



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

The contents of this document will be discussed at the Commission Meeting (Briefing) scheduled for Wednesday, November 14, 2012.

This document has been electronically approved and signed.

DATE: November 8, 2012

THIS MATTER IS NOT SCHEDULED FOR A BALLOT VOTE.

A DECISIONAL MEETING FOR THIS MATTER IS SCHEDULED ON: November 28, 2012

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Mary T. Boyle, Acting General Counsel
Kenneth R. Hinson, Executive Director

FROM: Patricia M. Pollitzer, Assistant General Counsel
Andrew J. Kameron, General Attorney

SUBJECT: Notice of Proposed Rulemaking: Safety Standard for Hand-Held Infant Carriers

The Office of the General Counsel is providing for Commission consideration the attached draft *Federal Register* notice on a proposed rulemaking. The proposed rule would establish a safety standard for hand-held infant carriers pursuant to the Danny Keysar Child Product Safety Notification Act, section 104 of the Consumer Product Safety Improvement Act of 2008.

Please indicate your vote on the following options:

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

(Signature)

(Date)

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

(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 of Proposed Rulemaking – Safety Standard for Hand-Held Infant Carriers

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Billing Code 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1225

CPSC Docket No. CPSC-2012- _____

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 [INSERT DATE 75 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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 e-mailed to oir_submission@omb.eop.gov.

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Other comments, identified by Docket No. CPSC-2012-____, 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 (e-mail), except through 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-____, into the “Search” box, and follow the prompts.

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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; e-mail: 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 Keysar 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

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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/cradles 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/cradle” is defined as “a 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/cradles 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. One type of popular hand-held bassinet/cradle is known as a Moses basket. This product typically has semi-rigid sides and semi-rigid hand holds or handles. The fact that the ASTM definition of “hand-held infant carrier” uses the term “rigid-sided” could create some

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confusion about the inclusion of Moses baskets in the standard. We request comments on whether some clarification or revision of these definitions is needed.

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/cradles are sold annually. Hand-held carrier seats and hand-held bassinets/cradles are typically produced and/or marketed by juvenile product manufacturers and distributors, except for Moses baskets, a unique type of hand-held bassinet/cradle 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/cradles 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).¹ 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

¹ 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, including hand-held infant carriers, comply with all applicable ASTM standards as well.

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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/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:

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- 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

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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

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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 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.

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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

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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

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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:

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- 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

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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

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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.

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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

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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,

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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,

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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,

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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

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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

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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;

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- 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. The exception is Moses baskets (a type of hand-held bassinet/cradle), 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

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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 x .75 x 4.1 million births per year).² 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 CPSIA, 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

² 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.

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suffocation hazards that have occurred as a result of incorrect or nonuse of harness straps. The modification proposed by the 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

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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

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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

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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

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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.

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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.³

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

³ 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.

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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 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.

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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 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.

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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.

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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

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labels is 1 hour per model x 43 entities x 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 x 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.

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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 **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**, 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

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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

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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 website at: 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.

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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 addressing whether the definition of “hand-held infant carrier” in ASTM F2050-12 as being a “rigid-sided” product leaves ambiguity about coverage of a type of hand-held bassinet/cradle known as a Moses basket, and whether some clarification of the product definitions in ASTM F2050-12 is needed.

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 by amending part 1112 and adding a new part 1225 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:

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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)(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

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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 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) ⁴

(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

⁴ A rigid cylinder 6.0 ± 0.1 inches (153 ± 2.5 mm) in diameter and 12 ± 0.1 inches (305 ± 2.5 mm) in height, having a mass of 16.75 ± 0.5 pounds (7.6 ± 0.2 kg) and with its center of gravity in the center of the cylinder. All edges shall have a radius of 0.2 ± 0.04 inches (5 ± 1 mm).

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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 in² (706 mm²) 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 in² (30 cm²), while not exceeding the size

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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/cradles. This warning requires exact language (including the use of bold font and uppercase characters as depicted):



WARNING

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:

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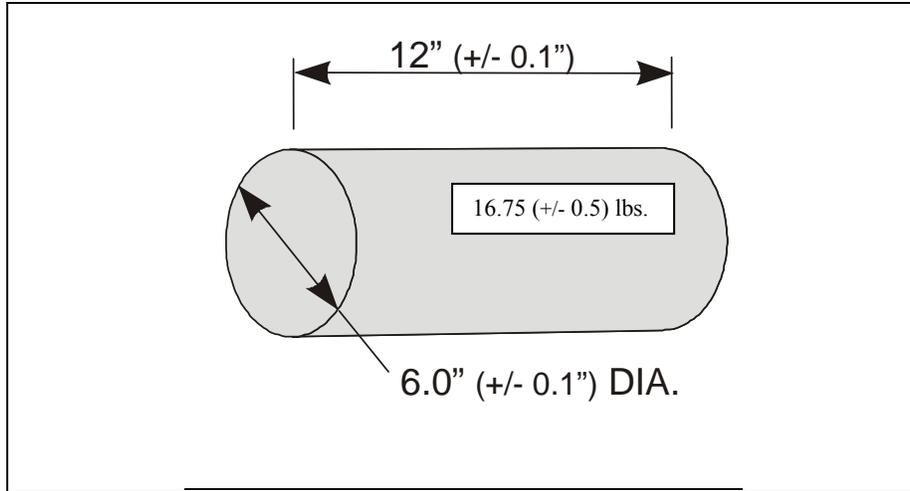


FIG. X Test Cylinder A

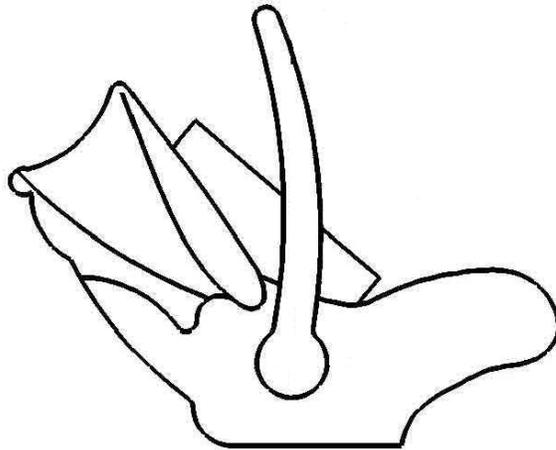


FIG. Y Test Cylinder Placed in Carrier

Dated: _____.

Todd A. Stevenson,
Secretary, Consumer Product Safety Commission



Staff Briefing Package

Hand-Held Infant Carriers Notice of Proposed Rulemaking (NPR)

November 7, 2012

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

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Briefing Memo



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

This document has been electronically
approved and signed.

Memorandum

November 7, 2012

TO: The Commission
Todd Stevenson, Secretary

THROUGH: Mary T. Boyle, Acting General Counsel
Kenneth R. Hinson, Executive Director
Robert J. Howell, Deputy Executive Director for Safety Operations

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

Patricia Edwards, Project Manager
Directorate for Engineering Sciences

SUBJECT: Notice of Proposed Rulemaking for Hand-held Infant Carriers

I INTRODUCTION

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

Infant carriers is a category that covers a variety of products, including hand-held infant carriers, hand-held bassinet/cradles, soft infant and toddler carriers, slings, and frame carriers. Each of these distinct products falls within the scope of an ASTM voluntary standard. Even though all of these products are intended to carry infants and/or toddlers, there are many different standards that cover these products due to the differences in product design and associated hazards.

This briefing package deals with products that are included in the scope of the voluntary standard ASTM F2050-12, "Standard Consumer Safety Specification for Hand-held Infant Carriers". Included in the scope of this standard are products known as hand-held infant carrier seats and hand-held bassinet/cradles. This briefing package also reviews the incident data and assesses the effectiveness of ASTM F2050-12. The package also discusses the impact of staff's recommendations on small businesses, reviews recent recalls associated with hand-held infant carriers, and provides staff recommendations to the Commission.

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Specifically, staff is recommending that the Commission publish a Notice of Proposed Rulemaking (NPR) that incorporates by reference the voluntary standard ASTM F2050-12, *Standard Consumer Safety Specification for Hand-Held Infant Carriers*, with two modifications, including a new warning label requirement and a revision to a test procedure.

II BACKGROUND

A. *Product Review*

Included in the scope of ASTM F2050-12 are hand-held infant carrier seats and hand-held bassinet/cradles. 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.” A hand-held carrier seat (See Figure 1) is defined as a hand-held infant carrier having a seat back that is intended to be in a reclined position (more than 10 degrees from horizontal).

The majority of hand-held infant carrier seats covered by ASTM F2050-12 are sold for dual use as motor vehicle child restraint systems.



Figure 1. Hand-Held Infant Carrier Seat

Once a seat is installed in an automobile, its performance is regulated by the National Highway Traffic Safety Administration (NHTSA) and it must meet the requirements in the Federal Motor Vehicle Safety Standard (FMVSS) No. 213. (49 CFR 571.213, S5.5.2(k)(3)) (FMVSS No. 213)¹. The NHTSA standard specifies requirements for child restraint systems used in motor vehicles and aircraft.

Figure 2 is the other type of infant carrier included in the scope of F2050-12 with a different definition, called a hand-held bassinet/cradle.



Figure 2. Hand-Held Infant Bassinet/Cradle

It is defined as “a freestanding product, with a rest/support surface to facilitate sleep (intended to be flat or up to 10 degrees 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.” It differs from a bassinet/cradle in that it is designed to be portable, and, when not being carried, it is placed on the floor². It does not have legs, a base, or a stand attached to it, nor does it have any restraints.

Some of the requirements in F2050-12 are different for hand-held bassinet/cradles versus hand-held infant carrier seats. This is because the intended position of the occupant (lying supine vs.

¹ The National Traffic and Motor Vehicle Safety Act of 1966 empowers NHTSA with the authority to regulate “motor vehicle equipment” which is defined “an accessory or addition to a motor vehicle; or any device or article . . . intended to be used only to safeguard motor vehicles and highway users against risk of accident, injury, or death.” 49 U.S.C. 30102(a)(7). Applying this definition, NHTSA properly considers child restraint systems, i.e., car seat, intended solely for use with motor vehicles to be “motor vehicle equipment” subject to its jurisdiction alone. However, it is staff’s view that once the seat is being used as an infant carrier outside the car, it is no longer motor vehicle equipment, and as such is subject to the jurisdiction of the Commission. CPSC has historically asserted jurisdiction over products that are used inside a car, including dual-purpose car seats, when they are not being used in connection with the operation of a motor vehicle. Moreover, congress has articulated its support for this position in stating that “children’s car seats [that] can be used in a car but also in a frame so that they can be used as strollers in the home” would be subject to the CPSC’s reporting requirements “to the extent that they have defects arising from uses outside a motor vehicle.” *H.R. Rep. No. 110-787, 110th Cong., 2d Sess. 70-71.*

² Some hand-held bassinet/cradles are sold with a separate stand that can be used to support the hand-held bassinet/cradle. When the hand-held bassinet/cradle is resting on its stand, it then falls within the scope of the bassinet/cradle standard.

reclined) and the product designs used to accommodate the occupant can create different hazards.

A Moses basket (Figure 3) is an infant sleep product that typically has semi-rigid sides. Its name is derived from the biblical reference to baby Moses in Exodus 2:1-10. Staff considers Moses baskets that have handles or hand holds to be a type of hand-held bassinet/cradle. The words “rigid-sided”, as a descriptor in the umbrella definition of a hand-held infant carrier leaves some ambiguity regarding the inclusion of Moses baskets in the scope because there is no definition for the term, rigid. For the purposes of this briefing package, staff is interpreting the definition to include products with semi-rigid sides.



Figure 3: Typical Moses Basket

Because the title of the ASTM standard references hand-held infant carriers, this memorandum refers to all the products collectively as hand-held infant carriers or carriers. Where it is necessary to distinguish between hand-held infant carrier seats and hand-held bassinet/cradles, that distinction is made.

B. Incident Data

As outlined in Tab A, CPSC staff is aware of a total of 242 incidents (36 fatal and 206 nonfatal) related to hand-held infant carriers that were reported to have occurred from January 1, 2007 through June 7, 2012. The age range of the victims for the extracted data was limited to zero up to, but not including, 2 years of age. The zero age group included children whose age was not reported. The upper age limit was chosen as 2 years because the weight of the 50th percentile 19- to 24-month-old child is 26.0 lbs., and it is impractical for caregivers to carry children at or beyond that weight level in hand-held carriers. In addition, only those incidents that occurred when the infant was in the carrier, or was being placed into or taken out of the carrier, are included for the purposes of this briefing package. Incidents were not included if the carrier was a child restraint system (car seat) and also was located in a vehicle at the time of the occurrence. For those incidents, as noted above, the carrier falls under the jurisdiction of NHTSA.

Because reporting is ongoing, the number of reported fatalities, nonfatal injuries, and noninjury incidents may change in the future.

1) Fatalities

A total of 36 hand-held infant carrier-associated fatalities were reported to have occurred from January 2007 through early June 2012. Age was not reported for two of the decedents. Among the remaining fatalities, 71 percent were 6 months or younger, and 91 percent were 12 months or younger. Three of the decedents were 15-, 18-, and 22-month-old children.

Twenty-nine fatalities involved a product-related issue. Nine strangulation deaths involved the carrier's harness, chest clips, or straps. In most of these cases, the infant was partially restrained in the seat with only the shoulder straps in place, but the crotch strap was left unsecured. This allowed the infant to slide forward on the seat just enough to get caught at the throat by the chest clip that connects the two shoulder straps. Besides these strangulation deaths, there was an additional death report that described the restraint straps as being too tight and impairing the decedent's breathing; no details were included in that report of how the restraints were positioned. Seven of the 36 fatalities involved an infant who was unrestrained in a hand-held carrier seat and found in a prone position, *i.e.*, face down on the seat, or on a blanket, covers, and/or a pillow. Two additional cases involved an unrestrained infant who was found prone on the seat of the carrier seat, which had also tipped over. Three more of the 36 fatality incidents reported an infant trapped under an overturned seat. Information on what caused the seat to overturn was not provided in these reports. One fatality resulted from a fall from a carrier seat that was placed in the upper chair portion of a shopping cart. There were six additional reports containing some information indicating that the use or misuse of a product feature contributed to the fatality; however, CPSC staff does not have enough information to identify conclusively the hazard pattern involved.

Five of the 36 fatalities were considered non-product-related; instead, these incidents resulted from the decedent and the carrier being placed in a hazardous environment. Two of the five fatalities resulted from the placement of an infant in a carrier atop a stove and the subsequent accidental ignition of the stove. Another infant died of hyperthermia when left unattended for an extended period of time in a carrier, swaddled in multiple blankets, in a room with a temperature exceeding 90 degrees. In another of the five deaths, an infant in a carrier was placed crosswise inside a bassinet; official reports concluded that the infant's movement knocked the carrier into a reclined position leading to the asphyxiation death. The fifth decedent suffocated on a blanket placed over his head.

For the remaining two fatalities, insufficient evidence exists to conclude that there was any product involvement or the presence of any hazardous external circumstances.

2) Nonfatal Incidents

A total of 206 nonfatal hand-held carrier-related incidents were reported to have occurred from January 1, 2007 through June 7, 2012. Of these, 60 incidents reported an injury to an infant using the carrier at the time of the incident. Two of these injury reports were of children requiring hospitalization due to serious head injuries suffered from a fall from a carrier that was on a shopping cart. Among the remaining 58 injury reports, some specifically mentioned the type of injury, while others mentioned only an injury, but no specifics about the injury. Bumps, bruises, abrasions, lacerations, allergic reactions, and near-choking episodes were some of the common

injuries reported. No age was reported for 17 of the injured. For incidents reporting age, all but two reported the child's age to be 12 months or younger; one child was 13 months and a second child was 23 months old.

The remaining 146 incidents reported that no injury had occurred or provided no information about any injury. However, many of the descriptions indicated the potential for a serious injury or even death.

3) National Injury Estimates

In addition to the incident data outlined above, the National Electronic Incident Surveillance System (NEISS) contains hand-held carrier related injury cases that resulted in treatment at U.S. hospital emergency departments. These include an estimated total of 57,700 injuries (sample size=2,398, coefficient of variation=0.11) over the 5-year period 2007–2011. Until NEISS data for 2012 is finalized in spring 2013, partial estimates for 2012 will not be available. Details concerning the breakdown by year, age, and injury type are in Tab A.

C. *Hazard Patterns*

CPSC staff considered all of the 242 non-NEISS-reported incidents (36 fatal and 206 nonfatal) to identify hazard patterns associated with hand-held infant carriers. In order of frequency of incident reports, the hazard patterns were associated with the following product components and issues

- Restraints
 - Handles
 - Carrier design
 - Accessories
 - Fabric/padding material
 - Hazardous environment
 - Falls
 - Other product-related issues
 - Other/unknown issues.
-
- **1) Restraints** were the most commonly reported hazard, resulting in the highest proportion of deaths and injuries. Eighty-one of the 242 incidents (approximately 33 percent of total incidents, 53 percent of deaths, and 38 percent of injuries) were associated with the use, incorrect use, or non-use of the harness straps. There were 10 fatal incidents where the decedent was restrained in the carrier seat incorrectly. A majority of these deaths resulted from the infant being left in the seat with only the shoulder straps connected, but with the crotch strap unrestrained, which allowed the infant to slide forward on the seat just enough to get caught at the throat by the chest clip and strangle. There were an additional nine fatal incidents where the decedent was not restrained in the carrier seat at all. In a majority of these nine deaths, the decedent was found later to have turned over to a prone position, face down on a soft surface. Most of the nonfatal incidents were associated with adjustment issues, such as difficulty with tightening or loosening of the harness straps. Other safety-related complaints on restraints reported inadequate design, failure to keep the infant secured, and poor quality.

- **2) Handle problems** were reported in 55 of the 242 (23 percent) incidents. Common issues reported were; handles detaching, handles not remaining locked in position, and handles breaking. Nearly half of the reports of handle problems were related to recalled products. This category includes 13 percent of the injuries—mostly due to falls—but no fatalities.
- **3) Issues with carrier design** were the next most commonly encountered hazard pattern, accounting for 28 of the 242 (12 percent) incident reports, eight percent of the fatalities, and 10 percent of the injuries). The design issues most commonly reported were instability, sharp surfaces, unsafe infant posture (too upright) while seated, and lack of structural integrity. All three fatalities in this category resulted from the occupied carrier tipping upside down, for unknown reasons, and trapping the infant. Lacerations on sharp surfaces were the most common injury.
- **4) Issues with accessories**, most of which were bought separately from the hand-held carrier, were reported in 28 of the 242 (12 percent) incidents. While there were no fatalities, 12 percent of the injuries were related to this issue. Some of the commonly reported issues were with toys or toy-attachment devices, head and body support devices, carrier seat covers, and canopies.
- **5) Problems with the fabric/padding material** of hand-held carriers were reported in 15 of the 242 (six percent) incidents. Most of the related injuries, accounting for 12 percent of all injuries, were caused by allergic reactions to the fabric or near-choking episodes from infants mouthing pieces of padding from the carrier seat. There were no fatalities in this category.
- **6) A hazardous environment** in or around the occupied hand-held carrier was responsible for another 12 reported incidents (five percent). Fourteen percent (five cases) of the fatalities and three percent of the injuries are in this category. Some of the hazardous scenarios include: placement of a carrier with an infant on top of a stove and the subsequent accidental ignition of the stove; an infant in a carrier, swaddled in multiple blankets, being left for a prolonged time period in a room with a temperature exceeding 90 degrees; and placement of a blanket over an infant's head.
- **7) Falls** from hand-held carriers while carriers were placed on shopping carts were reported in 11 of the 242 (five percent) incidents. This category includes one fatality and 12 percent of the injuries; two of the injuries were serious head injuries requiring hospitalizations.
- **8) Other product-related issues** were involved in 10 of the 242 (four percent) reported incidents. Most of these reports indicated the use or misuse of a product feature that contributed to the incident; however, not enough information was available for CPSC staff to identify conclusively the hazard pattern involved. While there were no injuries, six fatal incidents, which is 17 percent of the fatalities, are included in this category.
- **9) Other/unknown issues** accounted for the remaining two reports, both of which were fatalities. While it was reported that the infants were strapped in the seat at the time of death, there was insufficient evidence of any product involvement or the presence of any hazardous

external circumstances. In both cases, official reports were pending further information at the time of reporting to the CPSC.

In summary, there were six product-related issues associated with incident deaths and/or significant injuries: restraint issues, handle problems, design issues, fabric issues, falls, and miscellaneous product-related issues

In addition, there were multiple deaths and injuries associated with hazardous environments and accessories. These were considered to be non-product related, as were deaths and injuries associated with incidents where there was insufficient evidence of either product involvement or a hazardous environment.

Staff looked at each of these issues when reviewing the adequacy of the current voluntary standard, ASTM F2050-12.

D. History of F2050

In the late 1990's, hand-held infant carrier seats that also served as car seats were covered under the federal standard FMVSS 213 (49 CFR 571.213, S5.52(k)(3)) (FMVSS 213). That standard only applies to products when they are used in a vehicle as a restraint system for children. Thus, FMVSS 213 does not contain any requirements for handle performance or integrity. In response to incidents and recalls of hand-held infant carriers in the 1990s, CPSC staff requested that ASTM develop a voluntary standard for these products when used outside of a vehicle to address the hazards related to handle breakage and handle lock failures.

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*. This original version did not include hand-held bassinet/cradles in the scope.

The standard has been revised five times since then. The current version, ASTM F2050-12, was approved on July 1, 2012.

The original version of the standard, ASTM F2050-00, contained requirements to address the following issues:

- Sharp points
- Small parts
- Lead in paints
- Wood parts
- Openings (entrapment)
- Scissoring, shearing, and pinching
- Exposed coil springs
- Labeling
- Toy accessories
- Protective components
- Handle integrity

- Restraints requirements
- Slip resistance

The standard was revised in 2001, adding a clarification regarding the types of restraints required for carrier seats that were not for use in motor vehicles. In 2003, the standard was updated again to provide an illustration for one of the requirements. And in 2008, a new revision was issued that contained an updated handle integrity test method to account for greater weight capacities in carriers. In 2009, the openings performance requirement was clarified to limit the requirement to openings that are accessible to the toes and fingers of an occupant. The current version, approved in 2012, was the most significant revision. It includes:

1. New definitions for “hand-held bassinet/cradle” and “hand-held infant carrier seat”
2. A revision to the restraint system requirements based on these new definitions
3. Clarification of the carry handle integrity test requirement
4. A new requirement and test method for the handle lock impact test
5. A new requirement and test method for the handle auto-lock test

In September 2012, ASTM issued a ballot for new warning and labeling requirements pertaining to strangulation hazards. The results of the ballot were reviewed by the subcommittee at an October 24, 2012 hand-held infant carrier subcommittee meeting, which was attended by CPSC staff. One negative vote, pertaining to the color of the warning panel on the label was reviewed. The commenter felt it should be orange, not yellow. The subcommittee found the negative to be non-persuasive; the yellow color was chosen specifically to match the air bag warning label that is required under FMV213.

Affirmative votes, some with comments that suggested word changes in the requirements, were also reviewed by the subcommittee and a few minor changes were made for clarity. Due to these changes, ASTM will be issuing a second ballot before the end of the year containing the warning label requirement with the suggested changes for clarity.

E. Other Relevant Standards

In Tab B, ESME staff compares the performance requirements of ASTM F2050-12 to the performance requirements of other related standards (See Table 1).

TABLE 1: Review of Other Standards

Standard Number	Standard Name	Comments
EN 12790:2009	European/British Standard for Child Care Articles – Reclined Cradles	Contains similar requirements to ASTM F2050. Differences are detailed in Appendix B of Tab B.
ECE 44	European Provision for Restraining Devices for Child Occupants of Power-Driven Vehicles	This standard covers restraint devices while the occupant is in the vehicle. There are no provisions for carriers when they are removed from the vehicle.

Standard Number	Standard Name	Comments
FMVSS No. 213	NHTSA – Requirements for Child Restraint Systems Used in Motor Vehicles and Aircraft	This standard covers restraint devices while the occupant is in the vehicle. There are no provisions for carriers when they are removed from the vehicle.
JIS D 0401	Japanese Standard for Automotive Accessories – Child Restraints	This standard covers restraint devices while the occupant is in the vehicle. There are no provisions for carriers when they are removed from the vehicle.
AS/NZS 1754:2010	Australian/New Zealand Standard for Child Restraint Systems for Use in Motor Vehicles	This standard covers restraint devices while the occupant is in the vehicle. There are no provisions for carriers when they are removed from the vehicle.

Of these standards, ES staff found only one international standard, EN 12790 *European/British Standard for Child Care Articles – Reclined Cradles*, which addresses the product in a fashion similar to ASTM F2050 -12. However, reclined cradles are designed and intended for unattended sleep; and thus, this standard includes requirements that also pertain to that use pattern. While it is understood that sleeping in hand-held carrier seats designed to ASTM F2050-12 is a foreseeable use, the carrier seats are not specifically designed for sleep, like the EN 123790 cradles.

Several other standards only address requirements for restraint systems of products when used in motor vehicles, and therefore, they do not address other incident hazard patterns associated with hand-held infant carrier seats.

Staff believes that the current ASTM standard, F2050-12, is the most comprehensive of the standards to address the incident hazards. However, some individual requirements in the EN12790 standard are more stringent than F2050-12. EN 12790 includes requirements for flammability, surface chemicals, cords/ribbons, cradle angles, and cradle strength/durability. The hazard patterns noted in the incidents reported to CPSC do not necessitate adding similar requirements to ASTM F2050-12. However, staff will continue to monitor hazard patterns and recommend future changes, if necessary.

III DISCUSSION

A. Adequacy of F2050-12 Requirements

Staff believes that 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, and restraint systems are also included. It should be noted that restraints are required for hand-held infant carrier seats, but are prohibited from hand-held

bassinet/cradles. Thus, the following discussions regarding restraint hazards pertain only to hand-held infant carrier products.

This section discusses how each hazard pattern relates to ASTM F2050-12.

Hazard Pattern 1. Restraint Usage

Staff believes that the existing warning labels in F2050-12 for restraint usage are inadequate. Staff has been working with an ASTM task group to modify the labeling requirements in ASTM F2050-12 to improve caregiver awareness of the dangers of leaving children in carrier seats with loose or unbuckled restraints. Included in the task group discussions were technical and legal staff from NHTSA. At this time, staff is unable to recommend new performance or design requirements for the restraint system without first undertaking a joint venture with NHTSA, because hand-held carrier seats used as car seats must also meet NHTSA requirements for occupant crashworthiness. Design changes have the potential to affect this safety-related function of the carrier. Pursuing a change in design to address restraint hazards, while not affecting the performance of the product as a child restraint system, would most likely take several years of a joint effort with NHTSA. CPSC staff has shared data and information with NHTSA staff regarding the restraint hazards, but an official effort has not been initiated. Therefore, at this time, staff believes that an improved warning label is the best method to increase awareness of the proper use of restraints and recommends a revised warning label and associated requirements.

Hazard Pattern 2. Handle Problems

The previous editions of ASTM F2050 contained a handle preconditioning cycle test, followed by a static hang test, to check for handle lock integrity. To address concerns with handles detaching, breaking, or not locking in the carry position, staff worked with the ASTM task group to add a handle lock impact test and a handle auto-lock test. Both tests were approved and are included in the 2012 edition of ASTM F2050. During recent testing by CPSC staff of several hand-held carrier seats to the new auto-lock test, staff determined that there are some repeatability issues with some carrier seats as the test is currently written. Therefore, staff is also making a recommendation to modify the handle auto-lock test procedure to help address this repeatability problem.

Hazard Pattern 3. Design Issues

Several incidents in this hazard pattern could be related to the stability of the carrier when placed on tables, sofas, or chairs. Carrier seats are, in most cases, designed to meet NHTSA requirements for occupant crash worthiness. Because modifications of the carrier to improve stability when used outside the vehicle might affect how the carrier integrates into the carrier base and a vehicle, and thus would implicate issues within NHTSA's jurisdiction, staff is not making any recommendations to address stability issues at this time.

In addition to stability issues, this hazard pattern includes occupant positioning incidents. Six consumer complaints involve infant head slumping because of a possible insufficient angle of incline that tends to place the infant in an upright position. Of the six, one reported a nonspecific injury and there were no reported fatalities. And of the six consumer complaints received, none of them clearly indicated the location of the carrier when the consumer perceived the hazard.

Thus, the carrier could have been inside a vehicle, as opposed to being carried, or being used outside of a car. The staff's draft proposed rule only addresses hazards with carrier use that occur outside of a car.

Staff questioned whether the perceived slumping hazard was more applicable to the occupant position when the carrier is installed in a car. To explore this possibility, the Directorate for Engineering Sciences staff looked at two different model carrier seats to see if the occupant position angle differed when being used as a car seat versus being used as a carrier. When used as a car seat, carriers are attached to base units that are installed in the car. The base units use indicators, or level gauges, to ensure that when the car seat is on the base and installed in the car, it is at the proper angle to provide adequate crashworthiness protection. Staff's limited study found that for both of the two carrier models tested, the occupant's position angle led to a more upright positioning of the infant when the carrier is installed as a car seat on its base, rather than when the carrier is resting on a floor, or other horizontal surface. The results of this limited study were shared with NHTSA staff.

At this time, CPSC staff is not recommending changes to the carrier angle of incline. CPSC staff is unaware of any specific incidents that suggest that the angle of incline while used as a carrier (versus a car seat), leads to injuries.

Hazard Patterns 4 and 7. Issues with Accessories and Hazardous Environment

These two hazard patterns are considered "non-product-related" issues because the incidents involve carriers being placed in a potentially hazardous environment or a potentially hazardous product being placed on or near the carrier. No specific changes to the existing ASTM F2050-12 standard could address these hazard patterns. Therefore, staff is not making any recommendations at this time.

Hazard Pattern 5. Fabric/Padding Issues

This hazard pattern is not specific to the product. Similar incidents are seen with other durable children's products and are expected with any product with fabric or padding. Staff is not making any recommendations to address this hazard pattern at this time.

Hazard Pattern 6. Falls from Shopping Carts

ASTM F2372 – 11a *Standard Consumer Safety Performance Specification for Shopping Carts* is the voluntary standard that was developed to address injuries to children associated with falls from shopping carts. According to the standard, each shopping cart shall have warning statements instructing the user not to use a personal infant carrier but instead use the seat in the cart to accommodate the child and fasten the shopping cart's restraint securely. 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 was revised recently and includes a pictogram concerning the use of hand-held carriers in the cart. This new label is included in the latest version of ASTM F2372, which was approved in December 2011 and published in January 2012. Staff is not making any additional recommendations to address this hazard pattern at this time.

Hazard Patterns 8 and 9. Other Product-Related Issues and Other/Unknown Issues

Insufficient information on the hazard patterns exists at this time for staff to recommend performance changes to the existing standard.

B. Staff's Recommendations for the Proposed Safety Standard

1) New Restraints Warning Label and Associated Requirements

Adding a new strangulation warning label represents the best available alternative to address the hazards associated with the non-use or partial use of restraint straps in light of the need to defer to NHTSA on any issues that implicate in-car use. Any attempts to design out the risk may impact the integrity or safety of the carrier while in a vehicle and would require extensive analysis, studies, and testing by CPSC staff, ASTM, and NHTSA staff to ensure that any design changes meant to address the hazard do not inadvertently create a new hazard.

An ASTM task group, with assistance from CPSC staff, developed a new strangulation warning label for carrier seats intended for use as child restraint devices in motor vehicles. NHTSA staff was also included in the development of the warning label. This new label and the requirements associated with it were balloted by ASTM on September 14, 2012. Figure 4 displays the recommended strangulation warning label. Details regarding the development of the recommended warning label can be found in Tab C.



Figure4. ASTM-balloted warning label

A number of factors were considered by the ASTM task group in the development of the recommended label to improve its noticeability and comprehension:

Size

During discussions with NHTSA staff regarding the development of a new label, a request was made that the new strangulation warning label be of a size that does not overwhelm or detract from the required air bag warning label in FMVSS No. 213. ASTM included in the ballot a requirement that the strangulation warning label be the same minimum size specified by FMVSS No. 213, which states that the air bag pictogram shall be no less than 30 mm in diameter, and the

message area must be no less than 30 square cm. CPSC staff concurs with the size requirement as balloted.

Even with the size limitation, the recommended strangulation warning label is significantly larger than the warning label that is currently required in the ASTM standard, an improvement that staff believes advances safety.

Location

The warning should be placed in a location where the caregivers are expected to notice it during regular interaction with the carrier and the infant. Warnings, when placed close to the hazard, are believed to have a higher noticeability. Staff believes that the recommended strangulation warning label should be easily visible to the caregivers while they are placing the child into the carrier. Accordingly, staff's recommendation for the location of the new strangulation warning label mirrors the airbag warning label, and requires that the label be affixed to the outer surface of the cushion or padding in or adjacent to the area where a child's head would rest. The location recommended by the staff was also balloted by ASTM.

Color and Contrast

Color and contrast are design factors that increase the noticeability of warnings. The ASTM ballot and staff's recommended label requires a black and white contrast, in addition to a prohibition symbol in red, which traditionally attracts attention; a check mark in green, which is usually associated with a positive action, and the signal word, WARNING, in a yellow background.

Pictorials

Users may notice a warning label but not actually read it. Research shows that pictorial symbols increase the noticeability of the warnings because they help capture a user's attention. Graphic warnings induce an emotional response, increase memory and awareness of the risks, and strengthen motivations to avoid the risks more than the text warnings. Pictograms are also helpful for users with limited or no English literacy³.

An ASTM task group, with assistance from CPSC staff, developed several pictorial symbols for carrier seats intended to be used as restraint devices in automobiles. The ASTM task group tested the pictorial symbols for comprehension by following the guidelines outlined in ANSI Z535.3 – 07⁴. The recommended pictogram tells users what actions not to take in addition to the appropriate action to be taken.

Content

³ See TAB C: Human Factors Assessment of Hazard Patterns and Mitigation Strategies in Hand-Held Infant Carriers for appropriate references.

⁴ *American National Standard Criteria for Safety Symbols* (ANSI, 2007).

Warning messages should explain the nature of the hazard, the consequences of the hazard, and give instructions on how to avoid the hazard. The ASTM balloted warning label and staff’s recommended strangulation warning label meets these requirements because it incorporates the nature of the hazard (strangulation), how it can occur (loose or partially buckled straps), and what the caregiver needs to do (fully restrain the child) to avoid the hazard.

Emphasizing the Severity of Injury

Providing explicit information about the consequences of not taking precautionary measures to avoid the hazard can increase the perception of injury severity and the perceived hazard (DeJoy, 1999a). Use of the statement “Children have STRANGLED” is intended to increase the awareness of the danger associated with inappropriate use of the harness straps.

Non-Car Seat Hand-held Infant Carriers

For hand-held infant carrier seats not for use in a vehicle, the ASTM task group developed a similar warning label that is also included in staff’s recommendations (Figure 5). This label also warns about the loose or partially buckled restraints and strangulation but does not reference a vehicle in the language. In addition, this warning label does not have a pictogram because carrier seats not-intended for cars, typically do not have chest clip-style restraints, and therefore, the pictogram would not be valid. This label is not required for hand-held bassinet/cradle products because those products are prohibited from having restraints.

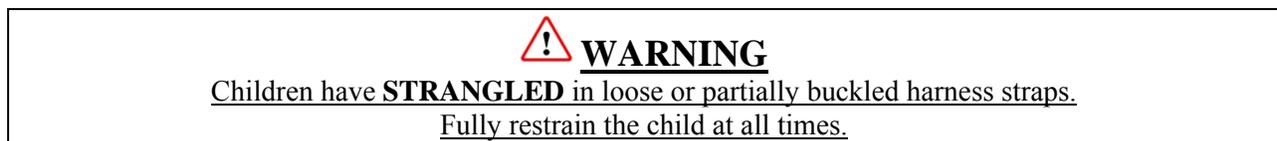


Figure 5

2) Modification to the Handle Auto-Lock Test Procedure

One new requirement in F2050-12 is the handle auto-lock test. This test helps to ensure that the carrier will not rotate and allow an unrestrained infant to fall from the carrier when a caregiver picks it up with the handle not locked in the carry position. This is accomplished by requiring the carrier handle to either have an auto-lock feature, or, when not locked in the carry position, to fall to a position that makes it 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 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 to serve as an occupant surrogate. During the testing, the CAMI is placed into the seat without being secured by restraints. The carrier and CAMI dummy are then lifted with the handle in an unlocked position. Staff found that during the testing of one carrier, the CAMI could be wedged into the seat padding, such that it does not fall out during the lift test when it otherwise would fall out. An unrestrained infant in this position would most likely fall from the carrier. Staff further found that CAMI placement in the carrier could be manipulated to achieve different

results. For example, a CAMI placed with its back high in the seat may be more likely to pass the test, while a CAMI placed lower in the seat may be more likely to fail. The ability to pass or fail the test based on friction or placement of the CAMI impacts the consistency and repeatability of the test results.

To resolve these CAMI-related test issues, staff 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 as 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. See Tab C for figures demonstrating this test.

Staff recommends that the ASTM F2050 auto-lock test be conducted 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 proposed in the recently published NPR for bassinets. 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.⁵

Staff's recommendation to modify the test procedure has been discussed with ASTM at the task group level, and the task group is currently involved in evaluating the use of the cylinder instead of the CAMI dummy.

The exact wording of staff's recommended modifications to F2050-12 are provided in Appendix A of this memorandum.

C. *Education and Information Efforts*

During development of staff's briefing package, NHTSA staff informed CPSC staff that the Child Passenger Safety (CPS) curriculum used to train CPS technicians to install child restraints in vehicles is currently being updated. NHTSA staff has asked for educational material, which could potentially be added to the curriculum, regarding the strangulation hazard in infant carriers when used outside the vehicle. Based on NHTSA's request, CPSC staff has developed educational materials outlining different strangulation hazard scenarios associated with straps when the infant carrier is used outside the vehicle. This information is currently undergoing internal review at CPSC.

D. *Compliance Recalls*

Between January 1, 2007 and June 7, 2012, there were 920,000 hand-held infant carriers, involving three manufacturers, subject to recall. At the time the products were recalled, 166 infants had been injured in incidents that resulted in minor lacerations and bruises as well as more severe head injuries, concussions, and skull fractures. Tab D contains a chart detailing these three recalls. Two of the recalls occurred in 2008 and 2009 and dealt with handle issues

⁵ Staff is recommending the use of the surrogate cylinder over the EN cylinder because we do not currently own an EN cylinder to validate its effectiveness in the test. The two cylinders are close in size and weight.

and involved 897,000 of the 920,000 carriers recalled. The recent changes in ASTM F2050-12 that pertain to handle performance and integrity were first developed as a result of these two recalls. One recall in 2010 involved 23,000 hand-held infant carriers and pertained to broken harness chest clip parts, responsible for lacerations.

E. Initial Regulatory Flexibility Analysis

The majority of hand-held carriers are produced and/or marketed by juvenile product manufacturers and distributors. The exception is Moses baskets, which are often marketed by bedding manufacturers and distributors. CPSC staff estimates that there are currently at least 43 suppliers of hand-held infant carriers to the U.S. market. Eleven are domestic manufacturers, 10 are domestic importers, and 20 are domestic firms supplying Moses baskets from unknown sources. There are also two foreign firms: a manufacturer and an importer that imports from foreign companies and distributes from outside of the United States. Based on U.S. Small Business Administration guidelines, 29 of the 43 suppliers of hand-held infant carriers to the U.S. market are small firms—6 domestic manufacturers, 4 domestic importers, and 19 firms supplying Moses baskets whose supply source is unknown—likely to be affected by the staff-recommended proposed standard, as described in the Directorate for Economic Analysis memo (Tab E).

The direct impact on four of the six small domestic manufacturers whose hand-held infant carriers meet the current voluntary standard is not expected to be significant. However, there could potentially be a significant direct impact on the two small domestic manufacturers whose hand-held infant carriers are not compliant with the current voluntary standard, regardless of how they choose to meet the staff-recommended warning label and auto-locking handle requirements.

The four small importers operating in the U.S. market would need to find an alternate source if their existing supplier does not come into compliance with the requirements of the staff-recommended final rule. They could also discontinue importing any noncomplying hand-held infant carriers, possibly replacing their product with another juvenile product. Moses basket suppliers would need to add warning labels and instructional literature to meet the staff-recommended standard's requirements. Alternatively, they could remove their product's handles, falling out of the scope of the standard.

IV STAFF RECOMMENDATIONS

CPSC staff recommends that the Commission publish a NPR that incorporates by reference the voluntary standard ASTM F2050-12, *Standard Consumer Safety Specification for Hand-Held Infant Carriers*, with one revision to the ASTM F2050-12 test method relating to the handle auto-lock test, and new warning and labeling requirements pertaining to strangulation hazards, as written in the appendix to this memo.

Staff also recommends that the Commission propose an effective date of 180 days following publication of the final rule.

Appendix A: Recommended Changes to ASTM F2050
(~~Strikeouts~~ show removed text, underline shows added text)

A) Carry Handle Auto-lock Test

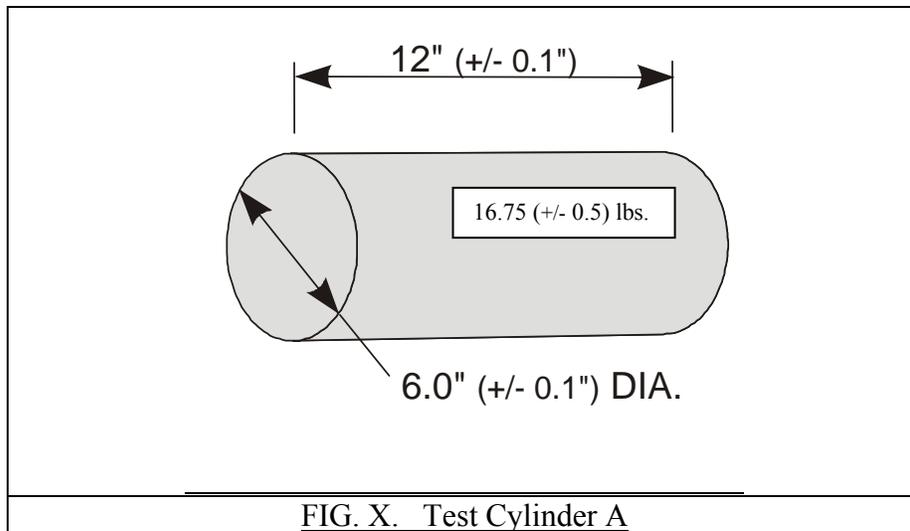
6.1.3 The carry handle shall lock in a position forward or rearward of the manufacturer's designated carry position such that an unrestrained Test Cylinder A (see Figure X) ~~dummy~~ does not fall out of the carrier when tested in accordance with 7.1.2 through 7.1.4.

7.1 Carry Handle Auto-Locking Test:

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. ~~Place the CAMI Infant dummy Mark II in the carrier on top of the harness and positioned per the manufacturer's instructions.~~ 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).

Test Cylinder A

A rigid cylinder 6.0 ± 0.1 inches (153 ± 2.5 mm) in diameter and 12 ± 0.1 inches (305 ± 2.5 mm) in height, having a mass of 16.75 ± 0.5 pounds (7.6 ± 0.2 kg) and with its center of gravity in the center of the cylinder. All edges shall have a radius of 0.2 ± 0.04 inches (5 ± 1 mm).



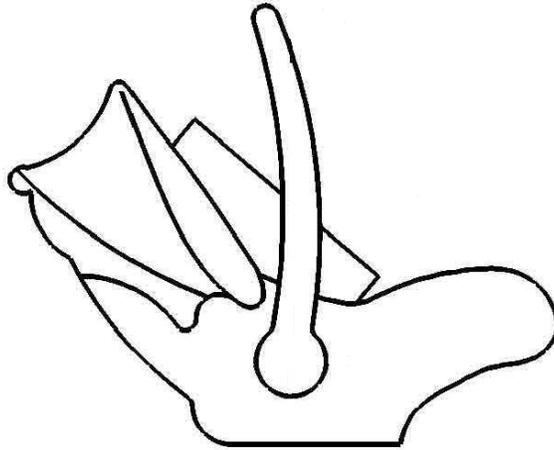


FIG. Y. Test Cylinder Placed in Carrier

B) Strangulation Warning Label

2. Referenced Documents

49 CFR 571.213, Federal Motor Vehicle Safety Standard (FMVSS) No. 213.

8. Marking and Labeling

8.3.2 The warning statements shall address the following except as otherwise noted:

~~8.3.2.3 Strangulation Hazard: Child can strangle in loose restraint straps. NEVER leave child in carrier when straps are loose or undone.~~

8.3.2.3 Strangulation Hazard: 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 upper case characters as depicted) and a specific location:



- The area of the pictogram is to be at least 1.09 in² (706 mm²), 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 in² (30 cm²), 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.

8.3.2.4 Strangulation Hazard: The following warning is required only for carriers not intended for use in a motor vehicle and are not hand-held bassinets/cradles. This warning requires exact language (including the use of bold font and upper case characters as depicted):



WARNING

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

9. Instructional Literature

9.1.1 The instructions shall contain statements, which address the warning statements in 8.3.2-
~~and the following.~~ 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:

9.1.1.1 Read all instructions before use of the infant carrier.

9.1.1.2 Keep instructions for future use.

9.1.1.3 Do not use the infant carrier if it is damaged or broken.

**TAB A:
Hand-Held Infant Carrier-Related Deaths, Injuries, and
Potential Injuries, and NEISS Injury Estimates: January 1,
2007–June 7, 2012**

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A**



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

Memorandum

Date: July 16, 2012

TO : Patricia Edwards
Hand-Held Infant Carriers Project Manager
Division of Mechanical Engineering
Directorate for Engineering Sciences

THROUGH: Kathleen Stralka
Associate Executive Director
Directorate for Epidemiology

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

FROM : Risana Chowdhury
Division of Hazard Analysis
Directorate for Epidemiology

SUBJECT : Hand-Held Infant Carrier-Related Deaths, Injuries, Potential Injuries, and
NEISS Injury Estimates: January 1, 2007 – June 7, 2012⁶

This memorandum characterizes the number of deaths and injuries and the types of hazards related to hand-held infant carriers over a period of more than 5 years, beginning in January 2007⁷. These characterizations are based on incident reports received by CPSC staff. The memorandum also presents national injury estimates from January 2007 through December 2011.

The ASTM voluntary standard for hand-held infant carriers, F2050-12, addresses safety issues related to hand-held infant carriers. According to the ASTM definition, a “hand-held infant carrier” is 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-

⁶ This analysis was prepared by CPSC staff. It has not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.

⁷ 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.

holds or handles. A hand-held carrier is often used as a car seat, as well as a seat on a stroller, highchair, and/or a shopping cart. Incidents that occur while the carrier is being used as a car seat inside a vehicle are outside the jurisdiction of the CPSC. Incidents involving the failure of the attachment mechanism of a hand-held carrier seat to a stroller or highchair will be addressed in the regulatory work for strollers or highchairs.

A major revision of the ASTM F2050-12 standard on hand-held infant carriers, published in 2009, was based on data provided by the CPSC staff through 2008. For this proposed rulemaking package, staff decided to review CPSC data from 2007 forward because that would take into consideration the time lag in data reporting in the CPSC databases. Due to the large number of injury reports received through the emergency departments during the 5-year timeframe, the estimates of emergency-treated injuries associated with hand-held infant carriers are presented separately from the rest of the incident data.

I. Incident Data⁸

CPSC staff is aware of a total of 242 incidents (36 fatal and 206 nonfatal) related to hand-held infant carriers, which were reported to have occurred from January 1, 2007 through June 7, 2012. The age range for the extracted data was limited to the age group zero to less than 2 years of age. The zero age group included children whose ages were not reported. The upper age limit of 2 years was chosen because the weight of the 50th percentile 19- to 24-month-old child is 26.0 lbs.,⁹ and it is impractical for caregivers to carry children at or beyond that weight level in hand-held carriers. However, only incidents that occurred when the infant was in the carrier, or was being placed into or taken out of the carrier, are included for the purposes of this memorandum.

Because reporting is ongoing, the number of reported fatalities, nonfatal injuries, and non-injury incidents may change in the future.

Table 1 indicates the breakdown of the incidents by the incident year. Given that these reports are anecdotal and that reporting is incomplete, CPSC staff strongly discourages drawing any inferences based on the year-to-year increase or decrease shown in the reported data.

⁸ The CPSC databases searched were the In-Depth Investigation (INDP) file, the Injury or Potential Injury Incident (IPII) file, and the Death Certificate (DTHS) file. These reported deaths and incidents are neither a complete count of all that occurred during this time period, nor a sample of known probability of selection. 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 hand-held infant carriers.

Date of extraction for reported incident data was 06/08/12. The incident reports involving carriers do not always clearly specify the type of the carrier involved. As such, all data coded under product codes 1519/1548/1549 and text keywords “Moses”/“basket” were extracted, yielding a very large initial data pool. Upon careful joint review with CPSC’s Engineering Sciences and Economic Analysis directorates, many cases were considered out of scope for the purposes of this memorandum. For example, cases with SIDS or other preexisting medical conditions as official cause of death, cases where a child was being transported in a carrier inside a vehicle, cases where a child was outside a carrier, playing with it and was injured by it, or cases where the product, although coded as a hand-held infant carrier, was, in fact, a rocker, bouncer, or some other infant seat, were excluded. However, all incidents where hazardous environments in and around the hand-held carrier resulted in fatalities, injuries, or near-injuries were retained. With the exception of incidents occurring in U.S. military bases, all incidents that occurred outside of the United States have been excluded. To prevent any double counting, when multiple reports of the same incident were identified, they were consolidated and counted as one incident.

⁹ Snyder, R.; Spencer, M.; Owings, C.; and Schneider, L. (1975). *Physical Characteristics of Children As Related To Death and Injury for Consumer Product Safety Design and Use*. (Report No. UM-HSRI-BI-75-5, Contract No. FDA 72-70). Prepared for the U.S. Consumer Product Safety Commission. Ann Arbor, MI: The University of Michigan.

**Table 1: Hand-Held Infant Carrier-Related Reported Incidents
01/01/07 through 06/07/12**

<i>Incident Year</i>	<i>Total Number of Reported Incidents</i>	<i>Number of Reported Fatal Incidents</i>	<i>Number of Reported Nonfatal Incidents</i>
2007	63	6	57
2008	48	10	38
2009	47	7	40
2010*	50	6	44
2011*	28	6	22
2012*	5	1	4
Unknown	1		1
Total	242	36	206

Source: CPSC epidemiological databases.
Note: * indicates data collection is ongoing

A. Fatalities

A total of 36 hand-held infant carrier-associated fatalities reportedly occurred during the time period from January 2007 through early June 2012. Age was not reported for two of the decedents. Among the remaining fatalities, 71 percent were 6 months or younger, and 91 percent were 12 months or younger. Three of the decedents were 15-, 18-, and 22-month-old children.

Most of the fatalities involved a product-related issue. Nine strangulation deaths involved the carrier's harness chest clips or straps. In most of these cases, the infant was partially restrained in the seat with only the shoulder straps in place, but the crotch strap was left unsecured. This allowed the infant to slide forward on the seat just enough to get caught at the throat by the chest clip that connects the two shoulder straps. Beside these strangulation deaths, there was an additional death report that described the restraint straps as being too tight and impairing the decedent's breathing; no details of how the restraints were positioned were included in that report. Seven of the 36 fatalities involved an infant who was unrestrained in a hand-held carrier and found in a prone position, face down on the seat, or on a blanket, covers, and/or a pillow. Two additional cases involved an unrestrained infant who was found prone on the seat of the carrier, which had also tipped over. Three more of the 36 fatality incidents reported an infant trapped under an overturned seat. Information regarding what caused the seat to overturn was not provided in these reports. One fatality resulted from a fall from a carrier seat that was on a shopping cart that was not equipped to attach such a seat. There were six additional reports with some information indicating the use or misuse of a product feature that contributed to the fatality; however, CPSC staff does not have enough information to identify conclusively the hazard pattern involved.

Five of the 36 fatalities were considered non-product related; instead, these incidents resulted from the decedent and the carrier being placed in a hazardous environment. Two of the five fatalities resulted from the placement of an infant in a carrier atop a stove and the subsequent accidental ignition of the stove. Another infant died of hyperthermia when left unattended for an extended period of time in a carrier, swaddled in multiple blankets, in a room with temperatures exceeding 90 degrees. In another of the five deaths, an infant in a carrier was placed crosswise

inside a bassinet; official reports concluded that movements of the infant knocked the carrier into a reclined position leading to the asphyxiation death. The fifth decedent suffocated on a blanket placed over his head.

For the remaining two fatalities, insufficient evidence exists to conclude any product involvement or the presence of any hazardous external circumstances.

B. Nonfatal Incidents

A total of 206 hand-held carrier-related nonfatal incidents reportedly occurred from January 1, 2007 through June 7, 2012. Of these, 60 incidents reported an injury to an infant using the carrier at the time of the incident. Two of the injury reports were of children requiring hospitalization due to serious head injuries from a fall from a carrier that was on a shopping cart. Among the remaining 58 injury reports, some specifically mentioned the type of injury, while others only mentioned an injury, but no specifics about the injury. Bumps, bruises, abrasions, lacerations, allergic reactions, and near-choking episodes were some of the common injuries reported. No age was reported for 17 (28 percent) of the injured. For incidents reporting age, all but two reported the child's age to be 12 months or younger; one child was 13 months, and a second child was 23 months old.

The remaining 146 incidents reported that no injury had occurred or provided no information about any injury. However, many of the descriptions indicated the potential for a serious injury or even death.

II. Hazard Patterns

CPSC staff considered all 242 reported incidents (36 fatal and 206 nonfatal) to identify hazard patterns associated with hand-held infant carriers. In order of frequency of incident reports, the hazard patterns were associated with the following product component and issues:

- Restraints
 - Handles
 - Carrier design
 - Accessories
 - Fabric/padding material
 - Hazardous environment
 - Falls
 - Other product-related issues
 - Other/unknown issues.
- ***Restraints*** were the most commonly reported hazard resulting in the highest proportion of deaths and injuries as well. Eighty-one of the 242 incidents (approximately 33 percent of total incidents, 53 percent of deaths, and 38 percent of injuries) were associated with the use, incorrect use, or non-use of the harness straps. There were 10 fatal incidents where

the decedent was restrained in the carrier incorrectly. A majority of these deaths resulted from the infant being left in the seat with only the shoulder straps connected, but unrestrained at the crotch strap, which allowed the infant to slide forward on the seat just enough to get caught at the throat by the chest clip and strangle. There were nine fatal incidents where the decedent was in the carrier and not restrained at all. In a majority of these deaths, the decedent was found later to have turned over to a prone position, face down on a soft surface. Most of the nonfatal incidents were associated with adjustment issues, such as difficulty with tightening or loosening the harness straps. Other safety-related complaints related to restraint issues reported inadequate design, failure to keep the infant secured, and poor quality.

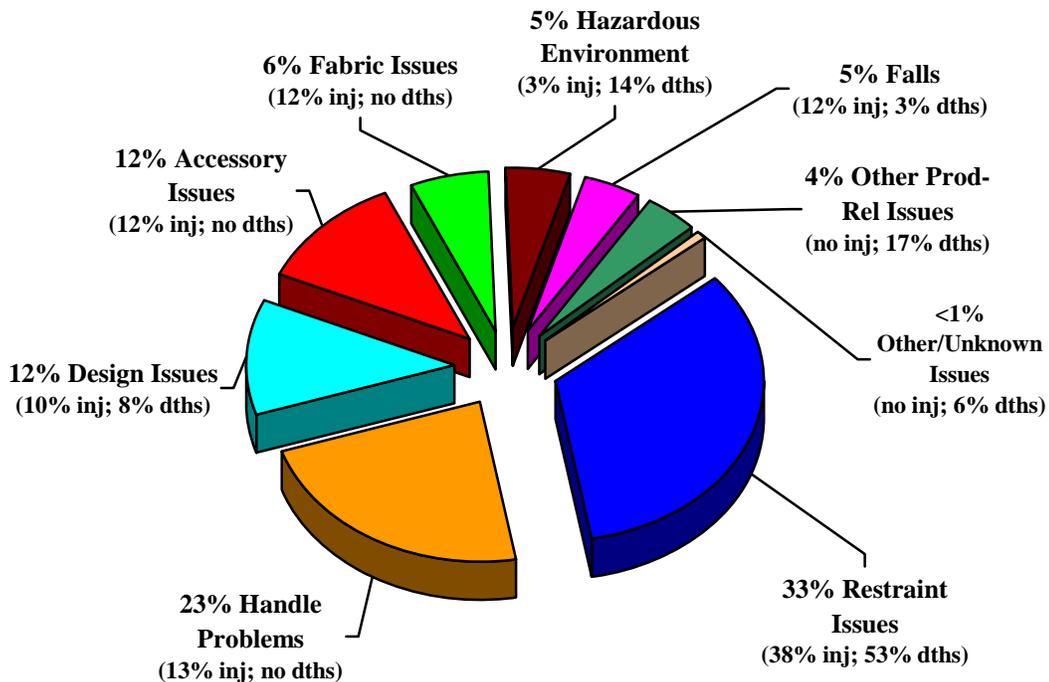
- **Handle problems** were reported in 55 of the 242 (23 percent) incidents. Common issues reported were: handles detaching, handles not remaining locked in position, and handles breaking. Nearly half of the reports of handle problems were related to recalled products. This category includes 13 percent of the injuries—mostly due to falls—but no fatalities.
- **Issues with carrier design** were the next most commonly encountered hazard, accounting for 28 of the 242 (12 percent) incident reports (eight percent of fatalities and 10 percent of injuries). Common design issues reported were of instability, sharp surfaces, unsafe infant posture while seated, and lack of structural integrity. All three fatalities in this category resulted from the occupied carrier tipping upside down for unknown reasons, and trapping the infant. Lacerations on sharp surfaces were the most common injury.
- **Issues with accessories**, usually bought separately from the hand-held carrier, were reported in 28 of the 242 (12 percent) incidents. While there were no fatalities, 12 percent of the injuries were related to this issue. Some of the commonly reported issues were with toys or toy-attachment devices, head and body support devices, and carrier seat covers, and canopies.
- **Problems with fabric/padding material** of hand-held carriers were reported in 15 of the 242 (six percent) incidents. Most of the related injuries, accounting for 12 percent of all injuries, were caused by allergic reactions to the fabric or near-choking episodes from infants mouthing pieces of padding from the carrier seat. There were no fatalities in this category.
- **A hazardous environment** in or around the occupied hand-held carrier was responsible for another 12 reported incidents (five percent). Fourteen percent of the fatalities (five cases) and three percent of the injuries are in this category. Some of these hazardous scenarios included: placement of a carrier with an infant on top of a stove and the subsequent accidental ignition of the stove; an infant in a carrier, swaddled in multiple blankets, being left for a prolonged time period in a room with temperatures exceeding 90 degrees; and placement of a blanket over an infant's head.
- **Falls** from hand-held carriers while carriers were placed on shopping carts were reported in 11 of the 242 (five percent) incidents. This category includes one fatality and 12

percent of the injuries; two of the injuries were serious head injuries requiring hospitalizations.

- **Other product-related issues** were involved in 10 of the 242 (four percent) reported incidents. Most of these reports indicated the use or misuse of a product feature that contributed to the incident; however, not enough information was available for CPSC staff to identify conclusively the hazard pattern involved. While there were no injuries, six fatal incidents, which is 17 percent of the fatalities, are included in this category.
- **Other/unknown issues** accounted for the remaining two reports, both of which were fatalities. While it was reported that the infants were strapped in the seat at the time of death, there was insufficient evidence of any product involvement or the presence of any hazardous external circumstances. In both cases, official reports were pending further information at the time of reporting to CPSC.

The distribution of the 242 reported incidents by the hazard patterns described above are shown in Fig. 1.

**Fig 1: Distribution of Incident Reports Associated with Hand-Held Infant Carriers by Hazard Pattern Characterizations
01/01/07-06/07/12**



Source: CPSC epidemiological databases IPII, INDP, and DTSH.

III. National Injury Estimates¹⁰

There were an estimated total of 57,700 injuries (sample size=2,398, coefficient of variation=0.11) related to hand-held infant carriers that were treated in U.S. hospital emergency departments over the 5-year period from 2007 to 2011. Until NEISS data for 2012 is finalized in spring 2013, partial estimates for 2012 will not be available. The injury estimates for individual years are reported in Table 2. Although there was a statistically significant increase observed in the estimated injuries from 2008 to 2009, and a statistically significant decrease observed in the estimated injuries from 2010 to 2011, there was no statistically significant trend observed over the 2007–2011 period.

Table 2: Hand-Held Carrier-Related Injuries Treated in U.S. Hospital Emergency Departments: 2007–2011

Calendar Year	Estimated Injuries	Sample Size	Coefficient of Variation
2007	11,500	507	0.10
2008	9,600	456	0.14
2009	12,800	488	0.15
2010	13,200	530	0.12
2011	10,600	417	0.12
Total	57,700	2,398	0.11

Source: NEISS, CPSC. Estimates rounded to nearest 100.

Of the 2,398 NEISS sample cases, there were two fatalities. Given the small sample size, any fatality estimate based on these cases would be considered unreliable.¹¹ The fatalities are, however, included in the overall NEISS injury estimates. The information available on the circumstances of these two fatalities indicates that in both cases, the occupied carrier was most likely placed in a hazardous environment. However, the details provided insufficient information for CPSC staff to identify conclusively the hazard. As such, they are excluded from the hazard pattern discussion in the previous section.

About 73 percent of the injured were 6 months of age or younger, and about 91 percent were 12 months or younger. For the emergency department-treated injuries related to hand-held carriers, the following characteristics occurred most frequently:

¹⁰ The source of the injury estimates is the National Electronic Injury Surveillance System (NEISS), a statistically valid injury surveillance system. NEISS injury data are gathered from emergency departments of hospitals selected as a probability sample of all the U.S. hospitals with emergency departments. The surveillance data gathered from the sample hospitals enable the CPSC staff to make timely national estimates of the number of injuries associated with specific consumer products.

All data coded under product codes 1519, 1548, and 1549 and text keywords “Moses”/“basket” were extracted. Age was limited to less than 2 years. Certain records were considered out of scope for the purposes of this memorandum. For example, all injuries sustained while in the carrier during travel in a vehicle were excluded. Another example was of a victim suffering an acute medical episode while sitting in the carrier. These records were excluded prior to deriving the statistical injury estimates.

¹¹ According to the NEISS publication criteria, an estimate must be 1,200 or greater, the sample size must be 20 or greater, and the coefficient of variation must be 33% or smaller.

- Hazard – falls (more than 75%); a majority of the reports did not specify the manner or cause of fall.
- Injured body part – head (66%) and face (17%).
- Injury type – internal organ injury (46%) and contusions/abrasions (29%).
- Disposition – treated and released (93%).

TAB B:

Staff's Recommended Changes to ASTM F2050-12, *Standard Consumer Safety Specification for Hand-Held Infant Carriers*, for Incorporation into Staff's Draft Proposed Rule

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

Memorandum

Date: September 27, 2012

TO: Patricia L. Edwards
Project Manager, Hand-Held Carriers

THROUGH: George A. Borlase, Ph.D., P.E.
Associate Executive Director
Directorate for Engineering Sciences

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

FROM: Vincent Amodeo
Division of Mechanical Engineering
Directorate for Engineering Sciences

SUBJECT: Staff's recommended changes to ASTM F2050-12, *Standard Consumer Safety Specification for Hand-Held Infant Carriers*, for Incorporation into Staff's Draft Proposed Rule

I. INTRODUCTION

The Danny Keysar Child Product Safety Notification Act, Section 104 of the Consumer Product Safety Improvement Act (CPSIA), *Standards and Consumer Registration of Durable Nursery Products*, requires the U.S. Consumer Product Safety Commission (CPSC) to assess the effectiveness of voluntary consumer product safety standards for durable infant or toddler products and to promulgate mandatory safety standards. Section 104 (b)(1)(B) states: —The Commission shall . . . promulgate consumer product safety standards that – (i) are substantially the same as voluntary standards; or (ii) are more stringent than such voluntary standards if the Commission determines that more stringent standards would further reduce the risk of injury associated with such products.

This memorandum assesses the effectiveness of ASTM F2050-12, *Standard Consumer Safety Specification for Hand-Held Infant Carriers* (F2050-12), and outlines staff's recommended changes to that standard for inclusion in the proposed mandatory rule on hand-held carriers.

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

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.

Figure 1-A is a typical hand-held infant carrier that also serves as a restraint system (car seat) as regulated by National Highway and Transportation Safety Administration under the Federal Motor Vehicle Safety Standard (FMVSS) No. 213. (49 CFR 571.213, S5.5.2(k)(3)) (FMVSS No. 213).



Figure 1-A. Hand-Held Infant Carrier

Figure 1-B is another type of hand-held infant carrier included in the scope of F2050-12, and is defined as a “hand-held bassinet/cradle.” It is a carrier with a horizontal rest/support surface used to facilitate sleep. It differs from a bassinet/cradle in that it is designed to be portable, and when not being carried, it is placed on the floor. It does not have legs, a base, or a stand attached to it.



Figure 1-B. Hand-Held Infant Bassinet/Cradle

A) History of F2050, *Standard Consumer Safety Specification for Hand-Held Infant Carriers*

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 programs in developing draft requirements. 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 four times since then. The current version, ASTM F2050-12, was approved on July 1, 2012.

ASTM F2050-00 contained requirements to address the following issues:

- Sharp points
- Small parts
- Lead in paints
- Wood parts
- Openings (entrapment)
- Scissoring, shearing, and pinching
- Exposed coil springs
- Labeling
- Toy accessories
- Protective components
- Handle integrity
- Restraints requirements
- Slip resistance

ASTM F2050-01 (approved October 10, 2001) clarified:

- Restraint requirements for carriers not for use in motor vehicles

ASTM F2050-03 (approved November 1, 2003) added:

- Figure showing examples of permissible openings in rigid materials

ASTM F2050-08 (approved December 1, 2008) modified:

- Handle integrity test to use the greater of manufacturer's maximum rated load or Civil Aerospace Medical Institute (CAMI) Mark II infant dummy
- 6. Added Figure for CAMI weighted vest

ASTM F2050-09 (approved October 15, 2009) clarified:

- 7. Requirements for allowable openings in rigid materials are applicable only to openings that are accessible to toes and fingers of the occupant when product is in any manufacturer's recommended-use positions

ASTM F2050-12 (approved July 1, 2012) added:

8. New definitions for hand-held bassinet/cradle and hand-held infant carrier seat
9. Revision to the restraint system requirements
10. Clarification of the carry handle integrity test requirement
11. New requirement and test method for handle lock impact test
12. New requirement and test method for handle auto-lock test

B) Federal Motor Vehicle Safety Standard FMVSS No. 213

The majority of hand-held infant carrier seats covered by ASTM F2050 are sold for dual use as motor vehicle child restraint systems. Once a carrier is installed in an automobile, its performance is regulated by the National Highway Traffic Safety Administration (NHTSA) and must meet the requirements of FMVSS No. 213. This standard specifies requirements for child restraint systems used in motor vehicles and aircraft.

II. INCIDENT HAZARD REVIEW

According to the Directorate for Epidemiology,¹² there were a total of 242 incidents involving 36 fatalities, and 206 nonfatal incidents related to hand-held carriers, reported from January 1, 2007 through June 7, 2011. However, data collection from 2010 through 2012 is ongoing, and the number of reported incidents may change in the future.

The following is a listing of the hazard patterns identified in incident reports in order of frequency.

1. Restraint Usage

The greatest hazard found in the fatality data pertains to loose or partially unbuckled harness straps where the infant was improperly restrained. This category includes incidents where children were left sleeping in their carrier, but without being fully restrained. A typical fatality scenario involves an occupant who is partially restrained in the carrier seat. An infant restrained with just the chest clip fastened, but not the crotch strap, can slide down the carrier seat and strangle on the chest clip. Another scenario involves an infant who is left to sleep in the carrier unrestrained, which allows the infant to turn over in the seat. The infant is found later asphyxiated with their face pressed into the back/sides of the seat.

2. Handle Problems

Problems related to carrier handles are the second greatest hazard found in the incident data. Handle-related injuries are mostly due to falls. No fatalities are attributed to handle problems. The most commonly reported issues are handles detaching, breaking, or not remaining in the locked carry position. Almost half of the handle-related incidents occurred with recalled products.

¹²Chowdhury, Risana, "Hand-Held Infant Carrier-Related Deaths, Injuries, and Potential Injuries, and NEISS Injury Estimates; 2007–Present," July 16, 2012.

3. Design Issues

The next most frequent hazard pattern is attributed to the design of the carrier. Design issues are related to instability, sharp surfaces, unsafe infant posture while seated, and structural integrity. The fatalities are all attributed to the carrier tipping over and trapping the infant underneath the overturned carrier.

4. Issues with Accessories

Issues with accessories primarily purchased separately from the carrier comprise the next greatest number of incidents. Incidents include: choking on a string/device for attaching a toy to the carrier handle, jamming arm on an attached toy protrusion, drooping carrier canopy onto infant's face, breaking pacifier holder, and detaching small parts.

5. Fabric Issues

In six percent of the incidents, the carrier fabric or padding is the cause of injury. Incidents include: allergic reactions to padding or items attached to padding, bruising from fabric stitching, and ingesting padding foam.

6. Falls from Shopping Carts

Falls from placement on shopping carts contribute to five percent of the incidents. Serious head injuries occurred in two cases.

7. Hazardous Environment

The environment in which the carrier is used contributes to five percent of the reported incidents. Incidents include: placement on stove, resulting in accidental ignition and death; placement near a leaking car battery, resulting in acid damage to carrier and an ill infant; minor burns from fireworks; and swaddling infant in a blanket while temperature in the house was in excess of 90 degrees.

8. Other Product-Related Issues

Staff is unable to identify a specific hazard pattern in four percent of the incidents because of insufficient information. However, the eight incidents in this category resulted in a death. 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.

9. Other/Unknown Issues

Two fatalities could not be attributed to design or performance of the carrier, although official reports were pending in both cases at the time of reporting. In both cases, the infant was properly restrained in the carrier.

III. ADEQUACY OF THE CURRENT ASTM F2050-12 REQUIREMENTS

ESME staff believes that 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, warning labels, and toys. Specific requirements for labeling, handle integrity, and restraint system are also included.

This section discusses how each hazard pattern relates to the current voluntary standard F2050-12.

Hazard pattern 1- Restraint Usage

At this time, staff is unable to recommend new performance or design requirements for the restraint system because carrier seats used in vehicles must also meet NHTSA requirements for occupant crash worthiness. Design changes have the potential to affect this safety-related function of the carrier and would require a long-term joint effort between NHTSA and CPSC staff that would include extensive testing, analysis, and evaluation of any considered change.

Another method to address restraint hazards is through improved warning labels. Although it will not likely be as effective as design changes, it is something that can be done quickly without undertaking a long-term joint project.

Staff believes that the existing warning labels for hand-held carriers are inadequate to address this hazard. Therefore, at this time, staff believes that an improved warning label is the best method to increase awareness of the proper use of restraints. Staff has been working with the ASTM task group to modify the labeling requirements in ASTM F2050 to improve caregiver awareness of the dangers of leaving children in carrier seats with loose or unbuckled restraints. A revised warning label, as recommended by staff and developed by the ASTM task group, can be seen in the Human Factors Memo, Tab C.

Hazard pattern 2 - Handle Problems

The previous editions of ASTM F2050 contained a handle preconditioning cycle test, followed by a static hang test to test for handle lock integrity. To address concerns with handles detaching, breaking, or not locking in the carry position, staff worked with the ASTM task group to add a handle lock impact test and a handle auto-lock test. Both tests were balloted and approved for inclusion in the 2012 edition of ASTM F2050.

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 a hanging weight dropped at the end of the carrier. The hanging weight simulates dynamic loads on the handle and handle lock that are imparted during normal use while walking with an infant in the carrier.

The handle auto-lock test helps ensure that the carrier will not rotate and spill an unrestrained infant when a caregiver picks it up when the handle is not locked in the carry position. 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 that 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 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 dummy¹³ during the lift test. Staff found that during the testing of one carrier, the CAMI could be wedged into the seat padding, such that it does not fall out during the lift test when it otherwise should fall (see Figure 2). An unrestrained infant in this position would fall from the carrier. Staff further found that CAMI placement in the carrier could be manipulated to achieve the desired results. For example, a CAMI placed with its back high in the seat may be more likely to pass the test, while a CAMI placed lower in the seat may be more likely to fail. The ability to pass or fail the test based on friction or placement of the CAMI impacts the capability of the test requirement to have consistent and repeatable results.

To resolve these CAMI-related test issues, staff 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 (see Figure 3). 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.

Staff recommends that the ASTM F2050 auto-lock test be conducted 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 proposed in the recently published NPR for bassinets. 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.¹⁴

Staff's recommended modification to the auto-lock test procedure is shown in Appendix A.

Staff believes that inclusion of the handle lock impact test and the modified handle auto-lock test will reduce the number of handle-related incidents.

¹³ CAMI, Mark II 6 month infant dummy represents a 50th percentile, 6-month-old infant, with a weight of approximately 17 pounds, and a sitting height of approximately 17.5 inches, in accordance with FMVSS No. 213 Standard, specified in 49 CFR, Part 572, Subpart D.

¹⁴ Staff is recommending the use of the surrogate cylinder over the EN cylinder because we do not currently own an EN cylinder to validate its effectiveness in the test. The two cylinders are close in size and weight.



Figure 2. CAMI Remains Wedged in Tipped Carrier



Figure 3. Auto-lock Lift Test with Surrogate Cylinder

Hazard pattern 3 - Design Issues

Several incidents in this hazard pattern could be related to stability of the carrier when placed on tables, sofas, or chairs. Carrier seats are, in most cases, designed to meet NHTSA requirements for occupant crash worthiness. Because modifications of the carrier to improve stability when used outside the vehicle might affect how the carrier integrates into the carrier base and a vehicle, and thus would implicate issues within NHTSA's jurisdiction, staff is not making any recommendations to address stability issues at this time.

In addition to stability issues, this hazard pattern includes occupant positioning incidents. Six consumer complaints involve infant head slumping because of a possible insufficient angle of incline that tends to place the infant in an upright position. Of the six, one reported a nonspecific injury and there were no reported fatalities. And of the six consumer complaints received, none of them clearly indicated the location of the carrier when the consumer perceived the hazard. Thus the carrier could have been inside a vehicle, as opposed to being carried, or being used outside of a car. This rule only addresses hazards with carrier use that occur outside of a car.

Staff questioned whether the perceived slumping hazard was more applicable to the occupant position when the carrier is installed in a car. To explore this possibility, the Directorate for Engineering Sciences staff looked at two different carrier seats to see if the occupant position angle differed when being used as a car seat versus being used just as a carrier. When used as a car seat, carriers are attached to base units that are installed in the car. The base units use indicators, or level gages, to ensure that when the car seat is on the base and installed in the car, it is at the proper angle to provide adequate crashworthiness protection. Staff's limited study found that for both of the two carrier models tested, the occupant's position angle led to a more upright positioning of the infant when the carrier is installed as a car seat on its base, rather than when the carrier is resting on a floor, or other horizontal surface. The results of this limited study were shared with NHTSA staff.

At this time, CPSC staff is not recommending changes to the carrier angle of incline. CPSC staff is unaware of any specific incidents that suggest that the angle of incline while used as a carrier (versus a car seat), leads to injuries. Moreover, of necessity, CPSC would need to work with NHTSA to recommend design changes that may impact carrier use when installed as a car seat. Staff has shared the results of our limited study to compare incline angles with NHTSA staff, and will be available to coordinate with them, to appropriately address this issue if further information and evaluation demonstrates that such coordination would further reduce injuries related to use of handheld carrier seats.

Hazard pattern 4 and 7 - Issues with Accessories and Hazardous Environment

These two hazard patterns are considered "non-product-related" issues because the incidents involve products being placed in a potentially hazardous environment or a potentially hazardous product being placed on or near the product. No specific changes to the existing ASTM F2050 standard would address these hazard patterns, and therefore, staff is not making any recommendations at this time.

Hazard pattern 5 - Fabric Issues

The hazard pattern is not specific to the product. Similar incidents are seen in other durable children's products and are expected with any product with fabric or padding. Staff is not making any recommendations to address this hazard pattern at this time.

Hazard pattern 6 - Falls from Shopping Carts

ASTM 2372 – 11a, *Standard Consumer Safety Performance Specification for Shopping Carts*, is the voluntary standard developed to address injuries to children associated with falls from shopping carts. According to the standard, each shopping cart shall have warning statements instructing the user not to use a personal infant carrier but instead use the seat in the cart to accommodate the child and fasten securely. 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 was recently 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. Staff is not making any additional recommendations to address this hazard pattern at this time.

Hazard pattern 8 and 9 - Other Product-Related Issues and Other/Unknown Issues

Insufficient information on the hazard patterns exists at this time for staff to recommend performance changes to the existing standard.

IV. OTHER STANDARDS

ESME staff compared the performance requirements of ASTM F2050-12 to the performance requirements of other standards. ES staff found one international standard, EN 12790 *European/British Standard for Child Care Articles – Reclined Cradles*, which addresses the product in a fashion similar to ASTM F2050; however, reclined cradles are designed and intended for unattended sleep, and thus, this standard includes requirements that also pertain to that use pattern. While it is understood that sleeping in hand-held carrier seats designed to ASTM F2050 is a foreseeable use, the carriers are not specifically designed for sleep as are the EN 123790 cradles. Several other standards only address requirements for restraint systems of products when used in motor vehicles, and therefore, do not address hazard patterns associated with hand-held infant carrier seats.

Staff believes that the current ASTM F2050-12 standard is the most comprehensive of the standards to address the incident hazards. Some individual requirements in the EN12790 standard are more stringent than F2050-12. EN 12790 includes requirements for flammability, surface chemicals, cords/ribbons, cradle angles, and cradle strength/durability. The hazard patterns noted in the incidents do not necessitate adding similar requirements to ASTM F2050-12. However, staff will continue to monitor hazard patterns and recommend future changes, if necessary.

Appendix A summarizes and compares the requirements of EN 12790 to the requirements in ASTM F2050. Table 1 below, summarizes the review of the standards assessed for this memo.

TABLE 1: Review of Other Standards

Standard Number	Standard Name	Comments
EN 12790:2009	European/British Standard for Child Care Articles – Reclined Cradles	Contains similar requirements to ASTM F2050. Differences are detailed in Appendix B.
ECE 44	European Provision for Restraining Devices for Child Occupants of Power-Driven Vehicles	This standard covers restraint devices while the occupant is in the vehicle. There are no provisions for carriers when they are removed from the vehicle.
FMVSS No. 213	NHTSA - Requirements for Child Restraint Systems Used in Motor Vehicles and Aircraft	This standard covers restraint devices while the occupant is in the vehicle. There are no provisions for carriers when they are removed from the vehicle.
JIS D 0401	Japanese Standard for Automotive Accessories – Child Restraints	This standard covers restraint devices while the occupant is in the vehicle. There are no provisions for carriers when they are removed from the vehicle.
AS/NZS 1754:2010	Australian/New Zealand Standard for Child Restraint Systems for Use in Motor Vehicles	This standard covers restraint devices while the occupant is in the vehicle. There are no provisions for carriers when they are removed from the vehicle.

V. PROPOSED SAFETY STANDARD FOR HAND-HELD INFANT CARRIERS

ESME staff recommends that ASTM F2050-12 be adopted as the mandatory safety standard for hand-held infant carriers with two modifications.

The first recommended modification is a new warning label to address restraint issues. For a discussion on the development of this recommended warning label see Human Factors memo, Tab C.

The second recommendation is a change to the handle auto-lock test to ensure that testing is consistent and repeatable. The recommended change is shown in Appendix B.

VI. CONCLUSIONS

Staff recommends that the Commission approve a notice of proposed rulemaking that adopts, by reference, ASTM F2050-12 as the hand-held carrier mandatory standard with the following modifications:

- 1) Add a new warning label and pictogram to address fatal incidents related to the non-restrained or not fully restrained occupant.
- 2) Modify the handle auto-lock test to use a surrogate cylinder instead of the 6-month infant CAMI dummy to ensure that testing is consistent and repeatable.

APPENDIX A

Comparison of ASTM F2050 Standard Consumer Safety Performance Specification for Hand-Held Infant Carriers to EN 12790 European/British Standard for Child Care Articles – Reclined Cradles

	ASTM F2050-12		EN 12790	Comment
Para		Para		
	Requirement not in standard.	4.2	Flammability - No surface flash	See 4.
5.1	No hazardous sharp points or edges	5.4	Same	See 1.
5.2	No small parts	5.5	Same	See 1.
5.3	Comply with 16 CFR 1303 - lead paint	4.1	Similar	See 1.
5.4	Wood parts smooth & free of splinters		Requirement not in standard	
5.5	Openings - entrapment from holes and slots.	5.2	Similar	See 2.
5.6	Scissoring, Shearing, Pinching	5.3	Similar	See 1.
	Test not in standard.	5.6	Cords, ribbons, and parts used as ties	See 4.
5.7	Exposed coil springs	5.7	Similar	See 1.
	Not applicable.	5.8	Cradles that may be folded for storage or transportation	See 6.
	Test not in standard.	5.9	Reclining Systems	See 4.
	Test not in standard.	5.10	Cradle angles and height of seat	See 5.
	Test not in standard.	5.11.2	Handle Locking mechanism -	See 7.
	Auto-lock test added in recent ballot and will be included in F2050-12	5.11.3	Similar	
	Test not in standard.	5.12	Stability	See 3.
	Test not in standard.	5.13	Static strength	See 4.
	Test not in standard.	5.14	Durability	See 4.
5.8	Labeling			
5.8.1	Warning labels permanent	5.18	Similar	See 1.
5.8.3	No small parts from labels		Requirement not in standard	
5.9	Toys shall meet F963		Requirement not in standard	
5.10	Non-removal of protective components by infant		Requirement not in standard	
6.1	Handle integrity – static load	5.15	Similar	
6.2	Restraint system	5.17	Similar	
6.2.1	Carriers not used in motor vehicles		Requirement not in standard.	
6.3	Slip resistance	5.16	Similar	See 1.
8	Marking and Labeling	7	Similar	See 1.

Most of the requirements contained in ASTM F2050-12 and EN 12790 are similar. However, EN 12790 is intended to cover reclined cradles that are designed and intended for unattended sleep, and thus, the standard includes requirements that also pertain to that use pattern.

1. Both standards address many of the general hazards associated with durable nursery products, such as lead in paints, sharp edges/sharp points, small parts, scissoring/shearing/pinching, openings/entrapments, and warning labels.
2. Staff notes differences between ASTM F2050-12 and EN 12790 with entrapment dimensions cited for holes and slot openings. For example EN 12790 uses 7 mm to 12 mm for openings, whereas ASTM F2050 uses 5 mm to 9.5 mm. Discussion with HF staff indicated that the existing dimensions in ASTM F2050 were anthropometrically appropriate, and there were no hazard patterns reflected in the incidents that would warrant modifications.
3. Staff notes that EN 12790 includes requirements for stability when the carrier is on a 15-degree incline. Carrier seats are, in most cases, designed to meet NHTSA requirements for occupant crash worthiness. Because modifications of the carrier to improve stability when used outside the vehicle might affect how the carrier integrates into the carrier base and vehicle, staff is not making any recommendations to address design issues at this time. However, staff will continue to monitor hazard patterns and recommend future changes, if necessary.
4. EN 12790 includes requirements for flammability, surface chemicals, cords/ribbons, reclining systems, and cradle strength/durability. There were no hazard patterns noted in the incidents that necessitated adding similar requirements to ASTM F2050-12. However, staff will continue to monitor these hazard patterns and recommend future changes, if necessary.
5. EN 12790 includes a requirement for cradle angles and for seat height. The requirement ensures that the angle between the seat back and seat base is 90 degrees or greater and the angle between the seat back and horizontal is between 10 degrees and 80 degrees. Staff is not aware of any carrier seats that do not meet the seat back to seat base angle requirement. The seat back angle to horizontal requirement is very broad, allowing the seat back to be anywhere from almost flat to almost vertical, and staff is unsure what hazard the seat back angle requirement addresses. There is also a requirement for the bottom of the seat to be at least 15 mm above the horizontal surface to avoid the seat touching the floor; however, this requirement is not applicable to carriers used as car seats, and staff does not believe it applies to any hazard patterns.
6. EN 12790 includes requirements for folding cradles, which is a use pattern outside the scope of ASTM F2050.
7. EN 12790 includes a requirement for the handle locking mechanism. This tests that: (a) two separate consecutive actions are required to release the handle lock; (b) two separate

and simultaneous actions on two separate parts are required to release the handle lock; or (c) that the carrier returns to its initial locked position when held by the handle and tilted to 20 degrees in either direction. Staff is not aware of any carriers sold in the United States that do not meet criteria (b) of this requirement; therefore, no changes are recommended at this time.

APPENDIX B

Recommended Changes to ASTM F1050 Carry Handle Auto-Lock Test

(Underline indicates new text, ~~strikeout~~ indicates removed text).

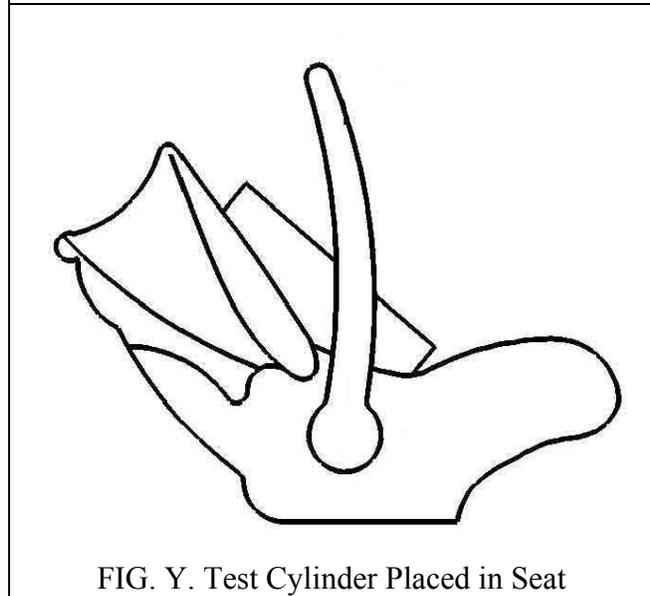
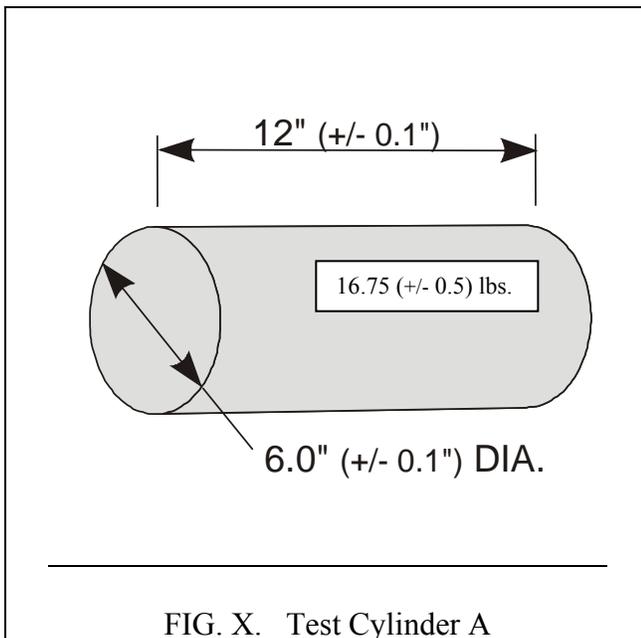
6.1.3 The carry handle shall lock in a position forward or rearward of the manufacturer's designated carry position such that an unrestrained Test Cylinder A (see Figure X) ~~dummy~~ does not fall out of the carrier when tested in accordance with 7.1.2 through 7.1.4.

7.1 Carry Handle Auto-Locking Test:

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. ~~Place the CAMI Infant dummy Mark II in the carrier on top of the harness and positioned per the manufacturer's instructions.~~ Position Test Cylinder A centrally against the backrest of carrier in such a way that the bottom edge is in contact with the seat/back junction line (see Figure Y).

Test Cylinder A

A rigid cylinder 6.0 ± 0.1 inches (153 ± 2.5 mm) in diameter and 12 ± 0.1 inches (305 ± 2.5 mm) in height, having a mass of 16.75 ± 0.5 pounds (7.6 ± 0.2 kg), and with its center of gravity in the center of the cylinder. All edges shall have a radius of 0.2 ± 0.04 inches (5 ± 1 mm)



TAB C:

**Human Factors Assessment of Hazard Patterns and
Mitigation Strategies in Hand-Held Infant Carriers**

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

Memorandum

Date: September 24, 2012

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

THROUGH: George A. Borlase, Ph.D., P.E.
Associate Executive Director
Directorate for Engineering Sciences

Robert B. Ochsman, Ph.D.
Director, Division of Human Factors
Directorate for Engineering Sciences

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

SUBJECT : Human Factors Assessment of Hazard Patterns and Mitigation Strategies in
Hand-Held Infant Carriers

I. INTRODUCTION

Section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), known as the Danny Keysar Child Product Safety Notification Act, requires the U.S. Consumer Product Safety Commission (CPSC or 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 such standards if the Commission determines that more stringent standards would further reduce the risk of injury associated with these products. Section 104(f) defines a “durable infant or toddler product” 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 includes hand-held infant carriers (104(f)(2)(H)).

The ASTM voluntary standard, ASTM F2050-12, *Standard Consumer Safety Performance Specification for Hand-Held Infant Carriers*, establishes requirements for hand-held infant carriers to mitigate potential safety hazards associated with handle integrity, product tip over, and falls from elevated surfaces (ASTM International, 2012).

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“Hand-held carriers” are defined in the voluntary standard 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. Many infant hand-held carrier seats are also infant car seats, designed to restrain newborns and infants while being transported in a motor vehicle. If a carrier is also a car seat, then it must also be compliant with the National Highway Traffic Safety Administration’s (NHTSA) standard for child restraint systems, Federal Motor Vehicle Safety Standard (FMVSS) No. 213 (FMVSS, 2003) (hereinafter FMVSS No. 213).

NHTSA staff was consulted during staff’s assessment of the hazards associated with hand-held carriers, and it was determined that addressing hazards with new requirements that might change the design of the car seat structure or its restraint system could affect the product’s ability to comply with FMVSS No. 213. Thus, design or performance requirements aimed at addressing the hazards associated with restraints were not pursued by CPSC staff, leaving warnings as the only viable option to address these hazards.

This memorandum provides human factors’ assessment of the hazard patterns and mitigation strategies associated with a recommended new warning label requirement on hand-held infant carrier seats.

II. DISCUSSION

A. Restraint Issues

According to the incident data analysis (Chowdhury, R., 2012), CPSC received reports of 36 fatalities related to hand-held carriers that occurred from January 1, 2007 through June 7, 2012. A majority of these fatalities (19) are associated with incorrect use or nonuse of the harness straps. Among the 19 fatalities, nine strangulation incidents occurred due to loose or partially buckled harness straps. Staff was able to discern from the fatalities that six children strangled on the chest clips; two children were entangled in the loose straps, and one case is unclear. In seven incidents, unrestrained infants turned into a compromising position, resulting in asphyxia. In addition, two fatalities occurred where the unrestrained infant became trapped under an overturned seat. One fatality resulted from straps being too tight, impairing the child’s breathing.

Based on the information available, staff was able to conclude that in at least 11 of the 19 fatalities involving harness straps, infant carrier seats were used as a sleeping environment at a residence. In at least two cases, infants were transported from the vehicle while asleep.

Staff believes that leaving a sleeping child in the carrier after having been transported from a vehicle to the destination is a foreseeable behavior. Further, caregivers may assume that because the child is not in a moving vehicle anymore, securing him with the harness straps is unnecessary. Caregiver’s focus may shift to making the sleeping child more comfortable, thus having a snug belt around his body may give an impression that the child is uncomfortable. In at least two fatal cases, caregivers transported the sleeping child from the vehicle in an infant carrier, kept the child in the carrier, released the crotch buckle but left the chest clips secure,

which allowed the infants to slide down on the seat and be strangled by the chest clip pressing against the throat.

The second scenario of using the carrier as a sleeping environment is also a foreseeable behavior. Parents may believe that their child sleeps better in a relatively inclined position, or they may leave the child in the carrier due to the lack of a better location (*e.g.*, at a relative or friend's home). In these situations, caregivers might consider the carrier solely as a sleeping environment and not recognize the benefits of the harness straps, unless the carrier is in a moving vehicle. Staff could determine, based on the available information, that the harness straps were completely loose in at least nine of the 11 incidents, which allowed the child either to turn over to a prone position, resulting in asphyxia, or to become strangled in the loose straps.

Thirty-three (33) nonfatal incidents were also associated with straps being too tight, becoming loose over time, or not having adequate adjustment for the child to be fastened properly. Staff believes that these incidents were likely due to the consumers not adjusting the harness correctly for proper fit.

B. Falls from a Shopping Cart

One fatal and 10 nonfatal incidents have been reported, in which infant carriers fell from shopping carts. ASTM F2372-11a, *Standard Consumer Safety Performance Specification for Shopping Carts*, is the voluntary standard that was developed to address injuries to children associated with falls from shopping carts (ASTM International, 2012). The latest revision of the standard, published in January 2012, includes a new warning label requirement, containing both text and a pictogram, which warns against using the personal infant carrier or car seat on the cart, and instead emphasizes the use of the cart seat to accommodate the infant. In addition, the standard requires retailers to provide additional safety information in the form of warning posters at the point of use.

C. Occupant Positioning¹⁵

Staff from the CPSC Directorate for Health Sciences has the following assessment regarding the consumer complaints received on positioning of the infants in hand-held carrier seats:

Three complaints were filed by nonusers, who commented on consumer use of the product, two complaints from the state of Michigan, and one from Chicago, IL. In all instances, the observer/commenter reported that the mothers were oblivious to the way they swung the carrier while the baby was in it and suggested that their behavior placed the infant at risk for shaken baby syndrome (SBS). The observers used the terms “violently shaken” and “whipped” to describe the baby’s head movement within the carrier. “SBS” is defined/generally referred to in the literature as “vigorous manual shaking of an infant who is being held by the extremities or shoulders, leading to whiplash-induced intracranial and intraocular bleeding and no external signs of head trauma.” (Paiva et. al., 2011). SBS is the subject of intense controversy and scrutiny among scientists (Paiva et. al., 2011, Squier, 2011 and Geddes et. al., 2003). CPSC

¹⁵ Communication September 21, 2012, with Dr. S. Wanna-Nakamura, CPSC Directorate for Health Sciences.

Health Sciences staff believes that an infant's head movement within the carrier from side-to-side is unlikely to produce the amount of external force of acceleration and deceleration on the head and neck to cause brain and cervical lesions and does not contribute or put the baby at risk for SBS. Also, the side-to-side movement in the carrier, as described above, does not fit the description/definition of SBS because the infant is fully supported and is not being held by the extremities or shoulders.

Six consumer complaints involve infant head slumping because of the insufficient angle of incline that tends to place the infant in an upright position. At this time, CPSC is not addressing the carrier angle of incline (slumping) because it is unclear from CPSC's incident data that injuries are resulting. Staff intends to monitor the data and if the angle of incline presents a hazard pattern going forward, CPSC can coordinate with NHTSA to appropriately address the issue.

D. Adequacy of the Current Warning Language

ASTM F2050 – 12 requires the following warning statements in infant carriers:

8.3.2 The warning statements shall address the following:

8.3.2.1 NEVER leave child unattended.

8.3.2.2 Suffocation Hazard: Infant carrier can roll over on soft surfaces and suffocate child. NEVER place carrier on beds, sofas, or other soft surfaces.

8.3.2.3 Strangulation Hazard: Child can strangle in loose restraint straps. NEVER leave child in carrier when straps are loose or undone.

8.3.2.4 Fall Hazard: Child's movement can slide carrier. NEVER place carrier near edges of counter tops, tables, or other elevated surfaces.

8.3.3 Infant carriers not intended for use as infant restraint devices in motor vehicles.

8.3.3.1 NEVER use this carrier as a means to transport an infant in a motor vehicle.

According to the standard, warnings shall be in contrasting color(s), permanent, conspicuous, and in *sans serif* style font. "Conspicuous" is defined in Section 3.1 of the standard as "a label that is visible, when the infant carrier is in a manufacturer's recommended use position, to a person standing near the infant carrier at any one position around the infant carrier but not necessarily visible from all positions." Even though the list attempts to address suffocation, strangulation, and fall hazards, a major drawback is its potentially poor noticeability by caregivers as they may not encounter the label during the regular use of the carrier.

The largest proportion of fatalities reportedly occurred due to incorrect use or nonuse of the harness straps. As the incident scenarios show, hazards related to nonuse or partial use of the harness straps when the carrier is not in a moving vehicle may not be evident to consumers who associate straps with occupant protection only. Therefore, the ASTM subcommittee decided to focus on developing a new label that communicates to caregivers that they should always fully secure the child with the harness straps no matter where the carrier is used (*i.e.*, inside or outside the vehicle). Staff believes that such a label would be beneficial to help prevent both *strangulation* and *asphyxia* incidents.

Staff also notes that adding a new strangulation warning label represents the best available alternative to address the hazards associated with the non-use or partial use of restraint straps in

light of the need to defer to NHTSA on any issues that implicate in-car use. Any attempts to design out the risk may impact the integrity or safety of the carrier while in a vehicle and would require extensive analysis, studies, and testing by CPSC staff, ASTM, and NHTSA staff to ensure that any design changes meant to address the hazard do not inadvertently create a new hazard.

E. Staff-Recommended Label

An ASTM task group, with assistance from CPSC staff, developed a new strangulation warning label after several iterations and evaluations. NHTSA staff was also included in the development of the warning label. Figure 1 displays the recommended strangulation warning label for hand-held carrier seats intended to be used as a restraint in motor vehicles. This new label and the requirements associated with it were balloted by ASTM on September 14, 2012.



Figure 1. Staff recommended warning label

A number of factors were considered by the ASTM task group in the development of the label to improve its noticeability and comprehension:

Size

According to the warning literature, larger warning labels are more likely to capture attention. NHTSA staff had no objection to CPSC staff's recommendation to require the subject pictogram on the outer surface of the cushion or padding near the air bag warning label required by FMVSS No. 213 (49 CFR 571.213, S5.5.2(k)(3)). This label warns against the placement of rear-facing child carrier seats on the front seat with an airbag.

But NHTSA staff did ask that the new strangulation warning label be of a size that does not overwhelm or detract from the required air bag warning label in FMVSS No. 213. Thus, CPSC staff is recommending a strangulation warning label that is the same minimum size stated by FMVSS No. 213, which specifies that the air bag pictogram shall be no less than 30 mm in diameter, and the message area must be no less than 30 square cm.

Even with the size limitation, the recommended strangulation warning label is significantly larger than the warning label that is currently required in the ASTM standard.

Location

The warning should be placed in a location where the caregivers are expected to notice it during regular interaction with the carrier and the infant. Warnings, when placed close to the hazard, are believed to have a higher noticeability. The current requirement for a “conspicuous” warning label may not be sufficient to make the label readily visible to the caregiver, as the current label potentially could be placed anywhere on the carrier with the exception of the bottom surface. A substantial number of carriers have warning statements on the side of the product, which is not within the eye view of the caregiver while placing the child into the carrier. Staff believes that the recommended strangulation warning label should be easily visible to the caregivers while they are placing the child into the carrier. Accordingly, staff’s recommended location for the new strangulation warning label mirrors the airbag warning label and requires that the label be affixed to the outer surface of the cushion or padding in or adjacent to the area where a child’s head would rest.

Color and Contrast

Color and contrast are design factors that increase the noticeability of warnings. Staff’s recommended label requires a black and white contrast, in addition to a prohibition symbol in red, which traditionally attracts attention; a check mark in green, which is usually associated with a positive action, along with the signal word, WARNING, in a yellow background.

Pictorials

Users may notice a warning label but not actually read it. Attention must be maintained on the message for some time so that the meaning can be extracted from the material (Wogalter and Leonard, 1999). Pictorial symbols increase the noticeability of the warnings because they help capture a user’s attention (Wogalter and Leonard, 1999). Graphic warnings induce an emotional response, increase memory and awareness of the risks, and strengthen motivations to avoid the risks more than the text warnings (Hammond et al., 2007). Pictograms are also helpful for users with limited or no English literacy.

An ASTM task group, with assistance from CPSC staff, developed several pictorial symbols. The ASTM task group tested the pictorial symbols for comprehension by following the guidelines outlined in ANSI Z535.3 – 07, *American National Standard Criteria for Safety Symbols* (ANSI, 2007). The empirical procedure recommended by ANSI is intended to choose the symbol that best conveys the message so that reliance on the wording is minimized. In the final stage of the pictorial development process, six different manufacturers tested two candidate symbols with an audience of 159 people. Approximately 28 percent of the respondents were less than 30 years of age; 56 percent were between 31 and 50; and 16 percent were more than 50 years old. Approximately 30 percent of respondents had less than a college degree. The number of male and female respondents was about the same. More than 60 percent of the respondents had at least one child. Respondents were asked what the symbol meant and what action they would take in response to seeing the symbol. Each respondent saw no more than one symbol. ANSI suggests that a criterion of 85 percent correct responses with a maximum of 5 percent critical confusion is used to accept a given symbol. The pictogram shown in Figure 1 met the

acceptance criterion because 96.3 percent of the participants who reviewed the symbol interpreted it correctly. The recommended pictogram tells users what actions not to take, in addition to the appropriate action to be taken. The partially buckled harness straps are highlighted with a prohibition symbol (a red circle with diagonal slash), and the fully secured harness is emphasized with a green check mark, typically used to verify a correct action or outcome.

Content

Warning messages should explain the nature of the hazard, the consequences of the hazard, and give instructions on how to avoid the hazard (Wogalter and Laughery, 2006). Staff's recommended strangulation warning label meets these requirements. The warning label incorporates the nature of the hazard (strangulation), how it can occur (loose or partially buckled straps), and what the caregiver needs to do (fully restrain the child) to avoid the hazard.

Emphasizing the Severity of Injury

Providing explicit information about the consequences of not taking precautionary measures to avoid the hazard can increase the perception of injury severity and the perceived hazard (DeJoy, 1999a). Injury severity is believed to be a more important dimension than the likelihood of injury in precautionary behavior (DeJoy, 1999b and Wogalter et al. 1991). Thus, potential consequences associated with the nonuse or incorrect use of the harness straps should be very clear to consumers to increase consumer understanding and compliance. Use of the statement "Children have STRANGLED" is intended to increase the awareness of the danger associated with inappropriate use of the harness straps.

III. CONCLUSION

Nonuse or improper use of the harness straps is associated with the highest number of injuries and deaths involving hand-held infant carrier seats. Strengthening the warning label is currently the only mitigation strategy to address the hazard to avoid any potential adverse impact that a design change may cause when infant carrier seats are used as a car seat in a motor vehicle. In developing this new warning label, the ASTM task group, along with CPSC staff assistance, used many well-recognized strategies to strengthen the strangulation warning label, such as enlarging the size of the label, emphasizing the severity of injury, placing the label in a prominent location, and adding a pictorial symbol that has gone through a comprehension evaluation. Staff recommends that this new strangulation warning label be used on hand-held infant carrier seats to communicate the risk associated with inappropriate use of the straps, to help prevent both strangulation and asphyxia incidents.

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TAB D:

Durable Nursery Products: Summary of Hand-Held Infant Carrier Product Safety Recalls and Associated Injuries from January 1, 2007 to June 7, 2012

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

Memorandum

Date: September 27, 2012

TO : Patricia L. Edwards, Project Manager,
Directorate for Engineering Sciences

THROUGH: Marc J. Schoem, Acting Director, Office of Compliance and Field Operations

Mary F. Toro, Director, Division of Regulatory Enforcement

Troy Whitfield, Lead Compliance Officer,
Regulatory Enforcement Division, Mechanical Hazards Team

FROM : Dave Whiting, Compliance Officer,
Regulatory Enforcement Division, Mechanical Hazards Team

SUBJECT : Durable Nursery Products: Summary of Hand-Held Infant Carrier Product
Safety Recalls and Associated Injuries from January 1, 2007 to June 7, 2012

PURPOSE

This memorandum provides compliance information relevant to the drafting of a safety standard for hand-held infant carriers. Section 104 of the Consumer Product Safety Improvement Act of 2008, Pub. L. No. 110-314, 122 Stat. 3016 (August 14, 2008) (CPSIA) requires the Commission to study and develop safety standards for infant or toddler products, which includes hand-held infant carriers. CPSC staff is drafting a proposed rule for a hand-held infant carrier standard for Commission consideration. The proposed rule addresses the hazards associated with hand-held infant carriers through performance requirements focusing on carrier handle integrity, carrier handle auto-locking, improvements in restraint systems, and enhancements to the clarity and effectiveness of warning labels. The warning label enhancements address the potential for suffocation and strangulation hazards with a visually compelling graphic, enlarged size, and a prominent location. This memo summarizes the product safety recalls stemming from defect investigations conducted by the Office of Compliance and Field Operations (Compliance) and the reported injuries involving hand-held infant carriers.

Compliance Investigation Information

Staff received 759 incident reports involving hand-held infant carriers, relating to the three product safety recalls announced between January 1, 2007 and June 7, 2012 (see Table 1). There were 166 significant incidents relevant to the rulemaking review process. During the relevant period, 920,000 hand-held infant carriers involving three manufacturers were subject to recall. At

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the time the products were recalled, 166 infants had been injured in incidents, which resulted in minor lacerations and bruises to head injuries, concussions, and skull fractures.

Table 1: CPSC Recalls for Hand-Held Infant Carriers Jan. 1, 2007 through June 7, 2012

Announcement Date	Brand	Model	Quantity	Reason	Incidents Reported	Injuries Reported
11/4/2010	Britax Child Safety, Inc.	Chaperone Infant Car seat	23,000	Harness chest clip can break and cause a laceration hazard.	Three reports received.	Three reports of minor lacerations and scratches with one child placing clip in mouth.
12/18/2009	Dorel Juvenile Group, Inc.	Dorel Infant Car Seat / Carriers	447,000	Child restraint handle to seat can loosen and come off, posing a fall hazard to infants.	77 reports of handle fully or partially detaching.	Reports of 3 injuries - bumps, bruises and one head injury.
5/10/2007	Evenflo Company, Inc.	Evenflo Embrace Infant Car Seat / Carriers	450,000	Handle unexpectedly released.	Firm received 679 reports.	160 injuries to children. Injuries included a skull fracture, 2 concussions, numerous cuts, scrapes and bruises.
Totals			920,000		759	166

TAB E:
Initial Regulatory Flexibility Analysis of Staff-
Recommended Proposed Standard for Hand-Held Infant
Carriers

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

Memorandum

Date: September 26, 2012

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

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

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

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

SUBJECT : Initial Regulatory Flexibility Analysis of Staff-Recommended Proposed Standard for Hand-Held Infant Carriers

Introduction

On August 14, 2008, the Consumer Product Safety Improvement Act of 2008 (CPSIA) was enacted. Among its provisions, the Danny Keysar Child Product Safety Notification Act, section 104 of the CPSIA, requires the U.S. Consumer Product Safety Commission (CPSC or Commission) to evaluate the existing voluntary standards for durable infant or toddler products and promulgate a mandatory standard substantially the same as the applicable voluntary standard, or more stringent than the voluntary standard if the Commission determines that more stringent standards would further reduce the risk of injury. Infant carriers, a product category that includes hand-held infant carriers, are among the durable products specifically named in section 104. Upon review, CPSC staff recommends that the Commission adopt the voluntary ASTM International (formerly known as the American Society for Testing and Materials) standard for hand-held infant carriers (F2050-12) with two modifications: (1) strengthening the strangulation warning that appears on labels and in the instructional literature; and (2) changing one of the components of the carry handle auto-lock test to improve test repeatability.

The Regulatory Flexibility Act (RFA) requires that proposed rules be reviewed for their potential economic impact on small entities, including small businesses. Section 603 of the RFA

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

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

The Product¹⁶

ASTM F2050-12 defines a “hand-held infant carrier” as a freestanding, rigid-sided product intended to completely support the occupant’s torso while being carried by hand-holds or handles. In the most recent version of the ASTM voluntary standard, F2050-12, hand-held carriers have been broken out further into hand-held bassinets/cradles and hand-held infant carrier seats. A hand-held bassinet/cradle is a hand-held infant carrier that inclines 10 degrees or less from horizontal and sits directly on the floor. It includes products such as Moses baskets with handles. A hand-held infant carrier seat, on the other hand, inclines by more than 10 degrees from horizontal and includes car seats. Many hand-held infant carriers are used with strollers and travel systems.

The Market for Hand-Held Infant Carriers

The majority of hand-held carriers are produced and/or marketed by juvenile product manufacturers and distributors. The exception is Moses baskets, which are often marketed by bedding manufacturers and distributors. CPSC staff believes that there are currently 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.¹⁷

¹⁶ ASTM F2050-12.

¹⁷ Determinations were made using information from Dun & Bradstreet and ReferenceUSAGov, as well as firm websites.

Staff expects that the products of 13 of the 43 hand-held infant carrier suppliers will be compliant with ASTM F2050-12, *Standard Consumer Safety Specification for Hand-Held Infant Carriers* (six are JPMA certified to F2050-09; three claim compliance with F2050; and four have JPMA-certified strollers with hand-held infant carrier attachments).¹⁸ 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, three supply bassinet attachments for strollers, and two supply other types of bassinet-style carriers).

The market data available is limited to infant car seats, which represent 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*),¹⁹ 68 percent of new mothers own infant car seats. Approximately 25 percent of infant car seats were handed down or purchased secondhand.²⁰ Thus, about 75 percent of infant car seats were acquired new. This suggests annual sales of about 2.1 million infant car seats (.68 x .75 x 4.1 million births per year).²¹ These 2.1 million infant car seats represent the minimum number of units sold per year that might be affected by the proposed hand-held infant carrier standard. It is unknown how many Moses baskets and other bassinet/cradle-style carriers are sold annually.

Based on a review of the incident data, as well as manufacturers' recommended use instructions, it appears that infant car seats are typically used for 1–2 years.²² Therefore, we have estimated the risk of injury based on the number of infant car seats in the households of new mothers, taking into consideration that many new mothers will continue to use their infant car seats into their child's second year. Based on data from the *2006 Baby Products Tracking Study*, approximately 2.1 million infant car seats are owned by new mothers. This suggests that at least 2.1 million infant car seats may be available to children during the first year of their lives and up to 4.2 million available during the first 2 years of their lives, although there may be some redundancy with one infant car seat being used by more than one child in a family. According to CPSC Directorate for Epidemiology (EPI) staff, during 2011, there were an estimated 10,600 emergency department-treated injuries to children younger than age 5 related to hand-held infant

¹⁸ 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 staff-recommended proposed standard is based, will become effective for JPMA certification purposes in March 2013. Firms that supply JPMA-certified strollers are expected to ensure that all of their attachments, including hand-held infant carriers, comply with all applicable ASTM standards as well.

¹⁹ The data collected for the *Baby Products Tracking Study* do not represent an unbiased statistical sample. The sample of 3,600 new and expectant mothers is drawn from American Baby magazine's mailing lists. Also, because the most recent survey information is from 2005, it may not reflect the current market.

²⁰ The data on secondhand products for new mothers was not available. Instead, data for new mothers and expectant mothers were combined and broken into first-time mothers and experienced mothers. Data for first-time mothers and experienced mothers have been averaged to calculate the approximate percentage that was handed down or purchased secondhand.

²¹ 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.

²² Memorandum from Risana T. Chowdhury, Division of Hazard Analysis, Directorate for Epidemiology, dated July 16, 2012, Subject: Hand-Held Infant Carrier-Related Deaths, Injuries, and Potential Injuries, and NEISS Injury Estimates; January 1, 2007–June 7, 2012.

carriers.²³ Because the vast majority of the incident data is associated with hand-held infant carriers that are also infant car seats, there may have been about 18.9 to 37.7 emergency department-treated injuries annually for every 10,000 infant car seats available for use in the households of new (and second year) mothers.²⁴

Reason for Agency Action and Legal Basis for the Draft Proposed Rule

The Danny Keysar Child Product Safety Notification Act 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 staff worked closely with ASTM to develop the new requirements and test procedures that have been added to ASTM F2050-12, which forms the basis of the staff-recommended proposed rule. These new requirements expand the scope of the standard and address known hazard patterns with handles and restraints that will help to reduce injuries and deaths.²⁵ However, CPSC staff recommends further modifying the carry handle auto-locking test and the strangulation warnings for the proposed rulemaking to address the associated hazards better.

Requirements of the Proposed Rule

CPSC staff recommends adopting the voluntary ASTM standard for hand-held infant carriers (F2050-12) with additional modifications to the strangulation warnings and the carry handle auto-locking 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,

²³ Ibid.

²⁴ Over the period since January 2007, EPI staff has identified three basket incidents. There were also several incidents with insufficient information to determine whether the product was a car seat, a basket, or another type of hand-held carrier.

²⁵ Ibid; and memorandum from Vincent J. Amodeo, Mechanical Engineer, Division of Mechanical Engineering, dated September 27, 2012, Subject: Staff's recommended changes to ASTM F2050-12, *Standard Consumer Safety Specification for Hand-Held Infant Carriers*, for Incorporation into Staff's Draft Proposed Rule.

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.

CPSC staff recommends further modifying the carry handle auto-locking test and the strangulation hazard warning. Staff participated in the development of the ASTM F2050-12 carry handle auto-locking test. However, additional staff testing raised concerns about the potential for inconsistent test results, particularly due to differences in CAMI dummy placement. Staff determined that using a cylinder similar to the one specified in the European standard for reclined cradles (EN 12790, *Child use and care articles — Reclined cradles*), rather than a CAMI dummy, yielded more consistent results.²⁶ Therefore, staff recommends modifying the existing test procedure to use the cylinder employed for bassinet mattress flatness testing.²⁷ The carry handle auto-locking requirement applies only to suppliers of hand-held infant carriers that are rigid, adjustable, rotate about a singular axis, and lock in the manufacturer's designated carry position; therefore many suppliers, most notably Moses basket suppliers, would not be affected. Several suppliers 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 additional auto-lock positions close to the one intended for use. This would prevent the handle from moving so far out of position as to spill 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.²⁸ 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.²⁹

CPSC staff has been working closely with the ASTM task group to develop a revised strangulation warning that would appear on labels and in the instructional literature. The revised warning makes changes to 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. The warning will be required on the product itself, as well as within the product's instructional literature.³⁰ 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. However, one firm that we have spoken to in the past said that their warning and label development processes are more intensive than most, involving several levels of approval.

²⁶ The cylinder recommended by staff is more readily available to U.S. test labs than the comparable EN cylinder.

²⁷ Amodeo, 2012.

²⁸ During the production process, a hard tool, which is a mold of the desired hand-held infant carrier component shape, is injected with plastic or another material, using a molding machine.

²⁹ E-mail correspondence with Vincent J. Amodeo and Patricia L. Edwards.

³⁰ Memorandum from Rana Balci-Sinha, Division of Human Factors, Directorate for Engineering Sciences, dated September 24, 2012, Subject: Human Factors Assessment of Hazard Patterns and Mitigation Strategies in Hand-Held Infant Carriers.

Other Federal or State Rules

A final rule implementing sections 14(a)(2) and 14(i)(2) of the Consumer Product Safety Act (CPSA), as amended by the CPSIA, *Testing and Labeling Pertaining to Product Certification*, 16 CFR part 1107, will become effective on February 13, 2013 (the 1107 rule). Section 14(a)(2) of the CPSA requires every manufacturer of a children's product that is subject to a 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 children's product safety rule, they will also be subject to the third party testing requirements of section 14(a)(2) of the CPSA and the 1107 rule when the hand-held infant carrier mandatory standard and the notice of requirements become effective.

Impact on Small Businesses

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 of the staff-recommended proposed standard on small manufacturers will differ based on whether their hand-held infant carriers are already compliant with F2050-09. In general, 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 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 JPMA-certify strollers with bassinet/cradle 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 potentially 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 staff-recommended modifications. A redesign would be minor if most of the changes involve adding straps and fasteners or using different mesh or fabric, but they 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, as costing approximately \$500,000. Consequently, the staff-recommended proposed rule could potentially have a significant direct impact on some 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 substantially lower than \$500,000, 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, are, in fact, compliant with the standard. CPSC staff 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 staff-recommended proposed standard will be less significant than described above.

In addition to the direct impact of the staff-recommended 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 not included here.³¹

³¹ 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.

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 potentially could reduce some testing costs but 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 staff-recommended proposed rule, which may be the case with all four small importers of hand-held infant carriers, none of which are 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, they 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 who 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. Staff 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 additions to the scope of ASTM F2050, it is unlikely that any of them have 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 to add warnings and instructional literature. Alternatively, Moses basket suppliers could remove themselves from the scope of the staff-recommended 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 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 staff-recommended standard, it is expected that third party testing costs, at most, will be half the level for other types of hand-held infant carriers, \$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.

Alternatives

Under the Danny Keysar Child Product Safety Notification Act, one alternative that would reduce the impact on small entities would be to make the voluntary standard mandatory, with no modifications. Doing so would eliminate the impact on the three small manufacturers with compliant products. However, because of the number and severity of the incidents associated with falls and restraints,³² staff does not recommend this alternative.

A second alternative would be to set an effective date later than the staff-recommended 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.

³² Chowdhury, 2012; and Balci-Sinha, 2012.