The contents of this document will be discussed at the Commission Meeting (Briefing) scheduled for November 6, 2013.

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

This document has been electronically approved and signed.

DATE: October 30, 2013

THIS MATTER IS NOT SCHEDULED FOR A BALLOT VOTE.

A DECISIONAL MEETING FOR THIS MATTER IS SCHEDULED ON: **November 20, 2013**

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Stephanie Tsacoumis, General Counsel
Elliot F. Kaye, Acting Executive Director

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

SUBJECT: Final Rule: Safety Standard for Hand-Held Infant Carriers

The Office of the General Counsel is providing for Commission consideration the attached draft final rule for publication in the *Federal Register*. The draft final rule establishes 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 Final Rule to Establish a Safety Standard for Hand-Held Infant Carriers

Billing Code 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1225

CPSC Docket No. CPSC-2012-0068

Safety Standard for Hand-Held Infant Carriers

AGENCY: Consumer Product Safety Commission.

ACTION: Final Rule.

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 issuing a safety standard for hand-held infant carriers in response to the direction under Section 104(b) of the CPSIA. The rule would incorporate ASTM F2050-13a by reference, with one modification.

DATES: The rule will become effective on [INSERT DATE 6 MONTHS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The incorporation by reference of the publication listed in this rule is approved by the Director of the Federal Register as of [INSERT DATE 6 MONTHS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Julio Alvarado, Compliance Officer, Office of Compliance and Field Operations, U.S. Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814; e-mail: jalvarado@cpsc.gov.

SUPPLEMENTARY INFORMATION:

I. Background and Statutory Authority

The CPSIA (Pub Law 110-314) was enacted on August 14, 2008. Section 104(b) of the CPSIA requires the Commission to: (1) examine and assess the effectiveness of voluntary consumer product safety standards for durable infant or toddler products, in consultation with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts; and (2) promulgate consumer product safety standards for durable infant and toddler products. 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)(H) as a durable infant or toddler product. 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 hand-held 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.

On December 10, 2012, the Commission issued a notice of proposed rulemaking (NPR) for hand-held infant carriers. 77 FR 73354. The NPR proposed to incorporate by reference the then current voluntary standard, ASTM F2050-12, *Standard Consumer Safety Specification for Hand-Held Infant Carriers,* with certain modifications to strengthen the ASTM standard. One

proposed modification provided for a change in the warning label to better address suffocation and restraint-related hazards. The other proposed modification addressed the testing procedures for the carry handle auto-locking requirement and specified using an aluminum cylinder as the surrogate for the occupant of the carrier rather than a CAMI Mark II 6-month infant dummy (CAMI dummy).

Since the Commission published the NPR, ASTM has revised ASTM F2050 twice. On July 1, 2013, ASTM approved an updated version of the voluntary standard, ASTM F2050-13, which includes the warning label modification proposed in the NPR. On September 1, 2013, ASTM approved another revision of the voluntary standard, ASTM F2050-13a, which includes a carry handle auto-locking performance requirement that is different than the requirement proposed in the NPR. As explained in section VII of this preamble, the Commission agrees with the auto-locking requirement in ASTM F2050-13a. The draft final rule incorporates by reference the most recent version of the ASTM standard, ASTM F2050-13a, with one modification–a clarification of the definition of "hand-held infant carrier," to include a specific reference to both "rigid-sided" and "semi-rigid-sided" products.

II. The Product

ASTM F2050-13a 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 ASTM voluntary standard published in August 2012, for the first time referenced two types of hand-held infant carriers: hand-held bassinets/cradles and hand-held carrier seats. 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 10º 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 10º 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." Hand-held carrier seats often are used as infant car seats, or as attachments to strollers or high chairs bases. Some of the requirements in F2050-13a 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.

A Moses basket is a freestanding product with a rest/support surface to facilitate sleep and has hand-holds or handles intended to allow carrying an occupant. Some Moses baskets are rigid-sided, but most have semi rigid sides. In the NPR, the Commission sought comment on whether Moses baskets are or should be covered by this safety standard. The Commission also asked: (1) If Moses baskets should be included in this safety standard, does the present definition cover Moses baskets, and (2) if the present definition does not cover Moses baskets, how should the standard be amended to cover Moses baskets? The Commission received no comments in response to these questions and will clarify the definition of "hand-held infant carrier" in the rule to specify that the definition includes both "rigid-sided" and "semi-rigid-sided" products.

III. Incident Data

The preamble to the NPR summarized incident data involving bassinets and cradles reported to the Commission as of June 8, 2012. 77 FR 73354 (December 10, 2012). The NPR stated that, according to reports to the CPSC, 242 incidents involving hand-held infant carriers occurred between January 1, 2007 and June 7, 2012. Of the 242 incidents, there were 36 fatalities, 60 nonfatal injuries, and 146 incidents where no injury occurred or was reported. Staff

attributed the majority of the fatalities to the improper use or nonuse of the carrier's restraint system.

CPSC's Directorate for Epidemiology, Division of Hazard Analysis has updated this information to include hand-held infant carrier-related incident data reported to the Commission from June 8, 2012 through June 21, 2013. A search of the CPSC epidemiological databases showed that there were 10 new incidents related to hand-held infant carriers reported during this time frame. Seven of the 10 were fatal, and three were nonfatal. None of the nonfatal incidents involved injuries. All of the new incidents reportedly occurred in late 2011 and 2012. Reporting is ongoing, however, so the incident totals are subject to change.

A. Fatalities Reported Since the NPR

Most of the more recently reported seven fatalities involved a product-related issue. The ages of the decedents ranged from one month to 15 months. Staff attributes the majority of the fatalities to the improper use or nonuse of the carrier's restraint system. The incident reports indicate the following circumstances in these fatalities:

- infant was unrestrained and found in a prone position with the seat tipped over;
- infant was unrestrained and found with its face pressed into the side of the seat;
- infant strangled to death when restrained by the shoulder straps only and moved forward in the seat and was caught in the throat by the chest clip that connects the shoulder straps;
- infant was strapped into a hand-held infant carrier that was placed on a bed and overturned;
- infant was reported to have become entrapped in the carrier by other unsupervised children; although information on the exact manner of entrapment was unavailable;

- insufficient information to identify conclusively a hazard pattern but may have been the result of misuse of the product;
- insufficient information to identify hazard pattern.

B. Nonfatal Incidents Reported Since the NPR

There were three hand-held carrier-related nonfatal incidents reported to the Commission from June 8, 2012 through June 21, 2013. All of the incidents occurred in 2012; none of these involved an injury. Two of the incident reports stated that the carrier handle broke. The third report was a complaint about the poor quality and design of a Moses basket carrier.

C. Hazard Pattern Identification

Staff did not identify any new hazard patterns among the 10 incident reports that CPSC staff received since the Commission published the hand-held infant carrier NPR. In order of frequency of incident reports, staff grouped the hazard patterns of the incidents reported since the NPR into the following categories:

1. ***Restraint issues:*** Three of the incidents—all fatalities—were associated with the incorrect use or nonuse of the harness straps. In two of these fatal incidents, the decedent was not restrained in the carrier at all. The decedents were found later to have turned over to a prone position, face down on a soft surface. One death resulted when the infant was left in the seat with only the shoulder straps connected, but unrestrained at the crotch strap, which allowed the infant to slide forward in the seat, just enough to get caught at the throat by the chest clip and become strangled.
2. ***Handle problems:*** Two incident reports state that the handle broke. One of these incidents involved a product that was already recalled for handle problems. There were no injuries reported in these incidents.

3. ***Issues with carrier design:*** There was one fatality in this category, which resulted when the occupied carrier was left on a soft surface (*i.e.,* a bed), tipped upside down, and trapped the infant. In addition, one noninjury report complained about the poor and unsafe design of a Moses basket carrier.
4. ***Hazardous environment:*** One fatality resulted from an infant becoming trapped in the hand-held carrier by other unsupervised children. Details of the manner in which the entrapment occurred were unavailable.
5. ***Other product-related issue:*** One fatality report indicated that misuse of the product may have contributed to the incident; however, not enough information was available for CPSC staff to identify conclusively the hazard pattern involved.
6. ***Other/unknown issue:*** One fatality was reported with an undetermined official cause of death. There was insufficient evidence of any product involvement or the presence of any hazardous external circumstances.

IV. Overview of ASTM F2050

ASTM F2050, *Standard Consumer Safety Specification for Hand-Held Infant Carriers,* establishes safety performance requirements, test methods, and labeling requirements to minimize the identified hazard patterns associated with the use of hand-held infant carriers. 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.* ASTM has revised the standard six times since then. ASTM F2050-13 was approved on July 1, 2013, and the current version, ASTM F2050-13a, was approved on September 1, 2013. The more significant requirements of ASTM F2050 include:

- Scope – describes the types of products intended to be covered under the standard.

- Testing of the handle auto-locking mechanism – is intended to prevent unintentional rotation of the carrier and resulting expulsion of the child when the caregiver picks up the carrier by the handle and the handle is not in a locked position.
- Testing of the integrity of the handle – is intended to prevent unintentional separation of the handle from the carrier while in use.
- Occupant restraints − are intended to prevent incidents in which improper use of restraints has resulted in the entrapment and strangulation of children.
- Slip-resistance requirement – is intended to prevent the carrier from sliding when placed on a slightly inclined surface.
- Warning label – is intended to address: (1) improper use of restraints (to prevent strangulation and other injuries), and (2) improper placement of the carrier on an elevated surface (to prevent fall injuries).

The voluntary standard also includes: (1) torque and tension tests to prevent components from being removed; (2) requirements to prevent entrapment and cuts (minimum and maximum opening size, small parts, hazardous sharp edges or points, and edges that can scissor, shear, or pinch); (3) requirements for the permanency and adhesion of labels; and (4) requirements for instructional literature.

V. The NPR and ASTM 2050-12

The NPR proposed to incorporate by reference ASTM F2050-12 as a consumer product safety standard, with two modifications:

1. Warning Label: The NPR proposed requiring 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. Under the proposal, 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.

2. Handle Auto-Lock Test: The NPR proposed a modification of the test method for preventing the carrier from rotating and spilling 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 required the tester to use a standard CAMI dummy as an infant surrogate. The NPR proposed a change that would require the tester to use an aluminum cylinder designed as a surrogate for a 6-month-old infant, in lieu of the CAMI dummy, because testing had revealed that the CAMI dummy could be wedged into the seat padding or otherwise manipulated, so that the CAMI dummy did not fall out during the lift test when the CAMI dummy otherwise should fall. Furthermore, the Commission was concerned that the ability to pass or fail the test based on friction or placement of the CAMI would affect the consistency and repeatability of the test results.

The NPR also asked for comments regarding whether Moses baskets should be included in this safety standard, and if so, whether we should revise the definition of "hand-held infant carrier" to cover Moses baskets.

VI. ASTM F2050-13a

ASTM approved the current voluntary standard for hand-held infant carriers, ASTM F2050-13a, on September 1, 2013. ASTM balloted the NPR's provisions concerning the warning label requirement in 2013, and the provisions are now included in the latest revision of the voluntary standard, ASTM 2050-13a.

Several comments received in response to the NPR suggested that the aluminum cylinder was not an appropriate surrogate for use in the handle auto-lock test and maintained that other surrogates, including the CAMI dummy, would produce more repeatable and consistent test results if properly placed in the carrier. After considering these comments and the results of additional testing performed since the Commission published the NPR, Commission staff determined that using the CAMI dummy, with certain modifications to the test procedure, would produce more repeatable and consistent test results. ASTM F2050-13a retains the use of the CAMI dummy as the surrogate occupant and clarifies how the dummy should be situated in the seat during testing. The revised requirement also:

- specifies using webbing instead of hooks for lifting the carrier during the test;
- specifies that a pneumatic cylinder be used to provide the force needed for the lift; and
- narrows the lift speed range.

VII. Responses to Comments

The Commission received five comments on the NPR, including: one from a consumer's group (Consumers Union); one from the Juvenile Products Manufacturers Association (JPMA); and three from hand-held infant carrier manufacturers. The comments raised several issues, which resulted in ASTM changing the handle auto-lock test procedures and including guidance for the placement of the CAMI dummy in the seat during the handle-auto lock test in ASTM F2050-13a. Several commenters made general statements supporting the overall purpose of the proposed rule. All of the comments can be viewed at: www.regulations.gov, by searching under the docket number of the rulemaking, CPSC-2012- 0068. Following is a summary of, and responses to, the comments.

Handle Auto-Locking Test – CAMI Dummy v. Aluminum Cylinder

Comment: Two commenters supported the proposal to use the aluminum cylinder surrogate instead of the CAMI dummy during the handle auto-locking test. The other three commenters opposed using the aluminum cylinder surrogate. Specific concerns with the cylinder included: (1) the cylinder is not the same shape as a child and can roll from side to side during testing; (2) the weight distribution and center of gravity of the cylinder are different for a child, and the cylinder can tip forward in an unrealistic manner during testing; and (3) testing with the cylinder can be dangerous because the cylinder can fall out of the carrier during testing and potentially injure a tester. The three commenters who raised concerns about using the cylinder as a surrogate in the handle auto-locking test preferred using the CAMI dummy as the surrogate for this test. One commenter suggested that whichever surrogate was specified, more detail be provided for placing the surrogate into the carrier before the lift test. One commenter suggested that CPSC should allow ASTM additional time to develop a test procedure that will provide more repeatable results.

Response*:* Since publication of the NPR, Commission staff has reviewed the comments, witnessed additional testing, and participated in discussions at ASTM hand-held infant carrier subcommittee and task group meetings. Based on this additional work, the Commission agrees with the three commenters who stated that using the cylinder during testing would produce unrepeatable results for some carriers. The Commission believes that most of the issues presented by use of the CAMI dummy can be addressed with clarifications and modifications to the ASTM test procedure set forth in ASTM F2050-12 so that the test produces more repeatable and reliable results. ASTM revised the requirement in the most recent version of F2050, and staff believes the revision, as now stated in ASTM F2050-13a, is adequate to address the hazards

associated with unlocked carry handles. Therefore, the final rule does not does not require any changes to the carry handle auto-locking requirement but incorporates by reference the latest version of the standard, ASTM F2050-13a.

Fall Hazard Warning

Comment*:* One commenter recommended that the Commission strengthen the warning regarding the fall hazard to discourage more strongly caregivers placing the carrier on elevated surfaces. The language in ASTM F2050-12 (the version in effect at the time of the NPR) stated: "Fall Hazard: Child's movement can slide carrier. NEVER place carrier near edges of counter tops, tables, or other elevated surfaces."

Response*:* The Commission agrees with the commenter that the fall hazard warning stated in ASTM F2050-12 was not sufficiently strong. Leaving hand-held carriers on elevated surfaces is a foreseeable behavior, and the warning language should highlight the importance of not leaving the carriers on elevated surfaces. ASTM F2050-13a revises this warning. The changes in the warning language from ASTM's '12 version to the '13a version are presented below (deletions are shown with strikethroughs; additions are underlined):

~~8.3.2.4~~ 8.3.2.5 Fall Hazard: Child's ~~movement~~ activity can ~~slide~~ move carrier. **NEVER** place carrier ~~near edges of~~ on counter tops, tables, or any other elevated surfaces.

The Commission agrees with the change in the ASTM standard, and thus, no further modifications are necessary in response to this comment.

Location of the Strangulation Warning Label

Comment: One commenter expressed concern that the requirement that the label be placed "in or adjacent to the area where the child's head would rest" does not specify sufficiently the proper placement of the label, and therefore, the label could be obscured when a child is in the seat. The

commenter suggested requiring the label to be placed "adjacent to where the infant's head or torso would rest with or without the child installed in the seat." The commenter explained that this change would permit the caregiver to see the warning label at all times and allow the manufacturer the space and flexibility to place the label in a location that is effective, without impacting NHTSA's airbag warning label.

Response*:* The requirement in ASTM F2050-13a specifying the location for the warning label mirrors NHTSA's airbag warning label requirement. The Commission believes the warning label location requirement clearly describes the proper location of the label and further believes that adopting the commenter's suggestion may create confusion regarding the placement of the label and may reduce the warning's effectiveness if a manufacturer decides to locate the label toward the lower end of the infant carrier. The Commission agrees with the current language in ASTM F2050-13a and believes that the warning label is more likely to be seen if placed on the outer surface of the cushion or padding, in or adjacent to where child's head rests, and also believes that there is sufficient area in that part of the seat to accommodate both NHTSA's and ASTM's labels independently. Therefore, the Commission declines to make the change suggested by the commenter.

Alert Mechanism

Comment: One commenter suggested that the Commission look for feasible means to bolster the protection against the hazards posed by improper use of the harness restraint system, by requiring an alert mechanism that would clearly signal or indicate whether a harness restraint system is properly secured.

Response: Although alerting the user to the existence of improperly secured or unsecured harnesses would be beneficial, the Commission is uncertain how to accomplish this. Visual

indicators are unlikely to get the attention of the user, and an auditory signal (similar to vehicle seat belt reminders) would require a power source that would energize the alert mechanism when the carrier is inside and outside of a vehicle. Adding a power source to the child restraint would require a redesign that may fall under NHTSA's jurisdiction.

Effective Date

Comment: One commenter supported the proposed six-month effective date. Another commenter requested an 18-month effective date, assuming that the final rule would reference the use of the cylinder as the surrogate for the carry handle auto-locking test. The commenter seeking an 18-month effective date expressed concern that requiring the cylinder might necessitate substantial design changes.

Response: Because the Commission has determined that the CAMI dummy will be used as a surrogate in the carry handle auto-locking test, the commenter's basis for requesting an 18-month effective date no longer exists. A six-month effective date should be sufficient for manufacturers of hand-held infant carriers to comply with the rule.

Moses Baskets

We did not receive any comments concerning Moses baskets. Despite the lack of comments, the Commission has determined that a revision to the definition of "hand-held infant carrier" is warranted to clarify that Moses baskets are subject to the standard. The final rule modifies the definition of "hand-held infant carrier" as follows (underline represents additional wording): "Hand-held infant carrier - a freestanding, rigid- or semi-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."

VIII. Assessment of Voluntary Standard ASTM F2050-13a and Description of Final Rule

Consistent with section 104(b) of the CPSIA, this rule establishes new 16 CFR part 1225, "Safety Standard for Hand-Held Infant Carriers." The new part incorporates by reference the requirements for hand-held infant carriers in ASTM F2050-13a, with one modification to clarify that semi-rigid sided products, such as Moses baskets, are included in the scope of the rule. The following discussion describes the final rule, the changes, and the additions to the ASTM requirements.

A. Scope (§ 1225.1)

The final rule states that part 1225 establishes a consumer product safety standard for hand-held infant carriers manufactured or imported on or after the date that is six months after the date of publication of a final rule in the FEDERAL REGISTER.

B. Incorporation by Reference (§ 1225.2)

Section 1225.2(a) explains that, except as provided in § 1225.2(b), each hand-held infant carrier must comply with all applicable provisions of ASTM F2050-13a, "Standard Consumer Safety Specification for Hand-Held Infant Carriers," which is incorporated by reference. Section 1225.2(a) also provides information on how to obtain a copy of the ASTM standard or to inspect a copy of the standard at the CPSC. The Commission received no comments on this provision in the NPR, but the Commission is changing the language in the incorporation in the final rule to refer to ASTM F2050-13a, the current version of the ASTM standard.

C. Changes to Requirements of ASTM F2050-13a

The final rule modifies the definition of "hand-held infant carrier" to clarify that the definition includes products with semi rigid sides, as well as products that are rigid-sided. ASTM revised the hand-held infant carrier standard in 2012, to include a separate definition for "hand-held bassinets/cradles." A Moses basket meets the definition of a "hand-held bassinet"

because a Moses basket is a freestanding product with a rest/support surface that is no more than 10º from horizontal, that sits directly on the floor, without legs or a stand, and has handles or hand-holds intended to allow carrying an occupant whose torso is completely supported by the product. However, because hand-held infant carriers (of which hand-held bassinets/cradles are a subset) are defined in part as "a rigid-sided product" and many Moses baskets have flexible sides, some manufacturers and importers may have interpreted the standard as excluding semi-rigid-sided products such as Moses baskets. Because Moses baskets meet the definition of "hand-held bassinet/cradle," and Moses baskets are not subject to any other durable children's product standard (specifically ASTM F2194-13, Standard Consumer Safety Specification for Bassinets and Cradles), the Commission has determined that Moses baskets are within the scope of the rule. The modification of the definition of "hand-held infant carrier" to include semi rigid-sided products clarifies that Moses baskets are covered by the rule.

IX. Effective Date

The Administrative Procedure Act (APA) generally requires that the effective date of a rule be at least 30 days after publication of the final rule. 5 U.S.C. 553(d). To allow time for hand-held carriers to come into compliance, the final rule provides that the standard will become effective 6 months after publication in the *Federal Register* for products manufactured or imported after that date.

VIII. Regulatory Flexibility Act

A. Introduction

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601–612, requires agencies to consider the impact of rules on small entities, including small businesses. Section 604 of the RFA requires that agencies prepare a final regulatory flexibility analysis when the agency promulgates

a final rule, unless the head of the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The final regulatory flexibility analysis must describe the impact of the rule on small entities and identify any alternatives that may reduce the impact. Specifically, the final regulatory analysis must contain:

- a succinct statement of the objectives of, and legal basis for, the rule;
- a summary of the significant issues raised by public comments in response to the initial regulatory flexibility analysis, a summary of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments;
- a description of, and, where feasible, an estimate of, the number of small entities to which the rule will apply;
- a description of the projected reporting, recordkeeping, and other compliance requirements of the 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
- a description of the steps the agency has taken to reduce the significant economic impact on small entities, consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the rule, and why each one of the other significant alternatives to the rule considered by the agency, which affect the impact on small entities, was rejected.

B. The Market

The majority of hand-held infant carriers are produced and/or marketed by juvenile product manufacturers and distributors. A potential exception is the Moses basket, which is often marketed by bedding manufacturers and distributors. The Commission estimates that currently, there are at least 47 suppliers of hand-held infant carriers to the U.S. market. Fifteen are domestic manufacturers, 22 are domestic importers, and 1 is a domestic firm with an unknown supply source. In addition, eight foreign firms distribute products from outside of the United States (four manufacturers, two importers, one retailer, and one firm with an unknown supply source). One firm, about which the staff has little information, sells hand-held infant carriers through an online marketplace. An additional 24 domestic firms supply Moses basket bedding, along with Moses baskets. Staff does not know the source of the Moses baskets supplied by these 24 firms.

We expect that the products of 29 of the 47 hand-held infant carrier suppliers will be compliant with ASTM F2050-13a (7 are JPMA certified to F2050; 6 claim compliance with F2050; and 16 have ASTM-compliant strollers with hand-held infant carrier attachments). We do not believe that any of the Moses baskets currently on the market comply with the voluntary standard; however, the requirements that apply to Moses baskets involve slip resistance, adding warnings, and instructional literature. Staff believes that the majority of Moses baskets on the market would not require adjustments to meet the slip resistance requirement, and that adding warnings and instructional literature would not be costly.

The product ownership data available is limited to infant car seats, which represented nearly the entire hand-held infant carrier market prior to the publication of ASTM F2050-12, which expanded the scope of the standard to include hand-held bassinets and cradles. 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 million births per year). (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 2010," *National Vital Statistics Reports* Volume 61, Number 1 (August 28, 2012): Table I. Number of births in 2010 is rounded from 3,999,386.) These 2 million infant car seats represent the minimum number of units sold per year that might be affected by the hand-held infant carrier standard. We do not know how many Moses baskets and other bassinet/cradle-style carriers are sold annually.

C. Reason for Agency Action and Legal Basis for 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, F2050-13a, upon which the rule is based.

The final rule modifies the definition of "hand-held infant carrier" in ASTM F2050-13a to clarify that the standard includes products with semi rigid sides, as well as products that are rigid-sided. This modification resulted from the Commission receiving no comments in response to the NPR's question whether Moses baskets should be included within the scope of this rule

and the Commission's determination that Moses baskets (which typically have semi rigid as opposed to rigid sides) should be covered by the rule.

D. Requirements of the Rule

The final rule adopts the voluntary ASTM standard for hand-held infant carriers (ASTM F2050-13a), with a modification of the definition of "hand-held infant carrier," as discussed above. Some of the more significant requirements of the current voluntary standard for hand-held infant carriers are listed below:

- Carry handle integrity—a series of endurance and durability tests is intended to prevent rigid, adjustable handles from breaking or unlocking 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).
- Marking and labeling requirements—intended to provide tracking information, as well as hazard warnings.

The voluntary standard also includes: (1) torque and tension tests to prevent components from being removed; (2) requirements for several hand-held infant carrier features to prevent entrapment and cuts (minimum and maximum opening size, coverage of exposed coil springs, small parts, hazardous sharp edges or points, smoothness of wood parts, and edges that can scissor, shear, or pinch); (3) marking and labeling requirements; (4) requirements for the

permanency and adhesion of labels; (5) requirements for instructional literature; and (6) toy accessory requirements. ASTM F2050-13a includes no reporting or recordkeeping requirements.

The final rule does not alter ASTM F2050-13a, except to clarify that the definition of "hand-held infant carrier" includes products with semi rigid sides, as well as products that are rigid-sided. We do not expect this modification to the final rule to have a negative economic impact on firms because it is a clarification of the intended scope, rather than a change. In the 2012 version of the hand-held carrier standard (F2050-12), ASTM changed the standard to include a separate definition for "bassinet-style carriers," which may have been interpreted by some manufacturers to include Moses baskets. The Commission proposed the same scope in the NPR but requested comments on including Moses baskets. In the absence of comments, the Commission determined that Moses baskets were intended to and should be included in the scope and that the definition of a "hand-held infant carrier" should be modified to include "semi rigid-sided," as well as "rigid-sided" products, consistent with the scope's intent.

E. Other Federal or State Rules

Two federal rules would interact with the hand-held infant carrier mandatory standard: (1) 16 CFR part 1107, *Testing and Labeling Pertaining to Product Certification* (1107 rule or testing rule); and (2) 16 CFR part 1112, *Requirements Pertaining to Third Party Conformity Assessment Bodies* (1112 rule).

The 1107 rule implementing sections 14(a)(2) and 14(i)(2) of the Consumer Product Safety Act (CPSA), as amended by the CPSIA, became effective on February 13, 2013. 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, the product 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 (NORs) become effective.

The 1112 rule, which became effective on June 10, 2013, established requirements for the accreditation of third party conformity assessment bodies to test for conformance with a children's product safety rule in accordance with section 14(a)(2) of the CPSA. The final rule also codified all of the NORs that the CPSC had published, to date. However, any new NORs require an amendment to this rule. Therefore, this rule amends 16 CFR part 1112 to establish the requirements for accepting the accreditation of a conformity assessment body to test for compliance with the hand-held infant carrier final rule.

F. Impact of the Rule on Small Business

There are at least 47 firms currently known to be marketing hand-held infant carriers in the United States, as well as 24 firms supplying Moses basket bedding and Moses baskets whose source is unknown. Under U.S. Small Business Administration (SBA) guidelines, a manufacturer of hand-held infant carriers is small if the firm has 500 or fewer employees, and importers and wholesalers are considered small, if they have 100 or fewer employees. Based on these guidelines, about 50 of the firms known to be marketing hand-held infant carriers in the

United States are small firms—10 domestic manufacturers, 17 domestic importers, 1 domestic firm with an unknown supply source, and 22 firms supplying Moses basket/bedding suppliers. There may also be additional small hand-held infant carrier suppliers operating in the U.S. market.

Small Manufacturers

Direct Costs from the Rule

The expected impact on small manufacturers of the standard will differ based on whether the firm's hand-held infant carriers already comply with F2050-12. Firms whose hand-held infant carriers meet the requirements of F2050-12 are likely to continue to comply with the voluntary standard as ASTM publishes new versions of the ASTM standard. In addition, firms currently in compliance are likely to meet any new standard within six months after approval because six months is the established amount of time that JPMA allows for products in JPMA's certification program to shift to a new standard. Compliance with the voluntary standard in the six-month time frame is part of an established business practice. Additionally, modifying warning labels and updating instructional literature should not result in significant expenditures for most firms. As a result, the direct impact of the rule on manufacturers whose products are likely to meet the requirements of ASTM F2050-13a (eight of ten small domestic manufacturers) is not likely to be significant. One or more firms might have to modify their carry handles to continue to pass the auto-locking test, but staff believes that a complete product redesign should not be necessary. Thus, for manufacturers whose products are likely to meet the requirements of ASTM F2050-13a (eight of ten firms), staff estimates little or no incremental impact on the costs of producing hand-held infant carriers.

For either or both of the hand-held infant carrier suppliers staff believes do not comply with the current version of the voluntary standard, however, meeting ASTM F2050-13a's requirements could necessitate product redesign. A redesign would be minor if most of the changes involve adding straps and fasteners or using different mesh or fabric; but 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 cost approximately $500,000. Consequently, the final rule could potentially have a significant direct impact on small manufacturers whose products currently do not conform to the voluntary standard, depending on the scope of the redesign that ultimately is necessary. Where the products need not be completely redesigned, actual costs are likely to be lower than the $500,000 level.

Even though the hand-held infant carriers sold by two firms are neither certified as compliant, nor claim compliance with F2050-12, the products may, in fact, comply with the current standard. 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 standard will be less significant than described above.

Indirect Costs from Testing and Certification

In addition to the direct impact of the standard described above, the rule will have 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 NOR is in effect, all manufacturers will be subject to the additional costs associated with the third party testing and certification

requirements. These costs will include any physical and mechanical test requirements specified in the final rule; lead and phthalates testing is already required, and hence, related costs are not included here.

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 such testing 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 F2050-13a is unlikely to be significant if only one hand-held infant carrier sample per model is necessary to comply with the third party testing requirements. However, if more than one sample would be needed to meet the testing requirements, that third party testing costs potentially could have a significant impact on one or more of the small manufacturers.

Small Importers

As with manufacturers of compliant hand-held infant carriers, we do not believe that the eight small importers of hand-held infant carriers currently in compliance with F2050-12 will experience significant direct impacts as a result of the final rule. In the absence of regulation, these importing firms would likely continue to their established practice of complying with the voluntary standard as the standard evolves.

Importers of hand-held infant carriers would need to find an alternate supply source if their existing supplier does not comply with the requirements of the rule, which may be the case with all four small importers of hand-held infant carriers, whom we believe do not comply with F2050-12. Some of these importers could react to the rule by discontinuing the import of 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 compliant hand-held infant carriers. Deciding to import an alternative product would be a reasonable and realistic way to offset any lost revenue. However, for some importers, switching suppliers might not be an option.

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

Staff also assessed the potential impact of the rule on firms that supply Moses baskets. There are 22 known small firms supplying Moses baskets to the U.S. market. Most of these firms also supply bedding; some of them manufacture the bedding, and others act as importers. Because a separate definition for "hand-held bassinets" was added to the standard relatively recently in 2012, and some manufacturers may be uncertain whether Moses baskets (a type of hand-held bassinet) are covered by the standard because they are not rigid-sided, Moses baskets currently on the market may not have been designed to comply with this standard.

Many Moses baskets on the market, however, might be able to comply with the standard with minimal modifications. For example, although Moses baskets would not be subject to most of the hand-held carrier standard's performance requirements, Moses baskets would likely have to meet the slip-resistance requirement. Because typical Moses baskets are fabricated from textured materials, we believe that these products likely would not require modifications to meet the slip-resistance requirement (that the product does not slip on surface 10 degrees from horizontal while facing forward, sideways, and to the rear). Therefore, the biggest changes might be to add warnings and instructional literature, actions that the staff expects would not be costly.

Alternatively, Moses basket suppliers could remove themselves from the scope of the final rule by eliminating the handles from their products. Because most Moses baskets come with warnings against carrying an infant in the basket, eliminating handles would conform to those instructions.

All Moses basket manufacturers within the scope of the rule will be subject to third party testing and certification requirements. Importers of Moses baskets could experience testing costs if their supplying firm does not perform third party testing. Because Moses baskets would not be subject to most of the mechanical tests in the standard, we expect that third party testing costs, at most, will be half the amount of other types of hand-held infant carriers, or approximately $250−$500 per model sample. Review of each firm's product line reveals that most firms use only one model of Moses basket for their bedding; although some firms have up to four variations of Moses baskets. The resulting costs are unlikely to have a significant impact on firms that must perform the testing themselves.

G. Alternatives

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

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 rule falls within the categorical exclusion.

X. Paperwork Reduction Act

This rule contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The preamble to the proposed rule (77 FR at 73363 through 73364) discussed the information collection burden of the proposed rule and specifically requested comments on the accuracy of our estimates. Briefly, sections 8 and 9 of ASTM F2050-13a 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).

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. OMB has assigned control number 3041-0158 to this information collection. The Commission did not receive any comments regarding the information collection burden of this proposal. However, the final rule makes

modifications regarding the information collection burden because the number of estimated suppliers subject to the information collection burden is now estimated to be 71 firms, rather than the 43 firms initially estimated in the proposed rule.

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

Table 1 – Estimated Annual Reporting Burden

16 C.F.R. Section	Number of Respondents	Frequency of Responses	Total Annual Responses	Hours per Response	Total Burden Hours
1221	71	2	142	1	142

Our estimates are based on the following:

Section 8.1 of ASTM F 2050-13a 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, be marked clearly and legibly on each product and its retail package. Section 8.2 of ASTM F 2050-13a requires a code mark or other means that identifies the date (month and year, as a minimum) of manufacture.

There are 71 known entities supplying hand-held infant carriers to the U.S. market. All 71 firms are assumed to use labels already on both their products and their packaging, but they might need to modify existing labels. The estimated time required to make these modifications is about 1 hour per model. Each entity supplies an average of two different models of hand-held infant carriers; therefore, the estimated burden associated with labels is 1 hour per model x 71 entities x 2 models per entity = 142 hours. We estimate the hourly compensation for the time required to create and update labels is $27.44 (U.S. Bureau of Labor Statistics, "Employer Costs for Employee Compensation," March 2013, 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 $3,896.48 ($27.54 per hour x 142 hours = $3,896.48). There are no operating, maintenance, or capital costs associated with the collection of information.

Section 9.1 of ASTM F2050-12 requires the supply of instructions with the product. Hand-held infant carriers often require installation or assembly, and products sold without such information would not be as attractive to consumers as 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 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.

XI. Preemption

Section 26(a) of the CPSA, 15 U.S.C. 2075(a), provides that where a consumer product safety standard is in effect and applies to a product, no state or political subdivision of a state may either establish or continue in effect a requirement dealing with the same risk of injury, unless the state requirement is identical to the federal standard. Section 26(c) of the CPSA also provides that states or political subdivisions of states may apply to the Commission for an exemption from this preemption under certain circumstances. Section 104(b) of the CPSIA

refers to the rules to be issued under that section as "consumer product safety rules," thus implying that the preemptive effect of section 26(a) of the CPSA would apply. Therefore, a rule issued under section 104 of the CPSIA will invoke the preemptive effect of section 26(a) of the CPSA when the rule becomes effective.

XII. Certification and Notice of Requirements (NOR)

Section 14(a)(2) of the CPSA requires 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.

The Commission published a final rule, *Requirements Pertaining to Third Party Conformity Assessment Bodies*, 78 FR 15836 (March 12, 2013), which is codified at 16 C.F.R. part 1112 (referred to here as part 1112). This rule became effective on June 10, 2013. Part 1112 establishes requirements for accreditation of third party conformity assessment bodies (or

laboratories) to test for conformance with a children's product safety rule in accordance with Section14(a)(2) of the CPSA. Part 1112 also codifies a list of all of the NORs that the CPSC had published at the time part 1112 was issued. All NORs issued after the Commission published part 1112, such as the hand-held infant carrier standard, require the Commission to amend part 1112. Accordingly, this rule amends part 1112 to include the hand-held infant carrier standard in the list 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 are required to meet the third party conformity assessment body accreditation requirements in 16 CFR part 1112. When a laboratory meets the requirements as a CPSC-accepted third party conformity assessment body, the laboratory can apply to the CPSC to have 16 CFR part 1225, *Safety Standard for Hand-Held Infant Carriers* included in the scope of accreditation of CPSC safety rules listed for the laboratory on the CPSC website at: www.cpsc.gov/labsearch.

In connection with the part 1112 rulemaking, CPSC staff conducted an analysis of the potential impacts on small entities of the rule establishing accreditation requirements, 78 FR 15836, 15855-58 (March 12, 2013), as required by the Regulatory Flexibility Act and prepared a Final Regulatory Flexibility Analysis (FRFA). Briefly, the FRFA concluded that the requirements would not have a significant adverse impact on a substantial number of small laboratories because no requirements are imposed on laboratories that do not intend to provide third party testing services under section 14(a)(2) of the CPSA. The only laboratories that are expected to provide such services are those that anticipate receiving sufficient revenue from providing the mandated testing to justify accepting the requirements as a business decision. Laboratories that do not expect to receive sufficient revenue from these services to justify

accepting these requirements would not likely pursue accreditation for this purpose. Similarly, amending the part 1112 rule to include the NOR for the hand-held infant carrier standard would not have a significant adverse impact on small laboratories. Most of these laboratories will have already been accredited to test for conformance to other juvenile product standards, and the only costs to them would be the cost of adding the hand-held infant carrier standard to their scope of accreditation. As a consequence, the Commission certifies that the NOR for the hand-held infant carrier standard will not have a significant impact on a substantial number of small entities.

To ease the transition to new third party testing requirements for hand-held infant carriers subject to the standard and to avoid a ''bottlenecking'' of products at laboratories at or near the effective date of required third party testing for hand-held infant carriers, the Commission, under certain circumstances, will accept certifications based on testing that occurred before the effective date for third party testing.

The Commission will accept retrospective testing for 16 CFR part 1225, safety standard for hand-held infant carriers, if the following conditions are met:

- The children's product was tested by a third party conformity assessment body accredited to ISO/IEC 17025:2005(E) by a signatory to the ILAC–MRA at the time of the test. The scope of the third party conformity body accreditation must include testing in accordance with 16 CFR part 1225. For firewalled third party conformity assessment bodies, the firewalled third party conformity assessment body must be one that the Commission, by order, has accredited on or before the time that the children's product was tested, even if the order did not include the tests contained in the safety standard for hand-held infant carriers at the time of initial Commission acceptance. For governmental third party conformity assessment bodies, accreditation of the body must be accepted by the

Commission, even if the scope of accreditation did not include the tests contained in the safety standard for hand-held infant carriers at the time of initial CPSC acceptance.

- The test results show compliance with 16 CFR part 1225.
- The hand-held infant carrier was tested on or after the date of publication in the *Federal Register* of the final rule for 16 CFR part 1225 and before [INSERT DATE 6 MONTHS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**]**.
- The laboratory's accreditation remains in effect through [INSERT DATE 6 MONTHS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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 amends 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:

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 2050-13a, Standard Consumer Safety Specification for Hand-Held Infant Carriers, approved on September 1, 2013. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from ASTM International, 100 Bar Harbor Drive, P.O. Box 0700, West Conshohocken, PA 19428; http://www.astm.org. You may inspect a copy at the Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone 301-504-7923, or at the National

Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal regulations/ibr_locations.html.

(b) Instead of complying with section 3.1.3 of ASTM F2050-13a, comply with the following:

(i) 3.1.3 *hand-held infant carrier, n* - a freestanding, rigid- or semi-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.

(ii) [Reserved]

Dated: _____.

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

Staff Briefing Package

Draft Final Rule for Hand-Held Infant Carriers under the Danny Keysar Child Product Safety Notification Act

October 30, 2013

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Briefing Memo

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

This document has been electronically approved and signed.

MEMORANDUM

October 30, 2013

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Stephanie Tsacoumis, General Counsel
Elliot F. Kaye, Acting Executive Director
Robert J. Howell, Deputy Executive Director for Safety Operations

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

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

SUBJECT: Staff's Draft Final Rule for Hand-Held Infant Carriers under the Danny Keysar Child Product Safety Notification Act

I. INTRODUCTION

The Danny Keysar Child Product Safety Notification Act of the Consumer Product Safety Improvement Act (CPSIA) of 2008 requires the U.S. Consumer Product Safety Commission (CPSC or Commission) to study and develop safety standards for certain infant and toddler products. Infant carriers are one of the product categories specifically identified in section 104(f)(2) of the CPSIA as a "durable infant or toddler product," and hand-held infant carriers fall into this category. The Commission is charged with promulgating a consumer product safety standard that is substantially the same as the voluntary standard for hand-held infant carriers or more stringent than the voluntary standard if the Commission determines that a more stringent standard would further reduce the risk of injury associated with these products.

Section 104 of the CPSIA also requires the Commission to consult with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts to examine and assess the effectiveness of the relevant voluntary standards. This consultation process commenced in 2011 during an ASTM International (formerly known as the American Society for Testing and

Materials) subcommittee meeting regarding the ASTM hand-held infant carrier voluntary standard, in which CPSC staff participated. Consultations with members of the ASTM subcommittee, who represent producers, users, consumer advocates, government, and academia, are ongoing.

This briefing package includes staff's responses to comments received in response to the hand-held infant carrier notice of proposed rulemaking (NPR). This package also assesses the hand-held infant carrier voluntary standard and presents staff's draft final rule to address potential hazards associated with these products.

II. BACKGROUND

A. Rulemaking History

In December 2012, the Commission issued an NPR for hand-held infant carriers (77 *Federal Register* 73354, December 10, 2012). The NPR proposed to incorporate by reference the voluntary standard, ASTM F2050-12, *Standard Consumer Safety Specification for Hand-Held Infant Carriers,* with two modifications to the voluntary standard to strengthen the ASTM standard:

1) Strangulation warning: Add a new warning label requirement that contains a pictogram and exact language to warn about the hazards associated with improper restraints usage.
2) Carry handle auto-locking test procedure: Modify the existing test procedure to increase the consistency and repeatability of the test. The modification proposed using an aluminum cylinder, designed as a surrogate for a 6-month old infant, in lieu of the CAMI Mark II infant dummy specified in the ASTM standard.

The ASTM standard 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*.

There are two subcategories of "hand-held infant carriers" that are defined in the standard. Both of these carrier types fall under the umbrella definition of a "hand-held infant carrier":

1) Hand-held infant carrier seats: *a hand-held infant carrier having a seat back that is intended to be in a reclined position (more than 10^{o} from horizontal)*, and

2) Hand-held bassinets/cradles: *a freestanding product, with a rest/support surface to facilitate sleep (intended to be flat or up to 10º from horizontal), that sits directly on the floor, without legs or a stand, and has hand-holds or handles(s) intended to allow carrying an occupant whose torso is completely supported by the product.*

A hand-held infant carrier seat often serves as an infant car seat and also can be used with strollers and travel systems. A hand-held bassinet/cradle includes products such as carriage baskets (removed from a stroller base) and Moses baskets (those with handles).

In the NPR briefing package, staff interpreted the definition of "hand-held infant carrier," to be an umbrella term that includes products with semi-rigid sides, even though the word "rigid" was not defined. The Commission was concerned, however, that the definition created a potential ambiguity that might lead some to interpret the standard to exclude Moses baskets, the sides of which are typically semi-rigid. Therefore, the NPR specifically asked for comments regarding the definition of "hand-held infant carrier" and queried whether the definition leaves ambiguity about whether the standard covers Moses baskets.

B. ASTM Voluntary Standard Overview

ASTM F2050, *Standard Consumer Safety Specification for Hand-Held Infant Carriers,* is the voluntary standard that addresses the identified hazard patterns associated with the use of hand-held infant carriers. In response to handle failure incidents and the associated recalls of hand-held infant carriers in the 1990s, CPSC staff asked ASTM to develop a voluntary standard for hand-held infant carriers when these products are used outside of a vehicle. The standard was first approved in 2000, as a complementary standard to the federal standard for car seats, FMVSS 213 (49 C.F.R. 571.213, S5.52(k)(3)). FMVSS 213 only applies to products when they are used in a vehicle as a restraint system for children and thus does not contain any requirements for handle performance or integrity. ASTM F2050 was revised in 2001, 2003, 2008, 2009, 2012, and 2013.

ASTM F2050-12 is the version the Commission proposed to incorporate by reference in the NPR. One of the significant changes included in the 2012 version was the addition of separate definitions for hand-held infant carrier seats and hand-held bassinet/cradles. Clear definitions to distinguish the products were needed, because the standard contains different requirements for each. For instance, the restraints requirement specifies that hand-held bassinets/cradles shall not contain a restraint system, but hand-held carrier seats must have such a system. In addition, the carry handle auto-locking requirement is

only required on products that have rigid and adjustable carry handles. This effectively exempts most Moses baskets from compliance with the handle auto-locking test.

Hand-held bassinet/cradle products often serve the same function as a bassinet/cradle, but they are not covered in the scope of the bassinet standard because they do not fit the definition of a bassinet/cradle[1].

Moses baskets and other hand-held bassinet/cradles meet the definition of hand-held bassinets/cradles found in ASTM F2050, thus it is staff's continued belief that the intent of ASTM F2050 is to include these products in the scope, to ensure there is a standard that covers them.

Since ASTM F2050-12, there have been two additional revisions to the ASTM standard, F2050-13, and the current version, ASTM F2050-13a. These will be discussed in more detail below.

Recent ASTM Changes

The ASTM strangulation labeling requirement was revised for the F2050-13 version of the standard to include the label as proposed in the NPR. While the actual ASTM label is identical to what was proposed in the NPR, the requirements associated with the label are not identical to the label requirements in the NPR. ASTM F2050-13 adds a note that allows manufacturers the flexibility to customize the pictogram on the label to match their products better. This note was not part of the NPR requirements.

The carry handle auto-locking performance requirement was revised in the F2050-13a version. This revised performance requirement is different from what was proposed in the NPR. The revision retains the use of the CAMI Mark II infant dummy as the surrogate occupant and adds clarity to the standard about how the dummy should be situated in the seat. The revised requirement also:

- Specifies using webbing instead of hooks when lifting the carrier during the test;
- specifies that a pneumatic cylinder be used to provide the force needed for the lift; and
- narrows the lift speed range.

The revisions ASTM made to the requirement were intended to improve the consistency and repeatability of the carry handle auto-locking test.

[1] To be considered a bassinet/cradle under the standard for bassinets/cradles (ASTM F2194), the product must be supported by free standing legs, a stationary frame/stand, or a wheeled or rocking base.

ASTM F2050-13a Summary

The current voluntary standard for hand-held infant carriers, ASTM F2050-13a, was approved on September 1, 2013, and contains the following performance requirements:

1) Carry handle auto-locking–This requirement applies only to products that have a rigid, adjustable carry handle that rotates about a singular axis and can lock in a designated carry position. The requirement addresses fall hazards associated with carriers being lifted with unrestrained occupants when the carry handle is unlocked but appears to be locked.

2) Carry handle integrity–This requirement includes endurance testing of the handles. The requirement applies only to products that have a rigid, adjustable carry handle that rotates in head-to-foot and foot-to- head directions. The requirement addresses fall hazards associated with handle breakage and failures.

3) Restraint system–This requirement specifies that hand-held carrier seats (carriers that have a seat back angle of greater than 10 degrees from horizontal) must contain a restraint system. The requirement also mandates that hand-held bassinet/cradles (carriers that have a seat back angle of 10 degrees or less from horizontal) not contain a restraint system.

4) Slip resistance–This requirement tests a carrier on a 10-degree laminate surface and specifies that the carrier shall not slip more than 0.12 in. (3 mm) when tested according to the standard's test procedure.

In addition, the standard contains general requirements to address sharp edges, scissoring, shearing, pinching, and small parts, as well as hazards associated with wood parts, openings, exposed coil springs, toys, permanency of labels, and protective components. The standard also contains marking, labeling, and instructional literature requirements. The labeling requirements include the strangulation warning label as discussed previously, and also contain warnings to address suffocation and fall hazards.

III. DISCUSSION

A. Overview of New Incident Data

CPSC staff is aware of a total of 10 incidents (seven fatal and three nonfatal) related to hand-held infant carriers that were reported since the extraction of the data presented in the NPR. All of the incidents were reported to have occurred in late 2011 and 2012. Of the 10 incidents, eight appear to have occurred in carriers that could also be used as an

infant car seat; one occurred in a car seat/car bed designed for premature infants; and one pertained to a Moses basket carrier.

Fatalities

Two of the seven fatalities involved an infant who was unrestrained in a hand-held carrier. In one fatality, the unrestrained infant was found in a prone position with the seat tipped over. In the other, the unrestrained infant was found with his face into the side of the seat. A third fatality was a strangulation death, where the partially restrained infant—with only the shoulder straps in place—scooted forward on the seat just enough to get caught at the throat by the chest clip that connects the two shoulder straps. A fourth fatal incident involved a strapped infant trapped under an overturned seat that was left on a bed. There was information indicating that misuse of the product contributed to the fifth fatality; however, CPSC staff does not have enough information to identify conclusively the hazard pattern involved.

One of the seven fatalities was considered non-product related; this incident resulted from the decedent and the carrier being placed in a hazardous environment. Specifically, the decedent was reported to have become entrapped in the carrier by other unsupervised children. Information on the exact manner of entrapment was unavailable.

For the last fatality, there was insufficient information to allow CPSC staff to make a determination on any product involvement or the presence of any hazardous external circumstances.

Nonfatal Incidents

There were three hand-held carrier-related, nonfatal, noninjury incidents reported since the extraction of the data presented in the NPR. All of the incidents occurred in 2012; none involved an injury. Two of the incidents reported breakage of the carrier handle, and the third was a complaint about the poor quality and design of a Moses basket carrier.

B. Staff Responses to NPR Comments

The CPSC received five comments regarding the NPR: three from different manufacturers, one from a manufacturers' trade association, and one on behalf of several consumer groups. The commenters made general statements concerning the overall purpose of the proposed rule and also provided specific comments regarding the two proposed modifications and other related issues. All of the comments can be viewed at: www.regulations.gov, by searching under the docket number of the rulemaking, CPSC-2012-0068. Below are summaries of the comments and staff's responses to the specific issues the comments raised. Staff's complete responses can be found in Tabs B, C, and D.

Handle Auto-Locking Test - CAMI Dummy vs. Aluminum Cylinder

Comment: Two commenters supported the proposal to use the aluminum cylinder surrogate for the handle auto-locking test. The other three commenters were opposed to the proposed use of the aluminum cylinder surrogate. Specific concerns with the cylinder included: (1) the cylinder is not the same shape as a child and can roll from side to side during testing; (2) the weight distribution and center of gravity are different for a child and the cylinder; the cylinder can tip forward in an unrealistic manner during testing; and (3) testing with the cylinder can be dangerous because the cylinder can fall out of the carrier during testing and potentially injure a tester. As a result, all three commenters preferred the CAMI dummy. One commenter suggested that whichever surrogate is specified, more detail should be provided about how the surrogate should be placed in the carrier prior to the carrier being lifted. One commenter suggested that the CPSC should allow ASTM additional time to develop a test procedure that will provide more repeatable results.

Response: As discussed in the NPR briefing package, staff believed that the CAMI dummy could become wedged in the padding on some carriers during the testing. Because of the wedging, staff noticed that the CAMI dummy did not fall out during testing with one model seat when it otherwise would have fallen out. Staff's testing, conducted with a limited number of hand-held infant carrier seats, showed that the aluminum cylinder surrogate eliminated the wedging issue, and thus staff believed, would provide more repeatable results than using the test method in ASTM F2050-12.

Since publication of the NPR, staff has reviewed the comments, witnessed additional testing, and participated in discussions at ASTM hand-held infant carrier subcommittee and task group meetings. Based on this additional work, staff agrees with the three commenters who opposed the use of the cylinder, and now believes that the cylinder would not necessarily provide more consistent and repeatable test results in some carriers. Staff now believes that most of the issues presented by use of the CAMI dummy can be addressed with clarifications and modifications to the test procedure found in ASTM F2050-12 to ensure that the test produces more repeatable and reliable results.

ASTM revised the handle auto-locking test procedure in the most recent version of F2050, and staff believes the revision is adequate to address the hazards associated with unlocked carry handles. Therefore, staff recommends referencing the latest version of the standard, ASTM F2050-13a, with no further changes to the carry handle auto-locking requirement.

Fall Hazard Warning

Comment: One commenter recommended that the Commission strengthen the warning regarding the fall hazard to discourage more emphatically the placement of carriers on elevated surfaces. The language in ASTM F2050-12 (the version in effect at the time of the NPR) stated: "Fall Hazard: Child's movement can slide carrier. NEVER place carrier near edges of counter tops, tables, or other elevated surfaces."

Response: Staff agrees with the commenter. Leaving a hand-held carrier on an elevated surface is a foreseeable behavior. Therefore, the warning language should highlight the importance of not leaving the carriers on elevated surfaces. This warning was revised in ASTM F2050-13a. The changes in the warning language are presented below (deletions are shown with strikethrough; additions are underlined):

~~8.3.2.4~~ 8.3.2.5 Fall Hazard: Child's ~~movement~~ activity can ~~slide~~ move carrier. **NEVER** place carrier ~~near edges of~~ on counter tops, tables, or any other elevated surfaces.

Staff agrees with the change in the standard; thus, no additional modifications are recommended to address the comment.

Location of the Strangulation Warning Label

Comment: One commenter suggested that the proposed strangulation warning label requirement is not clear, specifically regarding where to place the label on the carrier. The commenter suggested a change that would require the label to be placed "adjacent to where the infant's head or torso would rest with or without the child installed in the seat." The commenter explained that this change would permit the caregiver to see the warning label at all times and allow the manufacturer the space and flexibility to place the label in a location that is effective without impacting NHTSA's airbag warning label.

Response: The requirement in ASTM F2050-13a associated with the new warning label location is worded so that it mirrors NHTSA's airbag warning label requirement. Staff believes that the warning label location requirement clearly describes the proper location of the label and does not understand why the commenter feels it is unclear. In addition, staff feels the commenter's proposal pertaining to the location may create confusion regarding the placement of the label and may also reduce its effectiveness; for instance, if the label was located towards the lower end of the infant carrier, it would be covered up by the occupant any time the seat was used. Staff agrees with the current language in ASTM F2050-13a and believes that the warning label is more likely to be seen if placed on the outer surface of the cushion or padding in or adjacent to where a child's head rests, and that there is sufficient area to accommodate both NHTSA's and ASTM's labels

independently. Thus, staff does not recommend making the change suggested by the commenter.

Alert Mechanism

Comment: One commenter suggested that the Commission look for feasible means of further protecting against the hazards posed by improper use of the harness restraint system. The commenter suggested a mandatory alert mechanism that would clearly signal or indicate whether a harness restraint system is secured properly.

Response: Although alerting the user that a harness has been secured improperly would be beneficial, staff is uncertain how to accomplish this. Visual feedback is unlikely to get the attention of the user; and an auditory signal, similar to vehicle seat belt reminders, would require a power source that would energize the alert mechanism when the carrier is inside and outside of a vehicle. Adding a power source to the child restraint might require a redesign that may fall under NHTSA's jurisdiction.

Effective Date

Comment: One commenter supported the proposed six-month effective date; while another commenter requested an 18-month effective date, based on the assumption that the final rule would reference the use of the cylinder as part of the carry handle auto-locking test.

Response: Because staff is recommending referencing the latest ASTM standard, and is no longer recommending the use of the cylinder as a surrogate in the carry handle auto-locking test, we do not support an extension of the effective date of the final rule to 18 months. Accordingly, we believe that a six-month effective date should be sufficient.

Moses Baskets

We did not receive any comments regarding Moses baskets and the scope of the standard. Nevertheless, staff believes that additional clarity is needed to be clear that Moses baskets fall in the scope, and to remove any potential ambiguity. Therefore, staff recommends a slight modification in the standard of the umbrella definition of "hand-held infant carrier." Staff recommends modifying the definition as follows: (underline represents the recommended additional wording):

"Hand-held infant carrier" - *a freestanding, rigid- or semi-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.*

This change is consistent with the intent of the scope and the added definitions included in F2050-12, and would clarify that the scope is intended to cover Moses baskets, in addition to the more traditional rigid-sided hand-held carriers.

C. NPR vs. ASTM F2050-13a

CPSC staff recommends that the Commission incorporates by reference, the latest version of the voluntary standard, ASTM F2050-13a, in lieu of the version referenced in the NPR (ASTM F2050-12). ASTM F2050-13a differs from the NPR in two areas:

The Strangulation Warning Label

Since publication of the NPR, ASTM published F2050-13 and F2050-13a, both of which include a revised strangulation warning label identical to the warning label modification found in the NPR. The strangulation warning label requirement in ASTM F2050-13a gives flexibility to manufacturers to customize the warning label to reflect their product more accurately yet still conform to the content shown in the pictogram. The additional text found in ASTM F2050-13a, but not contained in the NPR language is as follows:

> *NOTE (added at the end of section 8.3.2.3): The pictogram can be customized to more accurately reflect the manufacturer's product, but shall conform to the content shown in the pictogram.*

Staff believes that a pictogram showing each manufacturer's harness design more realistically would increase comprehension of the pictogram. Therefore, staff agrees with including the additional text in the strangulation warning label requirement, as found in ASTM F2050-13a.

The Revised Handle Auto-Locking Test Procedure – Replace CAMI with the Cylinder

As discussed previously in this memorandum, and in more detail in Tab B, staff has considered the information provided in the comments and has conducted and witnessed additional testing. As a result, staff no longer recommends that the CAMI dummy be replaced with the cylinder in the carry handle auto-locking test, as outlined in the NPR. Both surrogates have issues regarding consistency and repeatability, but staff believes that providing additional guidance on how to position the CAMI dummy in the carrier for the procedure should reduce most of the problems. Staff developed the revised procedure along with the ASTM task group. In July 2013, ASTM balloted the new procedure, the ballot passed, and therefore, the revised procedure was incorporated into the latest revision of the standard, F2050-13a, which was approved on September 1, 2013. In addition to providing guidance for the placement of the CAMI dummy, the revised procedure uses a slower lift speed and requires the lift to be performed with specified

equipment. Both of these changes will add consistency to the test. Lastly, the new procedure includes replacing the specified hooks (used to lift the carrier during the test) with a webbing strap. This change is necessary because testing showed that some carrier handles did not fit properly using the specified hooks.

D. Potential Small Business Impact

The majority of hand-held infant 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. There may be about 50 domestic suppliers of hand-held infant carriers and Moses baskets that would be small businesses under U.S. Small Business Administration guidelines─10 domestic manufacturers, 17 domestic importers, one domestic firm with an unknown supply source, and 22 domestic Moses basket/bedding suppliers. The potential impact of the staff-recommended final rule on these firms is presented in the Directorate for Economic Analysis memorandum (Tab D).

There will be little or no impact of the rule on the eight small domestic manufacturers whose hand-held infant carriers meet the current voluntary standard. However, there could potentially be a significant impact on the two small domestic manufacturers whose hand-held infant carriers are not compliant with the current voluntary standard.

Similarly, the impact is not expected to be significant for the eight small importers whose hand-held infant carriers are expected to be compliant with ASTM F2050-13a. However, 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. This could be the case with the nine importers whose hand-held carriers are believed not to be compliant with the voluntary standard.
The biggest changes for Moses basket suppliers would be adding warning labels and instructional literature. Alternatively, Moses basket suppliers could remove themselves from the scope of the standard by eliminating handles and/or hand-holds on their product.

E. Effective Date of Final Rule

The Administrative Procedure Act (APA) generally requires that the effective date of a rule be at least 30 days after publication of the final rule (5 U.S.C. 553(d)). In the NPR, the Commission proposed a six-month effective date. CPSC staff believes that the Commission should set an effective date for the standard six months after publication of the final rule for products manufactured or imported on or after that date.

IV. STAFF-RECOMMENDED MODIFICATION

CPSC staff recommends that the Commission incorporate by reference the voluntary standard, ASTM F2050-13a, as the federal regulation for hand-held infant carriers, with one clarifying modification outlined below:

- To clarify that Moses baskets fall in the scope of the standard, staff recommends revising the definition of a hand-held infant carrier as follows (underline indicates new language):

"Hand-held infant carrier" - *a freestanding, rigid- or semi-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*.

TAB A: Hand-Held Infant Carrier-Related Deaths, Injuries, and Potential Injuries Reported Between June 8, 2012 and June 20, 2013 and 2012 NEISS Injury Estimates

TAB A

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

MEMORANDUM

Date: June 28, 2013

TO : Patricia L. 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, and Potential Injuries Reported Between June 8, 2012 and June 20, 2013, and 2012 NEISS Injury Estimates[2]

I. Introduction

This memorandum updates the data in the hand-held infant carrier notice of proposed rulemaking (NPR) briefing package presented to the Commission in November 2012. The date of extraction for the earlier data was June 8, 2012, and the time frame covered was January 1, 2007−December 31, 2011. This memorandum includes hand-held infant carrier-related incident

[2] 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.

data reported to CPSC staff between June 8, 2012 and June 20, 2013.[3] National injury estimates from January 2007 through December 2011 were presented in the hand-held carrier NPR; an injury estimate for 2012 is presented in this memorandum.

II. Incident Data[4]

CPSC staff is aware of a total of 10 incidents (seven fatal and three nonfatal) related to hand-held infant carriers reported since the NPR. All of the incidents reportedly occurred in late 2011 and 2012. Of the 10 incidents, eight apparently occurred in carriers that could also be used as an infant car seat; one occurred in a car seat/car bed designed for premature infants; and one pertained to a Moses basket carrier.

A. Fatalities

Seven fatalities were reported since the extraction of the data presented in the NPR briefing package. Two of the fatalities occurred in October 2011, while the remaining five occurred in 2012. The ages of the decedents ranged from one month to 15 months. Most of the fatalities involved a product-related issue. Two of the seven fatalities involved an infant who was unrestrained in a hand-held infant carrier seat; one of them was found with his face into the side of the seat, while the other infant was found in a prone position with the seat tipped over. The third fatality was a strangulation death where the partially restrained infant—with only the shoulder straps in place—scooted forward on the seat, just enough to get caught at the throat by

[3] 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.

[4] 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 06/21/13. The incident reports involving carriers do not always clearly specify the type of carrier involved. As such, all data coded under product codes 1519/1548/1549 and text keywords "Moses"/"basket" was extracted, yielding a very large initial data pool. Upon careful joint review with CPSC's Directorate for Engineering Sciences, many cases were considered out of scope for 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. Incidents that occur while the carrier is being used as a car seat inside a vehicle are considered outside of the jurisdiction of the CPSC. Incidents involving the failure of the attachment mechanism of a hand-held carrier seat to a stroller or highchair are being addressed in the regulatory work for strollers or highchairs, respectively. 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 on 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.

the chest clip that connects the two shoulder straps. The fourth fatal incident involved a strapped infant trapped under an overturned seat that was left on a bed. There was some information indicating that misuse of the product contributed to the fifth fatality; however, CPSC staff does not have enough information to identify conclusively the hazard pattern involved.

One of the seven fatalities was considered non-product related; this incident resulted from the decedent and the carrier being placed in a hazardous environment. Specifically, the decedent reportedly became entrapped in the carrier by other unsupervised children. Information on the exact manner of entrapment was unavailable.

For the remaining fatality, there was insufficient information to allow CPSC staff to make a determination on any product involvement or the presence of any hazardous external circumstances.

B. Nonfatal Incidents

There were three hand-held carrier-related, nonfatal incidents reported since presentation of the NPR briefing package. All of the incidents occurred in 2012; none were reported to have involved an injury. Two of the incidents reported breakage of the carrier handle; while the third incident was a complaint about the poor quality and design of a Moses basket carrier.

III. Hazard Patterns

There was no new hazard pattern identified among the 10 incident reports received by CPSC staff since the extraction of the data presented in the hand-held infant carrier NPR. In order of frequency of these 10 reports, the hazard patterns were grouped into the following categories:

- Restraint Issues
- Handle Problems
- Design Issues
- Hazardous Environment
- Other Product-Related Issues
- Other/Unknown Issues.

  - ***Restraint issues:*** Three of the incidents—all fatalities—were associated with the incorrect use or non-use of the harness straps. There were two fatal incidents where the decedent was not restrained in the carrier at all; the decedents were found later to have turned to a position with their face into a soft surface. The third death occurred when the infant was left in the seat with the shoulder straps connected but was unrestrained at the crotch strap. This allowed the infant to slide forward on the seat, just enough to get caught at the throat by the chest clip and strangle.

- ***Handle problems:*** Two incidents reported the handle breaking; one incident involved a product that had been recalled for handle problems. There were no injuries reported in these incidents.

- ***Issues with carrier design:*** There was one fatality in this category, which resulted from the occupied carrier tipping upside down when the carrier was left on a soft surface (*i.e.,* a bed), trapping the infant. In addition, one noninjury report included complaints about the poor and unsafe design of a Moses basket carrier.

- ***Hazardous environment:*** One fatality resulted from an infant getting trapped in the hand-held carrier by other unsupervised children. Details of the manner in which the entrapment occurred were unavailable.

- ***Other product-related issues:*** One fatality report 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.

- ***Other/unknown issues:*** One fatality was reported with an undetermined official cause of death. There was insufficient circumstantial evidence of any product involvement or the presence of any hazardous external circumstances.

IV. National Injury Estimates[5]

There were an estimated 9,100 injuries related to hand-held infant carriers treated in U.S. hospital emergency departments in 2012. There were no fatalities among these injuries. About 70 percent of the injured were six 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:

- Hazard – falls (89%); a majority of the reports did not specify the manner or cause of the fall.
- Injured body part – head (66%) and face (19%).
- Injury type – internal organ injury (47%) and contusions/abrasions (30%).
- Disposition – treated and released (93%).

[5] 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 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 younger than two 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.

TAB B: Staff Responses to Technical Comments on the Notice of Proposed Rulemaking for Hand-Held Infant Carriers and Recommendations for the Final Rule

TAB B

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

Memorandum

September 5, 2013

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

THROUGH: Mark Kumagai
Director, Division of Mechanical Engineering
Directorate for Engineering Sciences

FROM : Vincent J. Amodeo
Mechanical Engineer
Directorate for Engineering Sciences

SUBJECT : Staff Responses to Technical Comments on the Notice of Proposed Rulemaking for Hand-Held Infant Carriers and Recommendations for the Final Rule

I. Introduction

This memorandum provides a summary of the technical comments received on the notice of proposed rulemaking (NPR) for hand-held infant carriers, published on December 10, 2012, in the *Federal Register* (77 FR 73354), staff's responses to those comments, an overview of ASTM hand-held carrier subcommittee activities since the NPR publication, and a summary of staff's recommendations for the final rule. The NPR proposed a safety standard for hand-held infant carriers under the Danny Keysar Child Product Safety Notification Act, section 104(b) of the Consumer Product Safety Improvement Act of 2008 (CPSIA), which would incorporate ASTM F2050-12 by reference, with two modifications. One modification dealt with revising the warning label to address suffocation and restraint-related hazards. This modification was incorporated in ASTM F2050-13, which was approved on July 1, 2013, and is discussed in Tab C of this briefing package. The other modification dealt with the carry handle auto-locking performance requirement. This memorandum deals exclusively with that modification.

II. Public Comments and Staff Responses

CPSC received comments from three manufacturers, one manufacturers' organization, and one comment on behalf of several consumer groups regarding the proposed requirements. All technical comments received were related to the proposal to modify the existing ASTM F2050-12 carry handle auto-locking test by using an aluminum cylinder surrogate instead of a standard

CAMI, Mark II six-month infant dummy.[6] The carry handle auto-locking test helps ensure that the carrier will not rotate and spill an unrestrained infant when a caregiver picks it up while the handle is not locked in the carry position. The Commission proposed using the aluminum cylinder surrogate to make the carry handle auto-locking test more repeatable.

Comment: Two commenters supported the proposal to use the aluminum cylinder surrogate instead of the CAMI infant dummy during the handle auto-locking test. One commenter noted that, based on their testing, "the aluminum cylinder by its structure and composition ensures more consistent and relevant results" and "diminishes the potential for the carrier soft goods and covers to influence the test results." The commenter suggested that the test be conducted with soft goods in the carrier to reduce testing time and to provide results that are more indicative of real-world conditions.

The other three commenters opposed the proposed use of the aluminum cylinder surrogate. Two of those commenters noted that testing with the cylinder yields inconsistent results. Specific concerns with the cylinder included: (1) the cylinder is not the same shape as a child, and the cylinder can roll from side to side during testing; (2) the cylinder's weight distribution and center of gravity are different from a child's, which can cause the cylinder to tip forward in an unrealistic manner during testing; and (3) testing with the cylinder can be dangerous because the cylinder can fall out of the carrier during testing and potentially injure a tester. As a result, all three commenters preferred the CAMI dummy. One commenter suggested that whichever surrogate is specified, more detail should be provided for its placement into the carrier prior to the lift portion of the test. One commenter suggested that the CPSC should allow ASTM additional time to develop a test procedure that will provide more repeatable results.

Response: Based on the testing discussed in the NPR briefing package, staff noted that the CAMI dummy could become wedged in the padding on some carriers, such that the CAMI dummy did not fall out during the lift portion of the carry handle auto-locking test. This resulted in the carrier passing a test that the carrier otherwise would have failed. Staff also found that placement of the CAMI within the carrier could affect the 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.

Based on pre-NPR testing conducted with a limited number of carriers, staff believed that the aluminum cylinder, originally designed for mattress flatness testing in the ASTM F2194 standard for bassinets and cradles, eliminated the wedging issue and provided more repeatable results than using the CAMI dummy. Calculations made by staff indicated that, although the cylinder does not anatomically represent the CAMI dummy, the cylinder and the CAMI dummy have similar centers of gravity, and therefore, the CAMI dummy and the cylinder would rotate forward at similar angles during the lift portion of the handle auto-locking test.

[6] CAMI Infant Dummy, Mark II represents the 50th percentile, six-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 C.F.R. part 572, Subpart D.

Since publication of the NPR, staff has reviewed the comments, witnessed additional testing, and participated in discussions at ASTM hand-held infant carrier subcommittee and task group meetings (see details in next section). Based on this additional work, staff now agrees with the last three commenters and believes that the use of the cylinder during testing presents unrepeatable results in some carriers, results that were not anticipated based upon prior testing. Staff now believes that the use of the CAMI dummy during testing is the most realistic surrogate, and most of the issues presented by use of the CAMI dummy can be addressed with clarifications and modifications to the ASTM test procedure to ensure more repeatable and reliable results. Since the NPR, ASTM has approved a revised procedure (discussed in the next section) that addresses the NPR comments and staff's concerns.

III. ASTM F15.21 Hand-Held Infant Carrier Subcommittee Activity Since Publication of the NPR

1. Staff attended an ASTM hand-held infant carrier subcommittee meeting on January 8, 2013. Technical issues discussed at the meeting included a request for additional carry handle auto-lock testing to be conducted by task group members using the cylinder specified in the NPR and an alternate surrogate flat-hinged weight gage. The discussion noted that the center of gravity of the hinged weight gage is not consistent with a CAMI dummy or an infant, and the cylinder does not rotate beyond 90 degrees. One manufacturer discussed issues encountered when testing with the cylinder, noting that the cylinder would not sit flat on the seat bottom and could flop from left to right.

2. Staff attended an ASTM hand-held infant carrier subcommittee meeting on April 10, 2013. Attendees discussed technical issues related to the carry handle auto-locking tests conducted since the previous meeting. The consensus was that there were issues with all three test surrogates (CAMI dummy, cylinder, and hinged gage) during the carry handle auto-locking test. Attendees decided that the task group would meet at an independent laboratory to perform additional testing using all three surrogates on several carriers.

3. Staff attended an ASTM hand-held infant carrier task group meeting on April 26, 2013, held at an independent, third party laboratory. The task group conducted carry handle auto-lock testing with six carriers from six different manufacturers using four different surrogates:

    - CAMI Infant Dummy, Mark II;
    - Infant hinged weight gage;
    - Infant hinged "flex" gage (infant hinged weight gauge modified to allow greater rotation about the hinge); and
    - Aluminum cylinder (as specified in the NPR).

    The hinged weight gage was tested flat against the carrier seat back; whereas, the hinged "flex" gage was offset using a foam cushion to move the center of gravity to a position similar to the CAMI and the cylinder.

Based on the observed carry handle auto-locking test results, the task group discussed options for moving forward. They decided that the tests using the cylinder in the various carriers produced very unrepeatable results. While the two versions of the hinged weight gage were deemed the most consistent of the surrogates, the group agreed that the hinged weight was overwhelmingly passing carriers; on the other hand, the hinge "flex" gage was overwhelmingly failing carriers. Therefore, the task group decided that both hinged gages were inappropriate.

The group determined that although the CAMI dummy showed inconsistencies during carry handle auto-lock testing, the inconsistencies could be reduced by providing clarifications for CAMI positioning prior to testing. However, the group requested that manufacturers with CRABI 12-month-old ATD[7] dummies conduct testing to see if results were more consistent than with the CAMI dummy.

The group also agreed that the carry handle auto-locking test method could be modified to reduce inconsistencies observed during testing. The group focused on three issues:

a. The time specified to lift the carrier 12 inches should be narrowed from the current range of one to two seconds to one and one half to two seconds to provide smoother lift.
b. The hooks specified for lifting the carrier during the carry handle auto-locking test proved to be incompatible with some of the carrier handles. The group decided that additional testing should be done with alternative lift methods, such as child-restraint webbing instead of hooks.
c. There was some difficulty positioning carry handles in an unlocked position prior to lifting.

4. Staff attended by phone conference, an ASTM hand-held infant carrier task group meeting on June 3, 2013. Testing conducted by some of the task group members since the prior meeting was discussed.

    a. Test results indicated that the use of one and one half inch wide child-restraint webbing was easier to set up than the hooks specified in the existing carry handle auto-locking lift test.
    b. The CRABI ATD dummy had less variability than the CAMI when placed in the carrier due to its larger size; but test results could still be manipulated. Additionally, many manufacturers do not own the more expensive CRABI ATD dummy.
    c. The narrower (slower) lift time produced more consistent results. Use of an air cylinder to lift the carrier also improved consistency.
    d. The group ranked the CAMI and hinged gage over the other surrogates, and the group agreed that the focus should be on making the CAMI more repeatable or

[7] The CRABI 12-month-old anthropomorphic test device (ATD) dummy is made from fiberglass, steel, foam, and rubber and was developed to evaluate small child-restraint systems in automotive crash environments. The CRABI 12-month-old ATD dummy weighs 22 lbs.; whereas, the six-month CAMI, Mark II dummy weighs 17 lbs.

coming up with a more realistic hinge gage. The group's preference was to modify the procedure to specify more clearly placement of the CAMI.

5. The task group chair developed a draft ballot item with suggested changes to the existing carry handle auto-locking test method.

   The proposed revisions to ASTM F2050-13 were submitted for concurrent ASTM Main Committee F15 and Subcommittee F15.21 ballot on July 12, 2013, with a one-month comment period.

   The balloted revision addresses the following:

   a. Paragraph 6.1.3 clarifies that a mechanical stop built into the carry handle is an acceptable means to prevent further rotation of the carrier during the lift test. This was added after determining that some carriers on the market have a mechanical stop instead of a secondary locking position beyond the designated carry position, which adequately prevented the dummy from falling out of the carrier during the lift test.
   b. Paragraph 7.1 adds clarification to ensure the CAMI dummy is consistently placed in the carrier prior to the handle auto-locking test by:
      i. adjusting the soft goods to be suitable for a six-month-old infant;
      ii. adjusting the harness to lie flat against the carrier;
      iii. ensuring that the dummy is firmly seated in the carrier against the harness with the rump in the seat bight and the body fully seated against the seat back and bottom;
      iv. ensuring that the dummy's arms are prevented from interfering with the carrier's soft goods during the test, by attaching the dummy's hands together using duct tape or a similar means; and
      v. providing additional guidance notes for the placement of the CAMI dummy in the carrier.
   c. Paragraph 7.1.3.1 clarifies that the lift shall be accomplished using a pneumatic cylinder to improve consistency.
   d. Paragraphs 7.1.3.2 and 7.1.3.3 change from using hooks to grab the carrier handle to using child-restraint webbing. This modification allows for easier set up, accommodating variations in handle design.
   e. Paragraph 7.1.3.4 slows the allowable lift speed from one to two seconds to one and one half seconds to two seconds to ensure a smoother lift.

The ASTM closing report for the ballot item was published on August 15, 2013. The ballot passed, and therefore, the balloted language was incorporated into the latest revision of the standard, F2050-13a, which was approved on September 1, 2013. The revisions to the handle auto locking requirement are detailed in Appendix A.

IV. Staff Recommendations

ASTM has approved two revisions to the hand-held infant carrier standard since the NPR was published. ASTM F2050-13 incorporated a new strangulation warning label identical to the label included in the NPR. ASTM F2050-13a incorporated revisions to the handle auto-locking test requirements. Staff recommends that the Commission incorporate by reference, ASTM F2050-13a, with one modification, for the final rule. The modification includes a change to the "hand-held infant carrier" definition (discussed in the briefing memorandum).

Staff believes that the modifications to the carry handle auto-locking test included in ASTM F2050-13a, which were balloted and approved by the full ASTM F15 subcommittee, will address concerns presented by the Commission in the NPR and by NPR comments regarding reliability and repeatability of the test. The revisions will help ensure that the CAMI dummy is placed in the carrier consistently, the carrier handle is easier to grab, and the lift is smoother.

Appendix A.

F2050-13a *Standard Consumer Safety Specification for Hand-Held Infant Carriers*

Recent revision of sections 6.1 and 7.1, and Figures 4 and 5, to improve the repeatability and reliability of the lift test portion of the carry handle auto-locking test procedure

Deletions from the sections are shown by ~~strikethrough~~
Additions are shown by single underline

6.1 *Carry Handle Auto-locking*—This requirement applies only to products having a rigid, adjustable carry handle that rotates about a singular axis and locks in the manufacturer's designated carry position. The carry handle shall comply with 6.1.1, 6.1.2, or 6.1.3 when tested in accordance with 7.1.

6.1.1 The carry handle shall move unaided and lock into the manufacturer's designated carry position or move unaided into a position that is obvious to the caregiver that the carry handle is not in the manufacturer's designated carry position. The unaided movement shall occur within 5s of the carry handle being placed into an unlocked position in 7.1.2 and 7.1.4, before attempting to lift the carrier in 7.1.3. The manufacturer's designated carry position shall be clearly depicted in the instructional literature. A position obvious to the caregiver that is not the manufacturer's designated carry position is defined as any position that is not suitable for carrying the occupant. For example, the carry handle comes to rest at the position adjacent to the top of the occupants head.

6.1.2 The carry handle shall lock in the manufacturer's designated carry position when tested in accordance with 7.1.2-7.1.4.

6.1.3 The carry handle shall lock or be prevented from further movement by means of a mechanical stop in a position forward or rearward of the manufacturer's designated carry position such that an unrestrained dummy does not fall out of the carrier when tested in accordance with 7.1.2-7.1.4.

7.1 *Carry Handle Auto-Locking Test*:

7.1.1 Without a dummy in the carrier, secure the harness and adjust the soft goods to accommodate an infant weighing 17 lbs (development stage corresponding to the CAMI infant dummy Mark II) according to the manufacturer's instructions~~,~~. ~~and a~~ Adjust the harness such that ~~the harness~~ it contacts the seating surface along its entire exposed length ~~contacts the seating surface~~. Place the CAMI Infant dummy Mark II in the carrier on top of the buckled harness ~~and positioned in the carrier per the manufacturer's instructions.~~ Ensure that the dummy is firmly seated in the carrier against the harness with the rump in the seat bight and body fully seated against the seat back and bottom. Position the hands of the CAMI Infant dummy Mark II in front of the dummy at the head-to-toe centerline and attach the dummy's hands together using duct tape or a similar means, such that the dummy's arms are prevented from interfering with the carrier soft goods during the test.

NOTE: Positioning of the CAMI Infant dummy in the carrier is critical to ensure testing consistency and to eliminate test result variability that might be associated with the age/stiffness of the dummy. The dummy's crotch should be pressed back

against the buckled harness. The dummy's taped hands should rest on its lap. The carrier padding should not prevent the dummy from movement during rotation of the seat during the test.

7.1.2 Starting with the carry handle locked in the manufacturer's designated carry position, unlock the carry handle, and rotate the carry handle slightly rearward (toward the occupant's head end of the carrier) into a position that is as close to the designated carry position as possible without the carry handle being locked in the designated carry position.

7.1.3 If the carry handle remains in the unlocked position, conduct the test in this section.

7.1.3.1 A test fixture having a vertically sliding, rigidly mounted support (Fig. 4) shall be used to apply the vertical lifting force in this test. The vertical lifting force shall be applied using a pneumatically powered cylinder. The pneumatic cylinder shall be capable of producing a gradual lifting speed within the range of 1.5 – 2.0 s over 12 in. (30.5 cm).

7.1.3.2 The vertical lifting force shall be applied using ~~metal hooks~~ an 18 ± 0.25 in. (46 ± 0.6 cm) length of child restraint webbing having a width of 1.5 +/- 0.06 in. (38 +/- 1.5 mm) (Fig. 5). The fixture shall be fitted with a suitable clamping device that will prevent slippage of the webbing during the lift test. The webbing length shall allow a 4 – 6 in. distance between the top of the carrier handle and the clamping device when the webbing is in contact with the underside of the handle grip surface. (Fig. 4) ~~The metal hooks should be configured to allow ± 360° rotation about the vertical axis of the lifting fixture in order to accommodate both side-to-side and front-to-back configured handles. The metal hooks shall not prevent the rotation of the hand grip when the carrier is lifted, allowing the carrier to hang freely in its at rest position when lifted.~~

7.1.3.3 ~~Position the carrier hand grip over the metal hooks with~~ Align the lengthwise centerline of the webbing at the horizontal mid-point of the carrier hand grip ~~centered between the hooks, and with the hand grip centered within the radius of each hook~~. Clamp the ends of the webbing in the fixture.

7.1.3.4 Raise the sliding support until the ~~hooks~~ webbing contacts the underside of the grip surface and is taut. ~~then a~~Apply a vertical force gradually over 1.5 to 2 s to lift the carrier 12 in. (30.5 cm) from the at rest position. ~~The vertical force shall be limited to only that force that is sufficient to lift the carrier and the vertically sliding support.~~ If the carry handle remains in the unlocked position after completion of lifting process, gradually apply a downward force ~~manually~~ to the occupant's feet end of the carrier at the side-to-side midpoint. The force shall be manually applied and shall be the minimum amount needed to cause rotation of the carrier seat.

7.1.4 If the product design allows, repeat 7.1.2 and 7.1.3, rotating the carry handle slightly forward (toward occupant's feet end of the carrier) into a position that is as close to the designated carry position as possible without the carry handle being locked in the manufacturer's designated carry position. If the carry handle remains in the unlocked position after completion of lifting process, gradually apply a downward force manually to the occupant's head end of the carrier at the side-to-side midpoint. The force shall be manually applied and shall be the minimum amount needed to cause rotation of the carrier seat.

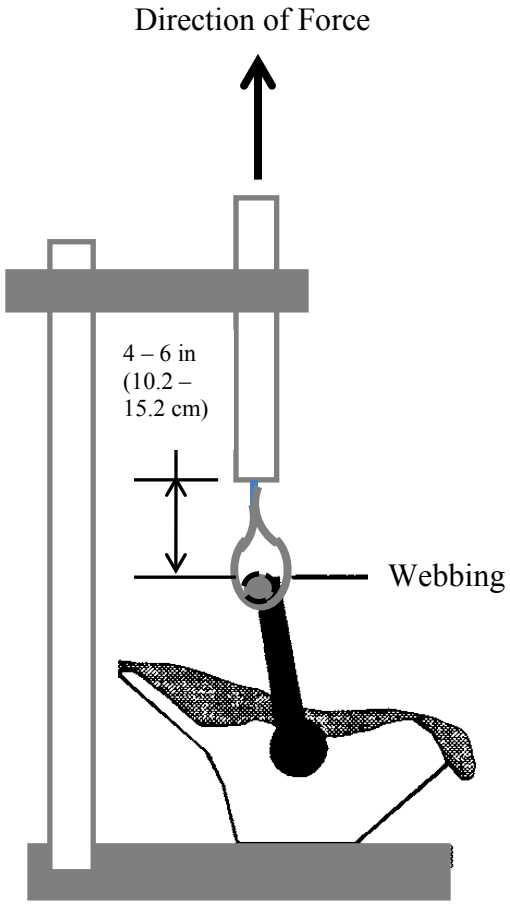

Fig. 4 Lifting Fixture

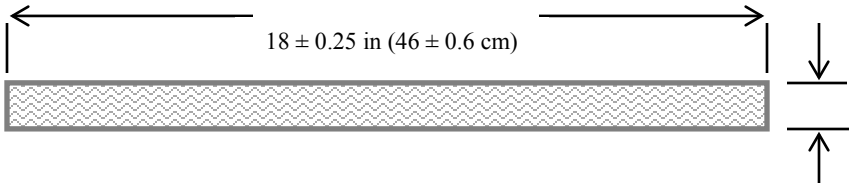

Fig. 5 Child Restraint Webbing

TAB C: Human Factors Staff Response to NPR Comments and Revised Warning Requirements for Hand-Held Infant Carriers

TAB C

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

Memorandum

Date: September 5, 2013

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

THROUGH: Bonnie Novak
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 Staff Response to NPR Comments and Revised Warning Requirements for Hand-Held Infant Carriers

I. INTRODUCTION

The Danny Keysar Child Product Safety Notification Act of the Consumer Product Safety Improvement Act (CPSIA) of 2008 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 younger than the age of 5 years, and includes infant carriers such as hand-held infant carriers (104(f)(2)(H)).

The ASTM voluntary standard, ASTM F2050-13a, *Standard Consumer Safety 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, 2013). ASTM F2050-13a was approved on September 1, 2013.

On November 8, 2012, CPSC staff delivered to the Commission a briefing package that assessed the effectiveness of the voluntary standard and a draft notice of proposed rulemaking (NPR) that included staff's draft proposed rule for hand-held infant carriers. Staff recommended that the Commission adopt the ASTM F2050-12 voluntary standard, the most current version of the

voluntary standard at the time the NPR was drafted, as the draft proposed rule for hand-held infant carriers, with two modifications: (1) a separate strangulation warning label requirement; and (2) a revision to the carry handle auto-locking test procedure.

On November 28, 2012, the Commission voted unanimously (3−0) to approve publication of the draft NPR, with amendments. The *Federal Register* published the NPR on December 10, 2012. The public comment period closed on February 25, 2013, and the CPSC received five comments.

II. DISCUSSION

A. Response to Public Comments

Staff's responses to human factors-related comments are as follows:

Alert mechanism

Comment:

One commenter suggested that the Commission look for feasible means of further protecting against the hazards posed by improper use of the harness restraint system, in the form of a required alert mechanism that would clearly signal whether a harness restraint system is properly secured.

Response:

Although alerting the user to harnesses that are secured improperly or that are not secured at all would be beneficial, staff is uncertain how this could be accomplished. Visual feedback is unlikely to get the attention of the user, and an auditory signal, similar to vehicle seat belt reminders, would require a power source that would energize the alert mechanism when the carrier is inside and outside of a vehicle. Adding a power source to the child restraint might require a redesign that may fall under NHTSA's jurisdiction.

Fall hazard warning

Comment:

One commenter recommended that the Commission strengthen the warning regarding the fall hazard to discourage more strongly placement on elevated surfaces. The language in F2050-12 (the version in effect at the time of the NPR) states: "Fall Hazard: Child's movement can slide carrier. NEVER place carrier near edges of counter tops, tables, or other elevated surfaces."

Response:

Staff agrees with the commenter. Leaving hand-held carriers on elevated surfaces is a foreseeable behavior, and the warning language should highlight the importance of not leaving

the carriers on elevated surfaces. This warning has been revised in ASTM F2050-13a. The changes in the warning language are presented below (deletions are shown with strikethrough, additions are underlined):

~~8.3.2.4~~ 8.3.2.5 Fall Hazard: Child's ~~movement~~ activity can ~~slide~~ move carrier. **NEVER** place carrier ~~near edges of~~ on counter tops, tables, or any other elevated surfaces.

Staff agrees with this change.

Location of the strangulation warning label

Comment:

One commenter suggested that the proposed strangulation warning label is not specifically clear regarding its placement on the carrier. The commenter believes that the change presented below (deletions shown with strikethrough and additions underlined) would make the label visually recognizable to caregivers at all times and allow manufacturers the space and flexibility to place the label in an effective location without diminishing the airbag warning label.

- *The warning label ~~shall~~ be permanently affixed to the outer surface of the cushion or padding, so that the label is visible on the cushion or padding, on an area ~~in or~~ adjacent to ~~the~~ where a child's head or torso would rest, with or without the child installed in the seat, ~~so that the label is plainly visible and easily readable~~.*

Response:

The requirement in ASTM F2050-13a associated with the new warning label location is worded so that it mirrors NHTSA's airbag warning label requirement. Staff believes that warning label location requirement clearly describes the proper location of the label and adopting the commenter's proposal pertaining to the location may create confusion regarding the placement of the label and may reduce its effectiveness in the case that the label is located towards the lower end of the infant carrier. Staff agrees with the current language in ASTM F2050-13a and believes that the warning label is more likely to be seen if placed on the outer surface of the cushion or padding in or adjacent to where child's head rests, and that there is sufficient area to accommodate both NHTSA's and ASTM's labels independently. Staff does not recommend making the change suggested by the commenter.

B. Changes to the Proposed Strangulation Warning Label

Since publication of the NPR, ASTM has approved F2050-13a, which includes a revised strangulation warning label that is identical to the warning label modification included in the NPR but also gives flexibility to manufacturers to customize the warning label to reflect more accurately their product and still conform to the content shown in the pictogram. The additional text in ASTM F2050-13a is as follows:

NOTE (added at the end of section 8.3.2.3): The pictogram can be customized to more accurately reflect the manufacturer's product, but shall conform to the content shown in the pictogram.

Staff believes that a pictogram showing each manufacturer's harness design more realistically would increase comprehension of the pictogram; therefore, staff agrees with this change.

III. CONCLUSION

Staff believes that the recently approved voluntary standard, ASTM F2050-13a, which includes several changes regarding warning labels, will improve the effectiveness of the warnings and increase consumer awareness. These changes include a new ASTM strangulation warning label that is identical to the label included in the NPR but which also allows manufacturers to customize the pictogram to reflect their product accurately.

Staff agrees with the commenter on the revision of the fall hazard warning language, which has already been addressed in ASTM F2050-13a. However, staff does not support the changes proposed by commenters regarding the location of the strangulation warning label or a restraint alert mechanism.

TAB D: Final Regulatory Flexibility Analysis of the Staff-Recommended Final Rule for Hand-Held Infant Carriers and the Accreditation Requirements for Conformity Assessment Bodies for Testing Conformance to the Hand-Held Infant Carrier Standard

TAB D

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

Memorandum

Date: September 6, 2013

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

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

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

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

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

Introduction

On August 14, 2008, the Consumer Product Safety Improvement Act (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.

On December 10, 2012, the CPSC published a notice of proposed rulemaking (NPR) in the *Federal Register* (FR) (77 FR 73354). The proposed rule incorporated by reference 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) using a cylinder rather than a CAMI dummy for the carry handle auto-locking test to improve consistency.

Since the issuance of the NPR, ASTM has adopted the proposed strangulation warning label with a note that allows firms to customize the accompanying pictogram to reflect the restraint systems used in their specific product(s). ASTM has also modified the carry handle auto-locking test procedure to improve the consistency and repeatability of the test using the CAMI dummy. Therefore, staff now recommends that the Commission adopt the most recent version of the voluntary standard, ASTM F2050-13a, as the final hand-held carrier mandatory standard with one change. ASTM added a definition for "hand-held bassinets/cradles" as part of 2012 version of the standard. Moses baskets[8] and other semi-rigid-sided bassinets/cradles meet this definition, and it is staff's belief that is the intent of ASTM F2050 to include these products in the standard's scope. Therefore, staff recommends clarifying this point by modifying the definition of a "hand-held infant carrier" to include "semi-rigid-sided," as well as "rigid-sided" products.

The Regulatory Flexibility Act (RFA) requires that final rules be reviewed for their potential economic impact on small entities, including small businesses. Section 604 of the RFA requires that agencies prepare a final regulatory flexibility analysis when the agency promulgates a final rule, unless the head of the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The final regulatory flexibility analysis must describe the impact of the rule on small entities and identify any alternatives that may reduce the impact. Specifically, the final regulatory flexibility analysis must contain:

1. a succinct statement of the objectives of, and legal basis for, the rule;
2. a summary of the significant issues raised by public comments in response to the initial regulatory flexibility analysis, a summary of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments;
3. a description of, and, where feasible, an estimate of, the number of small entities to which the rule will apply;
4. a description of the projected reporting, recordkeeping, and other compliance requirements of the 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. a description of the steps the agency has taken to reduce the significant economic impact on small entities, consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the rule, and why each one of the other significant alternatives

[8] Moses baskets are infant sleep products that typically have semi-rigid sides. They are often made of straw or wicker and can be used with a variety of rocking and stationary stands, thereby converting them into a bassinet/cradle. As with bassinets and cradles, they are not intended to be used once a child can push up on their hands and knees. The name is derived from the biblical reference to baby Moses in Exodus 2:1-10. Staff considers Moses baskets with handles or hand holds to be a type of hand-held bassinet/cradle, and thus, included in the scope of F2050.

to the rule considered by the agency, which affect the impact on small entities, was rejected.

The Product

ASTM F2050-13a defines a "hand-held infant carrier" as a freestanding, rigid-sided[9] product intended to completely support the occupant's torso while being carried by hand-holds or handles. 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. A hand-held bassinet/cradle includes products such as carriage baskets (removed from a stroller base) and Moses baskets with handles. A hand-held infant carrier seat, on the other hand, inclines by more than 10 degrees from horizontal and includes infant 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 infant 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 47 suppliers of hand-held infant carriers to the U.S. market. Fifteen are domestic manufacturers, 22 are domestic importers, and one is a domestic firm with an unknown supply source. There are also eight foreign firms that distribute products from outside of the United States (four manufacturers, two importers, one retailer, and one firm with an unknown supply source). There is one firm, selling through an online marketplace, about which nothing substantive could be determined. Staff has identified an additional 24 domestic firms that supply Moses basket bedding, along with Moses baskets whose sources are unknown.[10]

Staff expects that the products of 29 of the 47 hand-held infant carrier suppliers will be compliant with ASTM F2050-13a (7 are JPMA certified to F2050; 6 claim compliance with F2050; and 16 have ASTM-compliant strollers with hand-held infant carrier attachments).[11] Staff does not believe that any of the Moses baskets currently on the market comply with the voluntary standard; however, coming into compliance mostly consists of adding warnings and instructional literature.

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[9] As discussed above, staff recommends that this be modified to include "semi-rigid-sided" products (such as Moses baskets) as well.

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

[11] JPMA typically allows six months for products in their certification program to shift to a new standard once it is published. ASTM F2050-13a, the voluntary standard upon which the staff-recommended final standard is based was approved on September 1, 2013. Therefore, it should become effective for JPMA certification purposes prior to the hand-held infant carrier final rule going into effect. Firms that supply ASTM-compliant strollers are expected to assure that all of their attachments, including hand-held infant carriers, comply with all applicable ASTM standards as well.

The product ownership data available are limited to infant car seats, which represented nearly the entire hand-held infant carrier market prior to ASTM F2050-12 when the scope was expanded to include hand-held bassinets and cradles. According to a 2005 survey conducted by the American Baby Group (*2006 Baby Products Tracking Study*),[12] 68 percent of new mothers own infant car seats. Approximately 25 percent of infant car seats were handed down or purchased second-hand.[13] Thus, about 75 percent of infant car seats were acquired new. This suggests annual sales of about 2 million infant car seats (.68 x .75 x 4 million births per year).[14] These 2 million infant car seats represent the minimum number of units of hand-held infant carriers sold per year that might be affected by the final mandatory 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 manufacturer-recommended use periods, it appears that infant car seats are typically used for 1 to 2 years.[15] 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 2.7 million infant car seats are owned by new mothers. This suggests that at least 2.7 million infant car seats may be available to children during the first year of their lives and around 5.4 million available during the first two 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 Epidemiology (EPI) staff, there were an estimated 9,100 emergency department-treated injuries to children under age five related to hand-held infant carriers during 2012.[16] Because the vast majority of the incident data are associated with hand-held infant carriers that are also infant car seats, there may have been about 16.7 to 33.5 emergency department-treated injuries annually for every 10,000 infant car seats available for use in the households of new (and second year)

[12] The data collected for the *Baby Products Tracking Study* does 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.

[13] The data on second-hand products for new mothers was not available. Instead, data for new mothers and expectant mothers was combined and broken into first-time mothers and experienced mothers. Data for first-time mothers and experienced mothers has been averaged to calculate the approximate percentage that was handed down or purchased second-hand.

[14] 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 2010," *National Vital Statistics Reports* Volume 61, Number 1 (August 28, 2012): Table I. Number of births in 2010 is rounded from 3,999,386.

[15] 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; 2007 – Present.

[16] Memorandum from Risana T. Chowdhury, Division of Hazard Analysis, Directorate for Epidemiology, dated June 28, 2013, Subject: Hand-Held Infant Carrier-Related Deaths, Injuries, and Potential Injuries Reported Between June 8, 2012 and June 20, 2013, and 2012 NEISS Injury Estimates. NOTE: There were an estimated 10,600 emergency department-treated injuries in 2011; hence, the drop in risk estimates between the initial and final regulatory flexibility analyses.

mothers. The risk for other types of hand-held infant carriers could not be calculated; however, at least for Moses baskets, the risk is likely to be low, due to the rare occurrence of injuries.[17]

Reason for Agency Action and Legal Basis for the Staff-Recommended Final 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 recommends that the Commission adopt ASTM F2050-13a with a change to the hand-held infant carrier definition to clarify the scope, which is intended to include Moses baskets.

Requirements of the Staff-Recommended Final Rule

CPSC staff recommends adopting the voluntary ASTM standard for hand-held infant carriers (F2050-13a), with a clarification to the definition of a hand-held infant carrier.

ASTM F2050-13a

Some of the more significant requirements of ASTM F2050-13a are listed below. The requirements that were added or modified since the NPR are in italics.

- 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. *The carry handle auto-locking test method was updated for ASTM F2050-13a to improve its consistency and repeatability using the CAMI dummy, rather than the cylinder proposed in the NPR.*[18]
- Restraints—intended to minimize the fall hazard associated with inclined hand-held infant 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).
- Marking and labeling requirements—intended to provide tracking information, as well as hazard warnings. *The strangulation and fall hazard warnings were modified for ASTM F2050-13. The strangulation warning is now the same as the NPR proposal, except that it allows firms additional flexibility in the depiction of their restraint system in the accompanying pictogram. The fall hazard warning was*

[17] Over the period since January 2007, EPI staff has identified four 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 infant carrier.

[18] Memorandum from Vincent J. Amodeo, Directorate for Engineering Sciences, dated September 5, 2013, Subject: Staff Responses to Technical Comments on the Notice of Proposed Rulemaking for Hand-Held Infant Carriers and Recommendations for the Final Rule.

strengthened to better address the hazard associated with placing carriers on elevated surfaces, which was a concern expressed in the public comments received in response to the NPR.[19]

The voluntary standard also includes: (1) torque and tension tests to ensure that components cannot be removed; (2) requirements for several hand-held infant carrier features to prevent entrapment and cuts (minimum and maximum opening size, coverage of exposed coil springs, small parts, hazardous sharp edges or points, smoothness of wood parts, and edges that can scissor, shear, or pinch); (3) requirements for the permanency and adhesion of labels; (4) requirements for instructional literature, *which includes the updated strangulation and fall hazard warnings described above*; and (5) toy accessory requirements. ASTM F2050-13a includes no reporting or recordkeeping requirements.

Staff-Recommended Change

CPSC staff is recommending one modification to ASTM F2050-13a. The modification is not expected to have a negative economic impact on firms, as it is a clarification of the scope rather than a change in scope. In the 2012 version of the hand-held carrier standard (F2050-12), ASTM added a definition for bassinet-style carriers, which would include Moses baskets and other semi-rigid-sided bassinet/cradle carriers, and clarified the requirements this type of carrier should meet. The Commission proposed the same scope in the NPR, but requested comments on the inclusion of Moses baskets. In the absence of comments, staff recommends that the definition of a hand-held infant carrier be modified to include "semi-rigid-sided," as well as "rigid-sided" products, consistent with the ASTM standard's scope.

Issues Raised by Public Comments

There were several public comments submitted in response to the NPR that resulted in changes to the carry handle auto-locking test. Most objected to using a cylinder as a surrogate for a child because the cylinder does not realistically represent the interaction between a hand-held infant carrier and a child and does not produce repeatable results. In response to this, as well as additional testing and discussion within the ASTM task group, ASTM recently approved the publication of ASTM F2050-13a, which adopts the original CAMI dummy version of the test with modifications to make the test more consistent and repeatable. Staff agrees with these changes.

There were also two comments received that addressed the rule's effective date. One commenter supported the proposed six-month effective date, while another requested an 18-month effective date (although this was apparently predicated upon the acceptance of the cylinder as part of the carry handle auto-locking test). An extended effective date might have

[19] Memorandum from Rana Balci-Sinha, Division of Human Factors, Directorate for Engineering Sciences, dated September 5, 2013, Subject: Human Factors Staff Response to NPR Comments and Revised Warning Requirements for Hand-Held Infant Carriers.

been appropriate if the final rule incorporated the cylinder version of the carry handle auto-locking test. However, staff is now recommending that the Commission adopt ASTM F2050-13a, which includes modifications to the original CAMI dummy version of the test. Therefore, staff believes that a six-month effective date should be sufficient.

Other Federal or State Rules

There are two federal rules that would interact with the hand-held infant carrier mandatory standard: (1) *Testing and Labeling Pertaining to Product Certification*[20] (1107 rule or testing rule); and (2) *Requirements Pertaining to Third Party Conformity Assessment Bodies*[21] (1112 rule).

The final 1107 rule implementing sections 14(a)(2) and 14(d)(2) of the Consumer Product Safety Act (CPSA), as amended by the CPSIA, became effective on February 13, 2013. 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. 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 (NORs) become effective.

The 1112 rule, which became effective on June 10, 2013, established requirements for the accreditation of third party conformity assessment bodies to test for conformance with a children's product safety rule in accordance with section 14(a)(2) of the CPSA. The final rule also codified all of the NORs that the CPSC had published to date. However, any new NORs require an amendment to this rule; therefore, staff recommends an amendment to 16 C.F.R. part 1112 that would establish the requirements for accepting the accreditation of a conformity assessment body to test for compliance with the hand-held infant carrier final rule. The impact of the 1112 rule on small hand-held infant carrier certification bodies is discussed in a separate section at the end of this memorandum.

Impact on Small Businesses

There are at least 47 firms currently known to be marketing hand-held infant carriers in the United States, as well as 24 firms supplying Moses basket bedding, along with Moses baskets whose source is unknown. 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, about 50 are small firms—10 domestic manufacturers, 17 domestic importers, 1 domestic firm with an unknown supply source, and 22 domestic Moses basket/bedding suppliers.

[20] 16 C.F.R. part 1107.
[21] 16 C.F.R. part 1112.

There may also be other unknown small hand-held infant carrier suppliers operating in the U.S. market.

Small Manufacturers

The expected impact of the staff-recommended final standard on small manufacturers will differ based on whether their hand-held infant carriers are already compliant with F2050-12. In general, firms whose hand-held infant carriers meet the requirements of F2050-12 are likely to continue to comply with the voluntary standard as new versions are published. 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. It is likely that firms supplying hand-held infant carriers that comply with ASTM F2050-12 would also comply with F2050-13a before the final hand-held infant carrier rule becomes effective.

For manufacturers whose products are likely to meet the requirements of ASTM F2050-13a (8 of 10 firms), there will be little or no incremental impact on the costs of producing hand-held infant carriers. However, meeting ASTM F2050-13a's requirements could necessitate product redesign for either or both of the hand-held infant carrier suppliers not believed to be compliant with ASTM F2050-12. A redesign would be minor if most of the changes involve adding straps and fasteners or using different mesh or fabric, but 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 cost approximately $500,000. Consequently, the staff-recommended final rule could potentially have a significant direct impact on small manufacturers whose products do not conform to F2050-12. However, because most products would probably not need to be completely redesigned, actual costs are likely to be lower than the $500,000 level.

On the other hand, it is possible that one or both of the firms whose hand-held infant carriers are not expected to be compliant with F2050-13a would, in fact, be compliant with the standard. CPSC staff has identified many such cases with other products. To the extent that these firms may supply compliant hand-held infant carriers, the direct impact of the staff-recommended final rule will be less significant.

In addition to the direct impact of the staff-recommended final rule described above, there are indirect impacts. As discussed above, once the new requirements become effective, all manufacturers will be subject to the additional costs associated with third party testing and certification requirements triggered by the final rule. Those additional third party testing costs will pertain to any physical and mechanical test requirements specified in the hand-held infant carrier final rule; lead and phthalates testing is already required. Based on durable nursery product industry input and confidential business information supplied for the development of the third party testing rule, testing to the physical and mechanical requirements could cost $500 to $1,000 per model sample.

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 to $2,000 annually. Based on a review of firm revenues, the impact of third party testing to ASTM F2050-13a 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

As with manufacturers of compliant hand-held infant carriers, staff does not believe that the eight small importers of hand-held infant carriers currently in compliance with F2050-12 will experience significant direct impacts as a result of the staff-recommended final rule. In the absence of regulation, these importing firms would likely continue to comply with the voluntary standard as it evolves.

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 final rule, which could potentially be the case with the nine importers of hand-held infant carriers not believed to be in compliance with F2050-12. Some could respond to the rule by discontinuing the import of their non-complying hand-held infant carriers, possibly discontinuing the product line altogether. For some, the impact of such a decision could be mitigated by replacing the non-compliant carrier with a compliant carrier, or by deciding to import an alternative product. However, for some importers this might not be an option because they are directly affiliated with a particular foreign company.

As is the case with manufacturers, all importers will be subject to third party testing and certification requirements, and consequently, importers 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 may have to perform the testing themselves if more than one sample per model were required.

Moses Basket Suppliers

There are 22 known small firms whose supply of hand-held infant carriers to the U.S. market consists exclusively of Moses baskets. These firms specialize in the supply of bedding, and each sells Moses baskets with the bedding that lines the baskets. Staff has been unable to determine the source(s) of the Moses baskets themselves, although it is likely that most sellers purchase them from other suppliers. Because suppliers of these products have not typically participated in the ASTM process, it is unlikely that any of them have been designed to comply with this standard. However, it is probable that many might be able to comply with the staff-recommended final rule with minimal modifications.

While Moses baskets would not be subject to most of the hand-held carrier standard's performance requirements, they would have to meet the slip-resistance requirement. Although no testing was conducted, it is the technical opinion of the staff that it is unlikely that these products would require modifications to meet this requirement (that the product does not slip on

surface 10 degrees from horizontal while facing forward, sideways, and to the rear), given the texture of typical Moses basket fabrication materials. Therefore, the biggest changes might be to add warnings and instructional literature, which are generally not expected to be costly. Alternatively, Moses basket suppliers could remove themselves from the scope of the staff-recommended final rule by eliminating 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.

All Moses baskets will be subject to third party testing and certification requirements. Moses baskets suppliers who import their Moses baskets could experience testing costs if their supplying firm(s) does not perform third party testing. Since Moses baskets would not be subject to most of the mechanical tests in the staff-recommended final rule, it is expected that third party testing costs will be, at most, half the amount for other types of hand-held infant carriers, $250 to $500 per model sample. After reviewing each firm's product line, it appears that most firms use only one model of Moses basket for their bedding, although some firms have up to four variations of Moses baskets. The resulting costs are unlikely to have a significant impact on firms that must perform the testing themselves.

Alternatives

One alternative that would reduce the impact on small entities would be to set an effective date later than the staff-recommended six months that is generally considered sufficient time for suppliers to come into compliance with a 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. Staff believes that six months is sufficient for the staff-recommended final rule.

The 1112 Rule and the Impact on Small Conformity Assessment Bodies

Children's product firms must certify the compliance of their products, based on third party testing, as part of the 1107 rule. In accordance with section 14 of the Consumer Product Safety Act (CPSA), the third party testing must be performed by an accredited conformity assessment body, and section 14(a)(3) of the CPSA requires the Commission to publish a notice of requirements (NOR) for the accreditation of third party conformity assessment bodies (or testing laboratories) to test for conformance with each children's product safety rule. Effective June 10, 2013, the Commission published a final rule, *Requirements Pertaining to Third Party Conformity Assessment Bodies* (78 FR 15836), which codifies part 1112, establishing requirements for the accreditation of third party conformity assessment bodies (or laboratories) to test for conformance with a children's product safety rule in accordance with Section14(a)(2) of the CPSA. The final rule also codified all of the prior NORs that the CPSC had published. All new NORs, such as the hand-held infant carrier standard, require amendments to the 1112 rule.

A Final Regulatory Flexibility Analysis (FRFA) was conducted as part of the 1112 rule (78 FR 15836, 15855-58) as required by the RFA. Briefly, the FRFA concluded that the requirements would not have a significant adverse impact on a substantial number of small conformity assessment bodies (laboratories) because no requirements are imposed on laboratories that do not intend to provide third party testing services under section 14(a)(2) of the CPSA. The only laboratories that are expected to provide such services are those that anticipate receiving sufficient revenue from providing the mandated testing to justify accepting the requirements as a business decision.

Similarly, amending the 1112 rule to include the NOR for the hand-held infant carrier standard would not have a significant adverse impact on small laboratories. Few laboratories in the United States have applied for CPSC acceptance of the accreditation to test for conformance to other juvenile product standards; thus, it is likely that only a few laboratories will seek CPSC acceptance of their accreditation to test for conformance with the hand-held infant carrier standard as well. Most of these laboratories will have already been accredited to test for conformance to other juvenile product standards. Therefore, the only costs to them would be the cost of adding the hand-held infant carrier standard to their scope of accreditation. As a consequence, the Commission could certify that the NOR for the hand-held infant carrier standard will not have a significant impact on a substantial number of small entities.