2050-12, comply with the following:

(i) 8.3.2.3 *Strangulation Hazard*:

(ii) 8.3.2.3.1 Carriers intended for use as infant restraint devices in motor vehicles shall contain the following warning label. This label requires exact language (including the use of bold font and uppercase characters as depicted) and a specific location:



(iii) 8.3.2.3.2 The area of the pictogram is to be at least 1.09 in<sup>2</sup> (706 mm<sup>2</sup>) while not exceeding the size of the airbag warning pictogram in the label required under FMVSS No. 213. The message area in the label shall be no less than 4.65 in<sup>2</sup> (30 cm<sup>2</sup>), while not exceeding the size of the airbag warning message area in the label required under FMVSS No. 213. The pictogram shall be

black with a red circle and slash on a white background and green check mark. The heading area shall be yellow with the word "warning" and the alert symbol in black. The warning label shall be a separate and independent label from the airbag warning label required in FMVSS No. 213. The warning label shall be permanently affixed to the outer surface of the cushion or padding in or

adjacent to the area where a child's head would rest, so that the label is plainly visible and easily readable.

(iv) 8.3.2.3.3 The following warning is required only for carriers not intended for use in a motor vehicle and are not hand-held bassinets/cribbed. This warning requires exact language (including the use of bold font and uppercase characters as depicted):



Children have **STRANGLED** in loose or partially buckled harness straps.  
Fully restrain the child at all times.

(6) Instead of complying with section 9.1.1 of ASTM F2050–12, comply with the following:

(i) 9.1.1 The instructions shall contain statements, which address the

warning statements in 8.3.2. For carriers intended for use as infant restraint devices in motor vehicles, the warning statement contained in the warning label depicted in 8.3.2.3 must also be

included. In addition, the instructions shall include the following statements:

(ii) [Reserved]

(7) In addition to Figure 2, use the following:

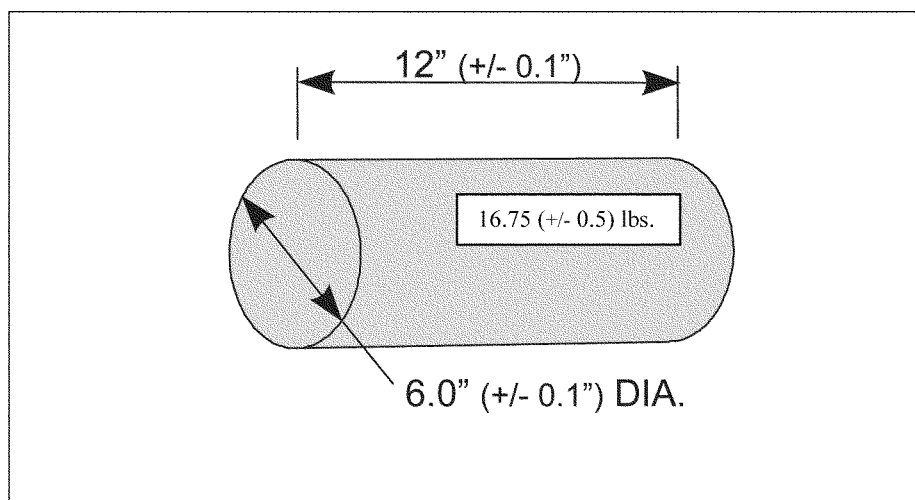


FIG. X Test Cylinder A

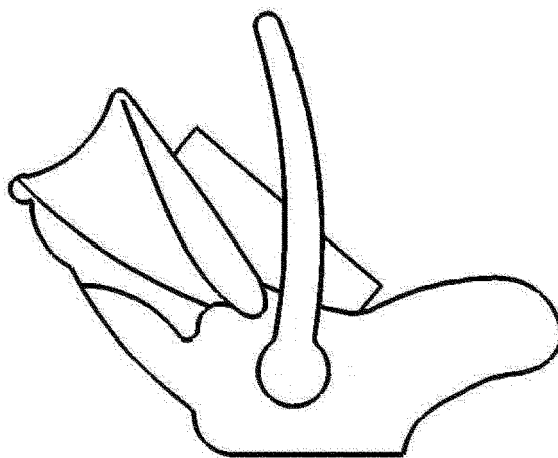


FIG. Y Test Cylinder Placed in Carrier

Dated: December 3, 2012.

**Todd A. Stevenson,**

*Secretary, Consumer Product Safety Commission.*

[FR Doc. 2012–29584 Filed 12–7–12; 8:45 am]

BILLING CODE 6355–01–P

## DEPARTMENT OF VETERANS AFFAIRS

### 38 CFR Part 3

RIN 2900–AN89

### Secondary Service Connection for Diagnosable Illnesses Associated With Traumatic Brain Injury

**AGENCY:** Department of Veterans Affairs.

**ACTION:** Proposed rule.

**SUMMARY:** The Department of Veterans Affairs (VA) is amending its

adjudication regulations concerning service-connection. This amendment is necessary to act upon a report of the National Academy of Sciences, Institute of Medicine (IOM), *Gulf War and Health, Volume 7: Long-Term Consequences of Traumatic Brain Injury*, regarding the association between traumatic brain injury (TBI) and five diagnosable illnesses. The intended effect of this amendment is to establish that if a veteran who has a service-connected TBI also has one of these diagnosable illnesses, then that