The contents of this document will be discussed at the Commission Meeting (Briefing) scheduled for Wednesday, March 20, 2013.

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

This document has been electronically approved and signed.

DATE: March 13, 2013

THIS MATTER IS NOT SCHEDULED FOR A BALLOT VOTE.

A DECISIONAL MEETING FOR THIS MATTER IS SCHEDULED ON: **April 3, 2013**

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Stephanie Tsacoumis, General Counsel
Kenneth R. Hinson, Executive Director

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

SUBJECT: Notice of Proposed Rulemaking: Safety Standard for Soft Infant and Toddler Carriers

The Office of the General Counsel is providing for Commission consideration the attached draft proposed rule for publication in the *Federal Register*. The proposed rule would establish a safety standard for soft infant and toddler 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: *Federal Register* Notice of Proposed Rulemaking to Establish a Safety Standard for Soft Infant and Toddler Carriers

Billing Code 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1226

Docket No. CPSC-2013-

Safety Standard for Soft Infant and Toddler Carriers

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: The Danny Keysar Child Product Safety Notification Act, Section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), requires the United States Consumer Product Safety Commission (Commission or CPSC) to promulgate consumer product safety standards for durable infant or toddler products. These standards are to be "substantially the same as" applicable voluntary standards or more stringent than the voluntary standard if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product. The Commission is proposing a safety standard for soft infant and toddler carriers in response to the direction under Section 104(b) of the CPSIA.

DATES: Submit comments by [INSERT DATE 75 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**]**.

ADDRESSES: Comments related to the Paperwork Reduction Act aspects of the marking, labeling, and instructional literature of the proposed rule should be directed to the Office of Information and Regulatory Affairs, OMB, Attn: CPSC Desk Officer, FAX: 202-395-6974, or e-mailed to oira_submission@omb.eop.gov.

Other comments, identified by Docket No. CPSC-2013- , may be submitted electronically or in writing:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: http://www.regulations.gov. Follow the instructions for submitting comments. The Commission does not accept comments submitted by electronic mail (e-mail), except through www.regulations.gov. The Commission encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

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

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

Docket: For access to the docket to read background documents or comments received, go to: http://www.regulations.gov, and insert the docket number, CPSC-2013- , into the "Search" box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Gregory K. Rea, Project Manager, Director, Division of Mechanical Engineering, Directorate for Laboratory Sciences, Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone: 301-987-2258; e-mail: grea@cpsc.gov.

SUPPLEMENTARY INFORMATION:

I. Background and Statutory Authority

The Consumer Product Safety Improvement Act of 2008 (CPSIA, Pub Law 110-314) was enacted on August 14, 2008. Section 104(b) of the CPSIA, part of the Danny Keysar Child Product Safety Notification Act, requires the Commission to: (1) examine and assess the effectiveness of voluntary consumer product safety standards for durable infant or toddler products, in consultation with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts; and (2) promulgate consumer product safety standards for durable infant and toddler products. These standards are to be "substantially the same as" applicable voluntary standards or more stringent than the voluntary 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."

In this document, the Commission is proposing a safety standard for soft infant and toddler carriers. "Infant carriers" are specifically identified in section 104(f)(2)(H) of the CPSIA as durable infant or toddler products. The Commission has identified at least four types of products that fall within the product category of "infant carriers," including: frame backpack carriers, handheld infant carriers, slings, and soft infant and toddler carriers. This proposed rule addresses hazards associated only with soft infant and toddler carriers. Recently, the Commission issued a proposed rule on handheld infant carriers (77 FR 73354 (Dec. 10, 2012)). Hazards associated with frame backpack carriers and slings will be addressed separately in future rulemaking proceedings.

Pursuant to Section 104(b)(1)(A), the Commission consulted with manufacturers, retailers, trade organizations, laboratories, consumer advocacy groups, consultants, and members of the public in the development of this proposed standard, largely through the ASTM process. The proposed rule is based on the voluntary standard developed by ASTM International (formerly the American Society for Testing and Materials), ASTM F2236-13, "Standard Consumer Safety Specification for Soft Infant and Toddler Carriers" (ASTM F2236-13), without alteration. The ASTM standard is copyrighted, but it can be viewed as a read-only document during the comment period on this proposal only, at: http://www.astm.org/cpsc.htm, by permission of ASTM.

II. Product Description

A. Definition of a Soft Infant and Toddler Carrier

ASTM F2236-13 defines "soft infant and toddler carrier" as "a product, normally of sewn fabric construction, which is designed to contain a full term infant to a toddler, generally in an upright position, in close proximity to the caregiver." Additionally, soft infant and toddler carriers are generally designed to carry a child "between 7 and 45 pounds." ASTM F2236-13 explains that soft infant and toddler carriers are "normally 'worn' by the caregiver with a child positioned in the carrier and the weight of the child and carrier suspended from one or both shoulders of the caregiver. These products may be worn on the front, side, or back of the caregiver's body, with the infant either facing towards or away from the caregiver." Typically children are carried in soft infant and toddler carriers on the front of a caregiver, but some products on the market can be configured to carry a child upright on a caregiver's front, back, or hip.

Two broad classes of soft infant and toddler carriers are available in the United States: structured and nonstructured. Structured soft infant and toddler carriers contain straps and waist belts that connect, to the seat area of the carrier and each other, with buckles, straps, and other mechanical fasteners. The straps, belts, and seating area of these products are often stiffened with padding and typically have a heavy textile covering. Nonstructured products, such as the mei-tai design, consist of a flat, textile center that acts as the seat area with waist straps and very long (5 to 6 feet) upper straps. The upper straps wrap over the caregiver's shoulders, cross in the back, and are brought around the waist to the front of the caregiver. The upper straps are then secured over the child's legs to form the leg openings and secure the child in an upright position. ASTM F2236-13 does not distinguish between products based on whether they are structured or nonstructured; requirements apply equally to all types of soft infant and toddler carriers.

The definition of a "soft infant and toddler carrier" is intended to distinguish it from other types of infant carriers that are also worn by a caregiver but that are not covered under ASTM F-2236-13, specifically slings (including wraps), and framed backpack carriers. Soft infant and toddler carriers are designed to carry a child in an upright position. Slings are designed to carry a child in a reclined position; although some slings may also be used to carry a child upright. Thus, the primary distinction between a sling and a soft infant and toddler carrier is the sling's design that allows for carrying a child in a reclined position. Different hazard patterns arise from carrying a child in a reclined position. Accordingly, slings are not included in the standard for soft infant and toddler carriers. Like soft infant and toddler carriers, framed backpack carriers are intended to carry a child in an upright position, but are distinguishable because typically, they are constructed of sewn fabric over a rigid metal structure and are solely intended for carrying a child on the caregiver's back.

B. Market Description

Soft infant and toddler carriers are generally produced and/or marketed by juvenile product manufacturers and distributors. Several of these firms focus exclusively on soft infant and toddler carriers, as well as substitute products, such as slings. CPSC staff believes that at least 39 firms supply soft infant and toddler carriers to the U.S. market. Thirty-one domestic firms supply soft infant and toddler carriers to the U.S. market: 15 are domestic manufacturers; eight are domestic importers; and the supply sources of eight domestic firms are unknown. Five foreign firms supply soft infant and toddler carriers to the U.S. market: three are foreign manufacturers; one is a foreign importer; and one firm has an unknown supply source. Insufficient information is available on the remaining three firms to categorize them.

According to a 2005 survey conducted by the American Baby Group (*2006 Baby Products Tracking Study*), 51 percent of new mothers own soft infant and toddler carriers. Approximately 30 percent of soft infant and toddler carriers were handed down or purchased secondhand, meaning that about 70 percent of the products were acquired new. This suggests that approximately 1.5 million soft infant and toddler carriers are sold to households annually (.51 x .70 x 4.1 million births per year). Typically, soft infant and toddler carriers are used during a child's first year, with some caregivers continuing to use these products into the second year. We estimate use into a child's second year under the assumption that approximately 25−50 percent of caregivers continue to use these products. Based on data from the *2006 Baby Products Tracking Study*, approximately 2.1 million soft infant and toddler carriers are owned by new mothers. Thus, we estimate that approximately 2.6−3.2 million households have soft infant and toddler carriers available for use annually.

III. Incident Data

CPSC's Directorate for Epidemiology, Division of Hazard Analysis is aware of 93 incidents related to soft infant and toddler carriers—reported over a period of nearly 13 years—beginning in January 1999 through early September 2012. Two incidents involved a fatality, and 91 incidents were nonfatal.

A. Fatalities

Two suffocation fatalities were reported to CPSC from January 1999 to September 2012. The first fatality involved a 5-week-old male who fell asleep in the soft infant and toddler carrier after a feeding. About 20 minutes after the feeding, he appeared unresponsive. The official cause of death was listed as positional asphyxia. The second fatal incident occurred when a 2-month-old female fell asleep in a soft infant and toddler carrier worn by her parent. The parent lay down on a couch to sleep for the night while still wearing the carrier with the infant inside. The parent awoke the next morning to find the child unresponsive with her face pressed into the parent's chest. Staff could not directly attribute the two reported fatalities to product design or mechanical failure of the soft infant and toddler carrier.

B. Nonfatalities

Approximately 33 percent (30) of the 91 nonfatal incidents involved reports of an injury to an infant during use of a soft infant and toddler carrier. A majority of the injuries resulted from falls from the carrier. All of the injuries in which the age of the victim was available were reportedly sustained by infants who were 1 month to 13 months old. However, most of the incidents involved infants 6 months and younger. Although the remaining 61 nonfatal incidents reported that no injury had occurred, many of the descriptions indicated the potential for a serious injury or death.

Eight of the nonfatal incident reports involved skull fractures as a result of the childfalling out of the product. Five skull fracture injuries reportedly required hospitalization; the three remaining skull fracture injury reports did not mention any hospitalizations. Some of the remaining injuries reported included: collarbone and limb fractures, contusions, abrasions, blisters, and scratches.

C. Hazard Pattern Identification

The primary hazard associated with use of a soft infant and toddler carrier is falling, either caregivers falling while wearing the carrier and injuring the child in the carrier, or children falling or facing the risk of falling from the carrier due to fastener problems, large leg openings, stitching or seam problems, or straps that slip. A majority of the reported incidents summarized in Table 1 below, and all seven of the recalls described in section III.E, involved an actual fall or potential risk of a child falling from a carrier.

Staff classified the 93 reported incidents by the issues—product feature, design element, or failure—primarily responsible for the incident and summarized this data in Table 1, below. An explanation of the categories represented in Table 1 follows.

Fastener problems: Twenty-five of the 93 incidents (27 percent) were related to fastener problems, such as snaps breaking/unexpectedly releasing, or buckles breaking/detaching/pinching/unexpectedly releasing. Six injuries, but no fatalities, were included among these reports.

Structure, fit, and position issues: Fourteen of the 93 incidents (15 percent) were related to aspects of the leg- and torso-opening design, how the carrier held the infant, and where the carrier was positioned on the caregiver. Examples of scenarios reported include: an infant slipping down far into the carrier and suffering an injury when the caregiver went into a bent

position; an infant falling out of the carrier when the caregiver bent forward; and leg circulation-related injuries. There were 10 injuries reported in this category. No reported fatalities were associated with this issue.

Problems with large leg openings: Twelve of the 93 incidents (13 percent) were related to leg openings that were too large and that allowed the infant to slip through completely and fall out of the carrier. While there were no fatalities among these reports, there were seven injuries; three involved infants who were hospitalized for skull fractures.

Issues with stitching/seams: Ten reports (11 percent) were received about stitching on the carrier coming undone or seams ripping, resulting in other components, like straps, detaching and creating a fall hazard. One injury was included among these reports.

Design and finish-related issues: Eight reports (nine percent) of inadequate back support, rough fabric, poor air flow in the carrier insert, and other design issues were received. No fatalities were noted, but two injuries were associated with these issues.

Strap issues: Eight incidents (nine percent) reported issues with straps, mostly about the adjuster breaking or slipping. No injuries or fatalities were reported in this category.

Other issues: Eleven reports (12 percent) were related to issues other than those described above. Two fatalities and four injuries, including two hospitalizations, were reported in this category. The two fatalities—one case of a parent falling asleep while wearing the carrier with the infant inside, and the other case of an infant suffering respiratory distress while being carried around facing in—are included in this category. In each case, CPSC staff concluded that there were too many confounding factors reported to determine that a specific factor contributed predominantly to the deaths. The remaining reports were of unspecified falls, an nonspecific abrasion injury, and an incidental injury to the infant, due to a caregiver's fall.

Table 1. Distribution of Reported Incidents by Hazard Patterns
Associated with Soft Infant and Toddler Carriers
Reporting Period: January 1, 1999–September 10, 2012

Issues	***Total Reports***		***Deaths***		***Injuries***	
	Count	*Percentage*	*Count*	*Percentage*	*Count*	*Percentage*
Mechanical Issues	**77**	**83**	**0**	**0**	**26**	**87**
Fasteners	*25*	*27*	*0*	*0*	*6*	*20*
Structure, fit, and position	*14*	*15*	*0*	*0*	*10*	*33*
Large leg openings	*12*	*13*	*0*	*0*	*7 (3 hosp.)*	*23*
Stitching/seams	*10*	*11*	*0*	*0*	*1*	*3*
Design and finish	*8*	*9*	*0*	*0*	*2*	*7*
Straps	*8*	*9*	*0*	*0*	*0*	*0*
Other	**11**	**12**	**2**	**100**	**4** *(2 hosp.)*	**13**
Consumer Comments	**5**	**5**	**0**	**0**	**0**	**0**
Total	**93**	**100**	**2**	**100**	**30**	**100**

Source: U.S. Consumer Product Safety Commission's epidemiological databases IPII, INDP, and DTHS.
Note: The percentages have been rounded to the nearest integer. Subtotals do not necessarily add to heading totals.

D. NEISS Data

In addition to the 93 incident reports received by the Commission, we estimated the number of injuries treated in U.S. hospital emergency departments using the CPSC's National Electronic Injury Surveillance System (NEISS). We estimate that over a 13-year-period, a total of 1,400 injuries related to soft infant and toddler carriers were treated in U.S. hospital emergency departments from 1999 through 2011. Because CPSC's NEISS data for 2012 will be finalized in spring 2013, partial estimates for 2012 are not available. The injury estimates for individual years are based on very small samples and are not reportable. According to the NEISS publication criteria, an estimate must be 1,200 or greater, the sample size must be 20 or greater, and the coefficient of variation must be 33 percent or smaller. Moreover, due to the unreliability of the yearly estimates, a trend analysis is not feasible.

No fatalities were reported through NEISS. Although data extraction criteria included ages up to 4 years, all of the injured children were reported to be less than 2 years of age. A

breakdown of the characteristics among the emergency department-treated injuries associated with soft infant and toddler carriers is presented in the bullets below.

- Hazard – Getting struck while in the carrier when caregiver fell (65%); falling out of the carrier (21%).
- Injured body part – Head (63%); face (11%).
- Injury type – Internal organ injury (48%); contusions/abrasions (19%); and fractures (12%).
- Disposition – Treated and released (79%); hospitalized (10%); and treated and transferred (9%).

E. Product Recalls

Seven product safety recalls, recalling 652,250 units, were announced between January 1, 1999 and June 17, 2010 that involved a fall hazard related to use of a soft infant and toddler carrier. These recalls related to 130 incident reports received by the CPSC. A breakdown of the specific product defect necessitating the recall, product units involved, and the number of incident reports received is presented in the chart below. At the time the products were recalled, nine infants had been injured significantly in incidents that ranged from bruises to skull fractures. Additional information on these recalls can be found on the Commission's websites at: www.cpsc.gov or www.saferproducts.gov.

Soft Infant and Toddler Carrier Recall Summary January 1, 1999 through June 17, 2010						
Manufacturer	**Model**	**Year Recalled**	**Units Recalled**	**Reason**	**Incident Reports**	**Injury Reports**
Evenflo Company & Hufco-Delaware, Inc.	Model 070 & 080 Snugli® Front and Back Pack™	1999	327,000	Infant shifts to side & slips through leg opening, falls out.	13	One - fractured skull; two - bruises
Baby Swede, LLC	Baby Bjorn	1999	240,000 (Recall to Repair)	Infants slip through leg openings - fall. Infants < 2 months - highest risk.	9	Six fractured skulls
Baby Swede, LLC	Baby Bjorn Carrier Active	2004	49,000	Back support buckles detach from shoulder straps - pose fall hazard.	93	No injuries reported.
Playtex Products, Inc.	Playtex Hip Hammock	2005	32,000	Shoulder strap detaches from Hammock, posing fall hazard.	2	No injuries reported.
Beco Baby Carrier, Inc.	Beco Baby Carrier Butterfly	2008	2,000	Shoulder strap buckles unexpectedly release tension - straps slip through - pose fall hazard.	8	No injuries reported.
Optave, Inc.	Action Baby Carrier	2008	250	Chest strap can detach from shoulder straps, posing fall hazard to infant.	2	No injuries reported.
Regal Lager, Inc.	CYBEX 2. GO Infant Carriers	2010	2,700 U.S. 400 Canada	Shoulder strap slider buckle can break, posing fall hazard to infant.	3	No injuries reported.

IV. Soft Infant and Toddler Carrier International Standard and ASTM Voluntary Standard

Section 104(b)(1)(A) of the CPSIA requires the Commission to consult representatives of "consumer groups, juvenile product manufacturers, and independent child product engineers and experts" to "examine and assess the effectiveness of any voluntary consumer product safety standards for durable infant or toddler products." As a result of fall-related incidents and recalls of soft infant and toddler carriers, CPSC staff previously requested ASTM to develop voluntary requirements to address the hazards related to large leg openings. Through the ASTM process, we

consulted with manufacturers, retailers, trade organizations, laboratories, consumer advocacy groups, consultants, and members of the public. The voluntary standard for soft infant carriers was first approved and published in April 2003, as ASTM F2236-03, *Standard Consumer Safety Performance Specification for Soft Infant Carriers.* It has been revised six times since then. The current version, ASTM F2236-13, renamed *Standard Consumer Safety Performance Specification for Soft Infant and Toddler Carriers*, was approved on March 1, 2013 and published in March 2013.

In addition to reviewing the ASTM standard, we reviewed the only international standard for soft infant carriers of which we are aware, EN13209-2:2005 *Child Use and Care Articles – Baby Carriers – Safety Requirements and test Methods – Part 2: Soft Carrier*.

A. International Standard

CPSC evaluated requirements in ASTM F2236-13 and EN13209-2:2005 and determined that the requirements in ASTM F2236-13 are more stringent than EN13209-2:2005, and that they address the incidents seen in the data and reduce the risk of injury from these products. The few EN13209-2:2005 requirements without an ASTM F2236-13 counterpart address hazard patterns not found in the incident reports considered for this proposed rule.

B. Voluntary Standard – ASTM F2236

1. History of ASTM F2236

Initially, ASTM F2236-03 addressed falls related to large leg openings. The standard's bounded leg opening performance requirement limited the size of the leg opening to prevent infants from falling through large adjustable leg openings. The standard also established requirements to address sharp points and edges, small parts, lead in paints, wood parts, locking and latching of fasteners, dynamic load testing, static load testing, and product labeling. The

scope of the standard was based on the manufacturers' recommended use of the product with infants weighing 7 to 25 pounds.

The next update of the voluntary standard was published in March 2008. ASTM F2236-03 addressed fall issues with bounded leg openings that were too large but did not consider the ability of an *unbounded* leg opening to retain the occupant. An unbounded leg opening is created by placing the soft carrier on a caregiver's torso, with a leg opening circumference comprised of carrier materials and the caregiver's torso. Accordingly, to address additional fall hazards, an unbounded leg opening performance requirement was added to ASTM F2236-08. ASTM F2236-08a was published in November 2008, to add general requirements included in other ASTM standards for durable children's products that address hazards associated with toy accessories and flammability.

ASTM F2236-09 was published in April 2009. The statement that the child occupant must face the caregiver until the child can hold its head upright was moved in this version of the standard from the warning label to be an informational statement. ASTM F2236-10, published in December 2010, clarified further that the informational statement for a child to face the caregiver until the child can hold its head upright was unnecessary for soft infant carriers that have only one use position with the child facing the caregiver.

ASTM F2236-12 was published in December 2012. Several sections of the voluntary standard were revised based on input from CPSC staff. The scope was expanded to increase the upper weight limit of products within the scope of the standard from 25 to 45 pounds and to include specifically in the title of the standard the word "toddler." ASTM F2236-12 also included a new definition in the terminology section of the standard for "carrying position," to clarify procedures for dynamic and static load testing. Finally, the test methods for dynamic

Noand static load testing were modified to increase the weight load required for testing to ensure adequate testing of products that are designed to carry heavier children.

2. Description of the Current Voluntary Standard – ASTM F2236-13

ASTM F2236-13 was published in March 2013. Together with the changes described in ASTM F2236-12, ASTM F2236-13 reflects the most significant revisions to the standard, to date. Revisions include modified and new requirements developed by CPSC staff, working with stakeholders on the ASTM subcommittee task group, to address the hazards associated with soft infant and toddler carriers. ASTM F2236-13 includes the following key provisions: scope, terminology, general requirements, performance requirements, test methods, marking and labeling, and instructional literature.

Scope. The scope of the standard was updated in December 2012, to broaden the upper weight limit from 25 to 45 pounds for products falling within the standard. Expanding the scope of the standard ensures that all soft infant and toddler carrier products currently on the market are covered by the standard. The name of the standard was altered at the same time to include the word "toddler," to clarify that toddlers can also be carried in these products. The scope of the standard also distinguishes soft infant and toddler carriers from other wearable infant carrier products, by describing that soft infant and toddler carriers are "normally of sewn fabric construction," hold the child "generally in an upright position," and "may be worn on the front, side, or back of the caregiver's body." Finally, the scope of the standard states that it does not apply to infant slings.

Terminology. Section 3.1 of the standard includes 14 definitions that help to explain general and performance requirements. Section 3.1.7 of the standard explains that a "leg opening" is the "opening in the soft carrier through which the occupant's legs extend when the

product is used in the manufacturer's recommended use position." Sections 3.1.4 and 3.1.13 of ASTM F2236-13, respectively, explain that a "dynamic load" is the "application of impulsive force through free fall of a weight," and that a "static load" is a "vertically downward force applied by a calibrated force gage or by dead weights." A new definition for "carrying position" was added in ASTM F2236-12, to clarify methods for dynamic and static load testing in section 7 of the standard. Also, a new definition for "fastener" was included in ASTM F2236-13, to aid in a new test for fastener strength and strap retention.

General Requirements. ASTM F2236-13 includes general requirements that the products must meet, as well as specified test methods to ensure compliance with the general requirements, which include:

- Restrictions on sharp points or edges, as defined by 16 CFR §§ 1500.48 and .49;
- Restrictions on small parts, as defined by 16 CFR part 1501;
- Restrictions on lead in paint, as set forth in 16 CFR part 1303;
- Requirements for locking and latching devices;
- Requirements for permanent warning labels;
- Restrictions on flammability, as set forth in 16 CFR part 1610;
- Requirements for toy accessories, as set forth in ASTM F 963.

The flammability requirement in section 5.7 of the standard was changed in ASTM F2236-13 from a flammable solids requirement (16 CFR § 1500.3(c)(6)(vi)) to meet the more stringent flammability requirement for wearing apparel (16 CFR part 1610). The flammability requirement was altered to be consistent with other wearable infant carriers made of sewn fabric, such as slings, to prevent a foreseeable fire hazard in all wearable infant carriers.

Performance Requirements and Test Methods. ASTM F2236-13 provides performance requirements and test methods that are designed to protect against falls from the carrier due to large leg openings, breaking fasteners or seams, and straps that slip, including:

Leg Openings – Tested leg openings must not permit passage of a test sphere weighing 5 pounds that is 14.75 inches in circumference.

Dynamic and Static Load – Beginning with the 2012 version of ASTM F2236, the dynamic load test was strengthened from requiring a 25-lb. shot bag to be dropped, free fall, from 1 inch above the seat area onto the carrier seat 1,000 times, to requiring testing with a 25-lb, shot bag, or a shot bag equal to the manufacturer's maximum occupant weight limit, whichever is heavier. Also, the static load test was altered from requiring a 75-lb. weight for testing, to requiring a 75-lb. weight, or a weight equal to three times the manufacturer's recommended maximum occupant weight, whichever is greater, to be placed in the seat area of the carrier for 1 minute. This revision means that products with a maximum recommended weight of 45 pounds must be tested to a 135-pound weight instead of 75 pounds, an 80 percent increase in the severity of the requirement.

Testing with the new required loads must not result in a "hazardous condition," as defined in the general requirements, or result in a structural failure, such as fasteners breaking or disengaging, or seams separating when tested in accordance with the dynamic and static load testing methods. Additionally, dynamic and static load testing must not result in adjustable sections of support/shoulder straps slipping more than 1 inch per strap from their original adjusted position after testing.

Fastener Strength and Strap Retention – ASTM F2236-13 added a new component-level performance requirement to evaluate the strength of fasteners and strap retention to help prevent

falls. Products recalled due to an occupant fall hazard were caused by broken fasteners that passed the static and dynamic performance requirements in ASTM F2236-10. Accordingly, the new performance requirement, section 6.4 of ASTM F2236-13, states that load-bearing fasteners at the shoulder and waist of soft infant and toddler carriers, such as buckles, loops, and snaps, may not break or disengage, nor may their straps slip more than 1 inch when subjected to an 80-pound pull force. Adjustable leg opening fasteners must also be tested, but are subjected to lower loads, a 45-pound pull force, because these fasteners do not carry the same load as fasteners at the shoulders and waist. When tested, fasteners must not break or disengage, and adjustable elements must not slip more than 1 inch.

Unbounded Leg Opening – ASTM F2236-13 clarifies the unbounded leg opening test procedure to improve test repeatability. An unbounded leg opening must not allow complete passage of a truncated test cone that is 4.7 inches long, with a major diameter of 4.7 inches and a minor diameter of 3 inches. The test cone is pulled through the leg opening with a 5-pound force for 1 minute.

Marking, Labeling, and Instructional Literature. ASTM F2236-13 requires that each product and its retail package be marked or labeled with certain information and warnings. The warning label requirement was updated to address fall and suffocation hazards. The warning label must provide a fall hazard statement addressing that infants can fall through wide leg openings or out of the carrier. The following fall-related warnings must be addressed on the warning label: adjust leg openings to fit baby's legs snugly; before each use, make sure all [fasteners/knots] are secure; take special care when leaning or walking; never bend at waist, bend at knees; only use this carrier for children between __ lbs. and __ lbs. Additionally, a suffocation hazard statement must address that infants under 4 months old can suffocate in the carrier if the

child's face is pressed tightly against the caregiver's body. The warning label must also address the following suffocation-related warnings: do not strap infant too tightly against your body; allow room for head movement; keep infant's face free from obstructions at all times. Products must also contain an informational statement that a child must face toward the caregiver until he or she can hold his or her head upright. Instructional literature must be provided with all products that includes: assembly, use, maintenance and cleaning, and required warnings.

Additionally, ASTM F2236-13 now includes an example warning label that identifies more clearly the hazards, the consequences of the ignoring the warning, and what to do to avoid the hazards. The format of the label was designed to convey more effectively these warnings to the caregiver (Fig. 1). The rectangular shape of this label may be altered to fit on shoulder straps, if the manufacturer chooses not to place label in the occupant space; however, the label must be placed in a prominent and conspicuous location where the caregiver will see it when placing the soft infant and toddler carrier on their body.

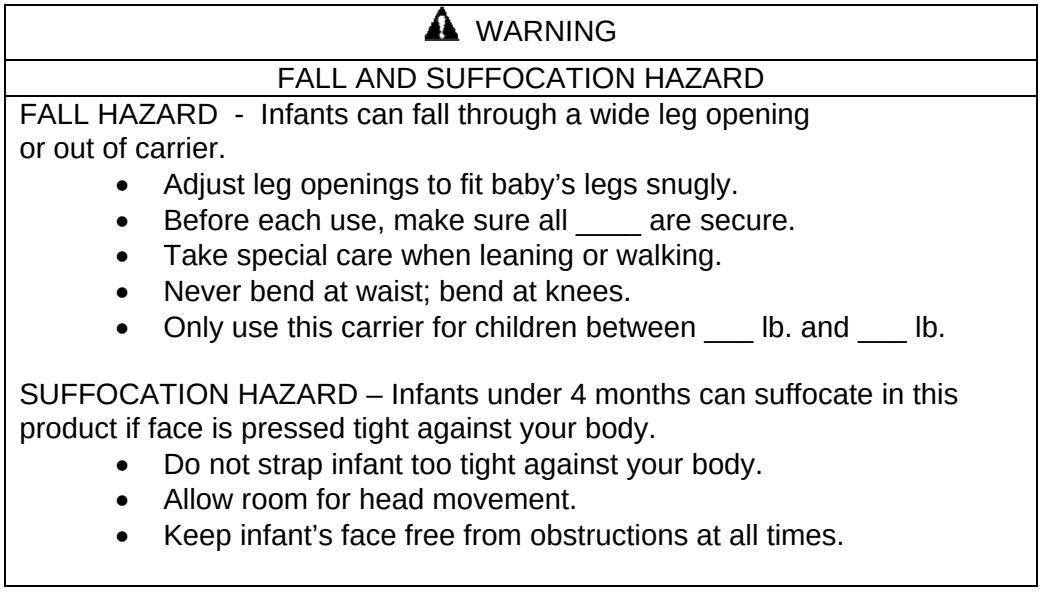

Figure 1. ASTM F2236-13 Example Warning label.

V. Assessment of Voluntary Standard ASTM F2236-13

In this section of the preamble, we evaluate ASTM F2236-13 to determine whether adopting this voluntary standard as a mandatory standard will address the incidents described in section III of this preamble, or whether more stringent standards are required to reduce further the risk of injury associated with soft infant and toddler carriers.

A. Large Leg Openings

Twenty-three percent of the injuries (7 of 30), including three hospitalizations, were caused when a child fell out of a large leg opening. The last incident occurred in 2005, involving a product purchased initially in 2000. The prevalence of this hazard led to product recalls in 1999 (see section III.E above) and led to the creation of ASTM F2236, whose first performance requirement (6.1 and corresponding test 7.1) was developed to limit the size of a soft infant and toddler carrier leg opening. New reports involving the large leg opening hazard ceased within 2 years of the first version of ASTM F2236's publication in 2003. This, combined with CPSC detailed incident reviews, lead us to conclude that the current ASTM standard adequately addresses the large leg opening hazard scenario.

B. Structure, Fit, and Position

Thirty-three percent of injuries reported to the CPSC (10 of 30) were related to the structure of the occupant seat area; fit of the occupant in the carrier; and the position of the soft infant and toddler carrier or the position of the wearer, or the position of the child in the seat area. These incidents occurred, for example, when an infant tucked down into the carrier and the caregiver bent at the waist breaking the child's leg; an infant fell out of the top of the carrier when the caregiver bent forward abrasions and/or blisters on infants from prolonged rubbing against the carrier while in use; and when infants suffered leg circulation-related injuries. New

language in ASTM F2236-13 requires that warning labels address ensuring that fasteners and knots are secure before each use, taking special care when leaning or walking, and bending at the knees, not at the waist, while wearing the carrier. The standard also includes requirements on the format of the label to enhance the label's effectiveness (Fig. 1).

Updated warning language on the product and in the instructional literature may address hazards arising from structure, fit, and position problems if consumers read, understand, and comply with the warnings. The diverse size of potential occupants, the broadrange of caregiver sizes and shapes, and numerous possible motions and activities that could lead to injury cannot be reliably replicated in a laboratory setting, making development of a repeatable test for structure, fit, and position types of injuries prohibitively difficult. A warning label would likely not address the hazard with circulation-related injuries because that hazard may be due to a design issue. The Commission will continue to study incoming reports of leg circulation-related injuries and determine whether any additional action is necessary.

C. Fasteners

Twenty percent of the injuries (6 of 30) were caused by fastener failures when a fastener suddenly broke or separated and the child fell to the ground. Although no hospitalizations resulted from breaking fasteners, three children suffered fractured collarbones, along with contusions and abrasions to heads and faces. The caregiver in a majority of the incidents was able to catch the child and prevent a fall. Fastener failures led to four of the five voluntary product recalls conducted since 2005.

ASTM F2236-13 addresses the hazards posed by fastener failures with a new performance requirement for fastener strength and strap retention, published in section 6.4 and a new test in section 7.7. New requirements state that all load-bearing fasteners, such as buckles,

loops, and snaps may not break or disengage, nor may their straps slip more than 1 inch, when an 80-pound pull force is applied across the fasteners. An exception is made for adjustable leg opening fasteners, which must be subjected to a 45-pound pull force. Adjustable leg opening fasteners see substantially less load than other load-bearing fasteners during foreseeable use and abuse, such as fasteners securing shoulder and waist straps. The fastener strength and strap retention requirements do not apply to non-load-bearing fasteners that attach accessories, such as bibs, rain hoods, and toys to the soft infant and toddler carrier. The Commission believes that the inclusion of this new requirement in ASTM F2236-13 will adequately address the fall hazard related to fastener failures.

D. Design and Finish

Seven percent of the soft infant and toddler injuries (2 of 30) are attributable to design and finish issues. Complaints include inadequate back support, rough fabric, poor air flow in the carrier insert, and one report of high lead levels in a zipper pull. The injuries consist of a pinched finger and a cut on the nose. ASTM F2236-13 includes language prohibiting sharp points and edges, but the standard does not specifically mention pinching. A pinching-shearing-scissoring hazard exists typically in products with rigid parts that move past one another; such a hazard does not generally exist with soft products. No changes to the voluntary standard for design and finish issues are recommended at this time. Section 101 of the CPSIA requires that children's products, such as soft infant and toddler carriers, not contain lead content in excess of 100 parts per million. Accordingly, such requirement does not need to be repeated in ASTM F2236-13.

E. Stitching/seams

Although only three percent of the injuries (1 of 30) involve stitching and seams, 11 percent of the total soft infant carrier reports (10 of 93) describe incidents in which stitching became undone or seams ripped, resulting in other components, like straps, becoming detached. One injury was reported when a seam failed, causing a 4-month-old child to fall and receive minor contusions. The new fastener strength test, and the more stringent dynamic and static load tests in sections 7.7 and 7.2 of ASTM F2236-13, respectively, all apply loads to soft infant and toddler carrier seams and sewn attachment points. The Commission believes that incidents related to ripping seams are adequately addressed by these new requirements in the voluntary standard, and therefore, we are not proposing any additional changes at this time.

F. Straps

Although there were no injuries related to soft infant carrier straps, nine percent of the reported incidents (8 of 93) involve issues with straps. The problems reported include broken strap length adjustment mechanisms and straps that permit unexpected slippage. The new fastener strength and strap retention requirements, and the more stringent dynamic and static load tests in sections 7.7 and 7.2 of ASTM F2236-13, respectively, all apply loads to soft infant and toddler carrier straps, and require that they not break or allow more than 1 inch of slippage. Accordingly, the Commission believes that incidents related to breaking and slipping straps are adequately addressed by these new requirements in the voluntary standard and is not proposing any additional changes at this time.

G. Other

Thirteen percent of the injury reports (4 of 30), including two deaths, contain insufficient information for the CPSC to determine the exact nature of the product's contribution to the

incident. This category includes two fatalities and four injuries, including two hospitalizations. The two fatalities discussed above in section III.A, both involving suffocation, are included in this category. In each case, CPSC staff concluded that there were too many confounding factors reported to determine that a specific factor contributed predominantly to the deaths. ASTM F2236-13 does, however, address in the warning label requirements a suffocation hazard arising from use of soft infant and toddler carriers. The new warning label requirements state that products must address the fact that infants under 4 months old can suffocate if their face is too tight against a caregiver's body, and the label also advises caregivers not to strap the infant too tightly against the body to allow room for head movement and to keep an infant's face free from obstruction at all times.

VI. Effective Date

The Administrative Procedure Act (APA) generally requires that the effective date of the rule be at least 30 days after publication of the final rule. 5 U.S.C. 553(d). To allow time for manufacturers of soft infant and toddler products to come into compliance, the Commission proposes that the standard become effective 6 months after publication of a final rule in the *Federal Register*. The Commission invites comment on whether 6 months will be sufficient time for soft infant and toddler carrier manufacturers to come into compliance with the rule.

VII. Regulatory Flexibility Act

A. Introduction

The Regulatory Flexibility Act (RFA) requires that proposed rules be reviewed for their potential economic impact on small entities, including small businesses. Section 603 of the RFA generally requires that CPSC staff prepare an initial regulatory flexibility analysis and make it available to the public for comment when the general notice of proposed rulemaking is

published. The initial regulatory flexibility analysis must describe the impact of the proposed rule on small entities and identify any alternatives that may reduce the impact. Specifically, the initial regulatory flexibility analysis must contain:

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

B. Market for Soft Infant and Toddler Carriers

Soft infant and toddler carriers are generally produced and/or marketed by juvenile product manufacturers and distributors. Several of these firms focus exclusively on soft infant and toddler carriers, as well as substitute products, such as slings. CPSC staff believes that there are at least 39 suppliers to the U.S. market. Thirty-one domestic firms supply soft infant and toddler carriers to the U.S. market: 15 are domestic manufacturers; eight are domestic importers; and the supply sources of eight domestic firms are unknown. Five foreign firms supply soft infant and toddler carriers to the U.S. market: three are foreign manufacturers; one is a foreign

importer; and one firm has an unknown supply source. Insufficient information is available to categorize the remaining three firms.[1]

According to a 2005 survey conducted by the American Baby Group (*2006 Baby Products Tracking Study*), 51 percent of new mothers own soft infant and toddler carriers.[2] Approximately 30 percent of soft infant and toddler carriers were handed down or purchased secondhand.[3] Thus, about 70 percent of soft infant and toddler carriers were acquired new. This suggests that approximately 1.5 million soft infant and toddler carriers are sold to households annually (.51 x .70 x 4.1 million births per year).[4]

Many soft infant and toddler carriers have expanded their maximum weight limits in recent years to accommodate older children. Staff believes, however, that most adult users would not be comfortable carrying older, heavier children in soft infant and toddler carriers. This belief is supported by a lack of incident data for children over 2 years old. It appears that soft infant and toddler carriers are used during a child's first year, with some caregivers continuing to use these products into the second year. We do not know the proportion who continues to use these products into the second year; accordingly, we estimate risk under the assumption that approximately 25−50 percent will do so. Based on data from the *2006 Baby Products Tracking Study*, approximately 2.1 million soft infant and toddler carriers are owned by new mothers.

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[1] Staff made these determinations using information from Dun & Bradstreet and Reference USAGov, as well as firm websites.

[2] 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.

[3] The data on secondhand products for new mothers was not available. Instead, data for new mothers and experienced mothers were combined and broken down into first-time mothers and experienced mothers. Data for first-time mothers and experienced mothers have been averaged to calculate the approximate percentage of soft infant and toddler carriers that were handed down or purchased secondhand.

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

Therefore, approximately 2.6−3.2 million households have soft infant and toddler carriers available for use annually. Based on Epidemiology staff's estimate of 1,400 injuries treated nationally in emergency departments from 1999 to 2011, it is estimated that an average of 108 emergency department-treated injuries involving children under age 2 related to soft infant and toddler carriers are treated annually. Therefore, about 0.34− 0.40 emergency department-treated injuries may occur annually for every 10,000 soft infant and toddler carriers available for use in the households of new (and second year) mothers.

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

The Danny Keysar Child Product Safety Notification Act, section 104 of the CPSIA, requires the CPSC to promulgate mandatory standards that are substantially the same as, or more stringent than, the voluntary standard for a durable infant or toddler product. CPSC staff worked closely with ASTM to develop the new requirements and test procedures that have been incorporated into ASTM F2236-13, which forms the basis of the proposed rule.

D. Requirements of the Proposed Rule

The requirments of the proposed rule are set forth above in section IV.B.2 of this preamble, which describes ASTM F2236-13.

E. Other Federal Rules

Section 14(a)(2) of the CPSA requires every manufacturer and private labeler of a children's product that is subject to a children's product safety rule to certify, based on third party testing conducted by a CPSC-accepted laboratory, that the product complies with all applicable children's product safety rules. Section 14(i)(2) of the CPSA requires the Commission to establish protocols and standards, by rule, for among other things, ensuring that a children's product is tested periodically and where there has been a material change in the

product, and for safeguarding against the exercise of undue influence on a conformity assessment body by a manufacturer or private labeler. A final rule implementing sections 14(a)(2) and 14(i)(2) of CPSA, *Testing and Labeling Pertaining to Product Certification*, 16 CFR part 1107, became effective on February 13, 2013 (the 1107 rule).

Soft infant and toddler carriers will be subject to a mandatory children's product safety rule, so they will also be subject to the third party testing requirements of section 14 of the CPSA and the 1107 rule when the final rule and the notice of requirements become effective.

F. Impact on Small Businesses

Under U.S. Small Business Administration (SBA) guidelines, a manufacturer of soft infant and toddler 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, 26 of the 31 domestic firms supplying soft infant and toddler carriers to the U.S. market are small firms—12 manufacturers, six importers, and eight firms whose supply source is unknown. Additional unknown small soft infant and toddler carrier suppliers may operate in the U.S. market as well.

Small Manufacturers. The expected impact of the proposed rule on small manufacturers will differ, based on whether their soft infant and toddler carriers are already compliant with ASTM F2236-10. Although ASTM F2236-12 was published in December 2012, and ASTM F2236-13 was published in March 2013, new standards are not in effect until 6 months after publication. Accordingly, firms are likely to be still testing to ASTM F2236-10. In general, firms whose soft infant and toddler carriers meet the requirements of ASTM F2236-10 are likely to continue to comply with the voluntary standard as new versions are published. In addition, they are likely to meet any new standard within 6 months because this is the amount of time

JPMA allows for products in its certification program to shift to a new standard. Many of these firms are active in the ASTM standard development process, and compliance with the voluntary standard is part of an established business practice.

The impact on seven of 12 domestic manufacturers who comply with ASTM F2236-10 is expected to be small. Firms already in compliance with ASTM F2236-10 may require slight, if any, modifications, in order to bring their product(s) into compliance with the current voluntary standard. Any strap/fastener modifications are expected to incur minimal costs, as are changes to the warning label.

Meeting ASTM F2236-13's requirements could necessitate some product redesign for five of the 12 domestic manufacturers who are not believed to be compliant with ASTM F2236-10. These redesigns would likely involve adding or changing straps, fasteners, or fabrics; and partial redesigns are generally less expensive than complete redesigns, based on past discussions with manufacturers. For the types of changes that might be required to be made to these products, staff does not believe that complete redesigns (*e.g.*, engineering time, prototype development, and tooling) would be required for any known products. Therefore, in most cases, the impact of the proposed rule is not expected to have a significant effect on products that are not believed to be compliant with ASTM F2236-10.

It is possible that some firms whose soft infant and toddler carriers are neither certified as compliant, nor claim compliance with ASTM F2236-10 (or a similar standard), in fact, are compliant with the standard. CPSC staff has identified many such cases with other infant and toddler products. To the extent that some of these firms may supply compliant soft infant and toddler carriers and have developed a pattern of compliance with the voluntary standard, the direct impact of the proposed rule will be less significant than described above.

Eight small firms have unknown supply sources, three of which appear to be compliant with ASTM F2236-10. If these firms are manufacturers, they will be affected as described above. If these firms are distributers or wholesalers, the impact will be similar to the impact on importers, as discussed below.

In addition to the direct impact of the proposed rule, indirect impacts exist. These impacts are considered indirect because they do not arise directly as a consequence of the proposed rule's requirements. Once the rule becomes final and the notice of requirements is in effect, all manufacturers will be subject to the additional costs associated with the third party testing and certification requirements. This will include any physical and mechanical test requirements specified in the final rule. Because lead and phthalates testing are already required for soft infant and toddler products, they are not included in this discussion.

Staff estimates that testing to the ASTM voluntary standard could cost about $500−$600 per model sample. On average, each small domestic manufacturer supplies two different models of soft infant and toddler carriers to the U.S. market annually. Therefore, if third party testing is conducted every year on a single sample for each model, third party testing costs for each manufacturer would be about $1,000−$1,200 annually. Based on a review of firms' revenues, the impact of third party testing to ASTM F2236-13─if only one soft carrier sample per model is required─is unlikely to be significant. However, these costs could be more significant if multiple models are needed for testing.

Small Importers. Most importers would not experience significant impacts as a result of the proposed rule. Five of the six small importers are believed to be compliant with the voluntary standard. In the absence of regulation, these firms would likely continue to comply with the voluntary standard as it evolves and would likely comply with the final mandatory

standard as well. The remaining importer might need to find an alternate source of soft infant and toddler carriers if its existing supplier does not come into compliance with the requirements of the proposed rule. Alternatively, the firm may discontinue importing soft infant and toddler carriers altogether and perhaps substitute another product.

As is the case with manufacturers, all importers will be subject to third party testing and certification requirements, and consequently, they will experience the associated costs 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. In addition, the impacts could be higher than those incurred by domestic manufacturers if importers have to test each batch imported in the case where the foreign manufacturer does not conduct testing.

G. Alternatives

Under the Danny Keysar Child Product Safety Notification Act, section 104 of the CPSIA, one alternative would be to set an effective date later than the proposed 6 months, which is generally considered sufficient time for suppliers to come into compliance with a proposed durable infant and toddler product rule. Setting a later effective date would allow suppliers additional time to modify and/or develop compliant soft infant and toddler carriers and spread the associated costs over a longer period of time.

VIII. Environmental Considerations

The Commission's regulations address whether we are required to prepare an environmental assessment or an environmental impact statement. If our rule has "little or no potential for affecting the human environment," it will be categorically exempted from this requirement. 16 CFR 1021.5(c)(1). The proposed rule falls within the categorical exemption.

IX. Paperwork Reduction Act

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

- a title for the collection of information;
- a summary of the collection of information;
- a brief description of the need for the information and the proposed use of the information;
- a description of the likely respondents and proposed frequency of response to the collection of information;
- an estimate of the burden that shall result from the collection of information; and
- notice that comments may be submitted to the OMB.

Title: Safety Standard for Soft Infant and Toddler Carriers

Description: The proposed rule would require each soft infant and toddler carrier to comply with ASTM F2236-13, *Standard Consumer Safety Specification for Soft Infant and Toddler Carriers*. Sections 8.1 and 9.1 of ASTM F2236-13 contain requirements for marking, labeling, and instructional literature that are disclosure requirements, thus falling within the definition of "collections of information" at 5 C.F.R. 1320.3(c).

Description of Respondents: Persons who manufacture or import soft infant and toddler carriers.

Estimated Burden: We estimate the burden of this collection of information as follows:

Table 1 – Estimated Annual Reporting Burden

16 CFR Section	Number of Respondents	Frequency of Responses	Total Annual Responses	Hours per Response	Total Burden Hours
1226	39	2	78	1	78

Our estimate is based on the following:

Section 8.1 of ASTM F2236-13 requires that all soft infant and toddler carrier products and their retail packaging be marked or labeled as follows: the manufacturer, distributor, or seller name, and either the place of business (city, state, mailing address including zip code), or telephone number, or both; and a code mark or other means that identifies the date (month and year as a minimum) of manufacture.

CPSC is aware of 39 firms that supply soft infant and toddler carriers in the U.S. market. All 39 firms are assumed to use labels on their products and on their packaging already, but they might need to make some modifications to their existing labels. The estimated time required to make these modifications is about 1 hour per model. Each of these firms supplies an average of two different models of soft infant and toddler carrier; therefore, the estimated burden hours associated with labels is 1 hour x 39 firms x 2 models per firm = 78 hours annually.

We estimate the hourly compensation for the time required to create and update labels is $27.92 (U.S. Bureau of Labor Statistics, "Employer Costs for Employee Compensation," September 2012, Table 9, total compensation for all sales and office workers in goods-producing private industries: http://www.bls.gov/ncs/). Therefore, the estimated annual cost to industry associated with the labeling requirements is $2,177.76 ($27.92 per hour x 78 hours = $2,177.76). No operating, maintenance, or capital costs are associated with the collection.

Section 9.1 of ASTM F2236-13 requires that all soft infant and carrier products provide instructions that are easy to read and understand. Where applicable, instructions for assembly, use, maintenance and cleaning of the product, and warnings, must also be included. Soft infant and toddler carriers are products that do not generally require installation but require instruction for proper use, fit, and adjustment on a caregiver's body. 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 soft infant and toddler carriers that lack any instructions to the user about proper use, fit, and assembly, we estimate tentatively that there are no burden hours associated with section 9.1 of ASTM F 2236-13 because any burden associated with supplying instructions with soft infant and toddler carriers would be "usual and customary" and would not fit within the definition of "burden" under the OMB's regulations.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), we have submitted the information collection requirements of this rule to OMB for review. Interested persons are requested to submit comments regarding information collection by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**, to the Office of Information and Regulatory Affairs, OMB (see the ADDRESSES section at the beginning of this notice).

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

- whether the collection of information is necessary for the proper performance of the CPSC's functions, including whether the information will have practical utility;

- the accuracy of the CPSC's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- ways to enhance the quality, utility, and clarity of the information to be collected;
- ways to reduce the burden of the collection of information on respondents, including the use of automated collection techniques, when appropriate, and other forms of information technology; and
- the estimated burden hours associated with label modification, including any alternative estimates.

X. Preemption

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

XI. Certification and Notice of Requirements (NOR)

Section 14(a) of the CPSA imposes the requirement that products subject to a consumer product safety rule under the CPSA, or to a similar rule, ban, standard or regulation under any other act enforced by the Commission, must be certified as complying with all applicable CPSC-

enforced requirements. 15 U.S.C. 2063(a). Section 14(a)(2) of the CPSA requires that certification of children's products subject to a children's product safety rule be based on testing conducted by a CPSC-accepted third party conformity assessment body. Section 14(a)(3) of the CPSA requires the Commission to publish a notice of requirements (NOR) for the accreditation of third party conformity assessment bodies (or laboratories) to assess conformity with a children's product safety rule to which a children's product is subject. The proposed rule for 16 CFR part 1226, "Safety Standard for Soft Infant and Toddler Carriers," when issued as a final rule, will be a children's product safety rule that requires the issuance of an NOR.

Effective June 10, 2013, the Commission published a final rule, *Requirements Pertaining to Third Party Conformity Assessment Bodies*, 78 Fed. Reg. 15836 (March 12, 2013), which codifies 16 CFR part 1112. 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. The final rule also codifies all of the NORs that the CPSC has published to date. All new NORs, such as the soft infant and toddler carrier standard, require an amendment to part 1112. Accordingly, the proposed rule would amend part 1112 to include the soft infant and toddler standard along with the other children's product safety rules for which the CPSC has issued NORs.

Laboratories applying for acceptance as a CPSC-accepted third party conformity assessment body to test to the new standard for soft infant and toddler carriers would be required to meet the third party conformity assessment body accreditation requirements in part 1112. When a laboratory meets the requirements as a CPSC-accepted third party conformity assessment body, it can apply to the CPSC to have 16 CFR part 1226, *Safety Standard for Soft*

Infant and Toddler Carriers, included in its scope of accreditation of CPSC safety rules listed for the laboratory on the CPSC website at: www.cpsc.gov/labsearch.

CPSC staff previously conducted an analysis of the potential impacts on small entities of the proposed rule for part 1112, and published an Initial Regulatory Flexibility Analysis (IRFA) in 77 FR 31086, 31123-26 (May 24, 2012). The IRFA concluded that the requirements in part 1112 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 likely not pursue accreditation for this purpose.

Amending part 1112 to include the NOR for the soft infant and toddler standard would also not have a significant adverse impact on small laboratories. Based upon the number of laboratories in the United States that have applied for CPSC acceptance of the accreditation to test for conformance to other juvenile product standards, we expect that only a few laboratories will seek CPSC acceptance of their accreditation to test for conformance with the soft infant and toddler standard. Most of these laboratories already will have been accredited to test for conformance to other juvenile product standards, and the only cost to them would be the cost of adding the soft infant and toddler standard to their scope of accreditation. As a consequence, the Commission could certify that the proposed NOR for the soft infant and toddler standard will not have a significant impact on a substantial number of small entities.

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

XII. Request for Comments

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

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 1226

Consumer protection, Imports, Incorporation by reference, Infants and Children, Labeling, Law Enforcement, and Toys.

For the reasons discussed in the preamble, the Commission proposes to amend Title 16 of the Code of Federal Regulations by amending part 1112 and adding a new part 1226, 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)(36) to read as follows:

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

* * * * *

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

* * * * *

(36) 16 CFR part 1226, Safety Standard for Soft Infant and Toddler Carriers.

PART 1226-SAFETY STANDARD FOR SOFT INFANT AND TODDLER CARRIERS

Sec.

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

§ 1226.1 Scope.

This part establishes a consumer product safety standard for soft infant and toddler carriers.

§ 1226.2 Requirements for Soft Infant and Toddler Carriers.

(a) Each soft infant and toddler carrier must comply with all applicable provisions of ASTM F2236-13, Standard Consumer Safety Specification for Soft Infant and Toddler Carriers, approved on March 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/cpsc.htm. You may inspect a copy at the Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone 301-504-7923, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:

http://www.archives.gov/federal_register/code_of_federal regulations/ibr_locations.html.

Dated: _____

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

Staff Briefing Package

Section 104 of the Consumer Product Safety Improvement Act of 2008:
Safety Standard for Soft Infant and Toddler Carriers
Notice of Proposed Rulemaking

March 13, 2013

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

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UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

This document has been electronically approved and signed.

Memorandum

Date: March 11, 2013

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Kenneth R. Hinson, Executive Director
Stephanie Tsacoumis, General Counsel

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

Gregory K. Rea
Project Manager for Soft Infant and Toddler Carriers
Director
Division of Mechanical Engineering
Directorate for Laboratory Sciences

SUBJECT : Notice of Proposed Rulemaking for Soft Infant and Toddler Carriers

I. INTRODUCTION

The Danny Keysar Child Product Safety Notification Act, section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), requires the U.S. Consumer Product Safety Commission (CPSC or the Commission) to: (1) examine and assess voluntary safety standards for certain infant or toddler products, and (2) promulgate mandatory consumer product safety standards that are substantially the same as the voluntary standards or more stringent than the voluntary standards if the Commission determines that more stringent standards would further reduce the risk of injury associated with these products. Soft infant and toddler carriers (SITC) currently are not subject to a mandatory standard, but the products fall within the definition of a "durable infant or toddler product" under section 104 of the CPSIA.

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 voluntary standards. This consultation process commenced in fall 2011, with staff participation in a task group within ASTM International Subcommittee F15.21 – Infant Carriers, Bouncers, and Baby Swings. This task group was formed at staff's request, specifically for this purpose.

This briefing package assesses the effectiveness of voluntary standards for soft infant and toddler carriers and presents staff's recommendations for a draft proposed rule.

II. BACKGROUND

A. Product Review

The voluntary standard, ASTM F2236-13, *Standard Consumer Safety Specification for Soft Infant and Toddler Carriers*, defines "soft infant and toddler carrier" as "a product, normally of sewn fabric construction, which is designed to contain a full term infant to a toddler, generally in an upright position, in close proximity to the caregiver." [1] Soft infant and toddler carriers (Figs. 1 and 2) are defined in this manner to distinguish them from slings and wraps, which allow the occupant to be reclined, and framed carriers that have a rigid structure (Fig. 3). In general, the intended occupant of a SITC is a child who weighs between 7 and 45 pounds. Most, if not all, products permit a child carried on the front of a caregiver to be positioned facing inward or outward. Although children are often carried in these products on the front of the caregiver, several SITCs available on the market can be configured to carry children on the caregiver's front, back, and hips.

Staff identified two broad classes of SITC products available in the United States. Structured SITCs contain straps and waist belts that connect to the seat area and each other with buckles, straps, and other mechanical fasteners (Fig. 1). The straps, belts, and seat area of these products are often stiffened with padding and have a heavy textile covering. Nonstructured products, such as the mei-tai design, consist of a flat, textile center with waist straps and very long (5 to 6 feet) upper straps (Fig. 2). These upper straps wrap over the caregiver's shoulders, cross in the back, and are brought around the waist to the front of the caregiver. They are then secured over the child's legs to form the leg openings and secure the child in an upright position. ASTM F2236 does not distinguish between products based on whether they are structured. Its requirements apply equally to all types of soft infant and toddler carriers. Additionally, the voluntary standard specifically excludes slings (Fig. 3.A and 3.B) in which children may be carried in a reclined position. [2]

[1] ASTM 2236-13, *Standard Consumer Safety Specification for Soft Infant and Toddler Carriers*, Scope section 1.3; ASTM International, W. Conshohocken PA (March 2013).
[2] Slings are subject to the voluntary requirements of ASTM F2907-12 *Consumer Safety Specification for Sling Carriers*, ASTM International, W. Conshohocken PA (February 2012).

Figure 1. Structured SITC products.

Figure 2. Unstructured SITC products (Mei-tai design).

(A) Traditional sling (B) Wrap sling (C) Framed backpack carrier

Figure 3: Non-SITC products.

B. Voluntary Standards Overview (Tab A)

1. *ASTM Soft Infant and Toddler Carrier Standard F2236*

The voluntary standard, ASTM F2236, *Standard Consumer Safety Specification for Soft Infant Carriers* (first published in April 2003), addressed the large leg opening hazard patterns associated with the use of SITCs (Tab A). The scope was based on manufacturers' recommended weight from 7 to 25 pounds. The standard's bounded leg opening performance requirement limited the size of the leg opening to prevent infants from falling through large adjustable leg openings.[3]

The next update of the voluntary standard occurred 5 years later. The first version of the standard addressed issues with bounded leg openings that were too large but did not consider the ability of an *unbounded* leg opening to retain the occupant.[4] An unbounded leg opening performance requirement was added to ASTM F2236-08 (published in March 2008) to address a new fall hazard. Products that meet this improved 2008 standard were able to secure children better inside a SITC with unbounded leg openings. Figure 4 shows examples of SITC with unbounded and bounded leg openings. ASTM F2236-08a (published in November 2008) added general requirements common to other standards for durable children's products' addressing hazards associated with toy accessories and flammability. Versions F2236-09 and F2236-10 (published in April 2009 and December 2010, respectively) clarified the labeling instruction that the child must be carried on the front and face the caregiver until he or she can hold their head upright.

Figure 4. SITC with (a) unbounded and (b) bounded leg openings.

[3] A bounded leg opening is a leg opening that is completely encircled by the product seating area, back support, or attachment straps, or both.
[4] An unbounded leg opening is a leg opening that is not completely encircled by the product seating area, back support, or attachment straps.

Five important changes have been incorporated into new ASTM F2236 revisions published within the past few months. These changes include modified and new requirements, developed by CPSC staff jointly with other stakeholders on the ASTM SITC subcommittee task group, which make the standard more stringent. Two substantial changes (and other changes that correspond with the change in scope) were made in ASTM F2236-12 (published in December 2012), and three changes were made in F2236-13 (published in March 2013).

a. Revisions in ASTM F2236-12

ASTM F2236-12 expanded the scope to increase the upper weight limit from 25 to 45 pounds, and to include specifically the word "toddler" in the title and content of the standard. The scope was expanded to include such products because staff was aware of SITCs where the manufacturer-recommended weight limits exceeded 25 pounds. For example, a 32-pound (15 kg) limit was common on products sold both in the United States and Europe, and some manufacturers allowed a 45-pound child to be carried in a SITC on the caregiver's back. To ensure that products marketed for use with a child who weighs up to 45 pounds were tested adequately to accommodate these weights without breaking, the static and dynamic test procedures in the standard were altered in tandem with the modified scope:

- *Static Test:* ASTM F2236-12 added the requirement that every SITC be able to hold three times the manufacturer's maximum recommended weight for 1 minute, without sustaining damage to fasteners or seams or incurring substantial strap slippage (greater than 1 inch). The previous version of the standard required this test probe performed with 75 pounds, which was three times the 25-pound maximum weight in the prior scope. This revision means that products with a maximum recommended weight of 45 pounds must be tested to a 135-pound weight instead of 75 pounds, an 80 percent increase in the severity of the requirement.

- *Dynamic Test:* The dynamic performance requirement in ASTM F2236-12 was increased from a load of 25 pounds, the maximum weight in the prior version of the voluntary standard's scope, to a load equal to the manufacturer's maximum recommended weight. The test requires that this load be dropped 1,000 times from a height of 1 inch above the occupant seat, without the SITC sustaining substantial damage to fasteners or seams or without substantial strap slippage occurring. The quantity and height of drops remain unchanged from previous versions of the voluntary standard.

The second change included in ASTM F2236-12 was a clarification of the unbounded leg opening test procedure to assist with test repeatability. The clarification elaborates on the

orientation of a truncated test cone prior to performing testing. Repeatability is enhanced by ensuring that the same positioning is achieved before testing commences.

b. Revisions in ASTM F2236-13

ASTM F2236-13 added a new component-level performance requirement to evaluate the strength of fasteners and strap retention. Staff was aware of products recalled due to an occupant fall hazard caused by broken fasteners. These recalled samples passed the static and dynamic performance requirements in ASTM F2236-10. In response, staff and ASTM stakeholders developed a new performance requirement that focused on a portion or component level of the SITC rather than on the entire or system level SITC. The new performance requirement, section 6.4 of ASTM F2236-13, states that load-bearing fasteners at the shoulder and waist of SITCs, such as buckles, loops, and snaps may not break or disengage, nor may their straps slip more than 1 inch when subjected to an 80-pound pull force. Adjustable leg opening fasteners are also tested but are subjected to lower loads than the shoulder and waist straps during foreseeable use and abuse. Because these fasteners do not carry the same load as fasteners at the shoulders and waist, they are only tested with a 45-pound pull force.

Second, ASTM F2236-13 updated and improved the warning label for content and format, and updates the instructional literature. An example warning label was added to the standard that identifies more clearly the hazards, the consequences of ignoring the warning, and what to do to avoid the hazards (Fig. 5). The format of the label was designed to convey more effectively these warnings to the caregiver. The rectangular shape of this label may be altered to fit on shoulder straps, if the manufacturer chooses not to place it in the occupant space; however, the label must be placed in a prominent and conspicuous location where the caregiver will see it when placing the SITC on the caregiver's body. The instructional literature must include the warning statements in Fig. 5, as well as additional warning statements that more appropriately belong in the instructions, such as warning against using a carrier while cooking, while driving, or while being a passenger in a motor vehicle.

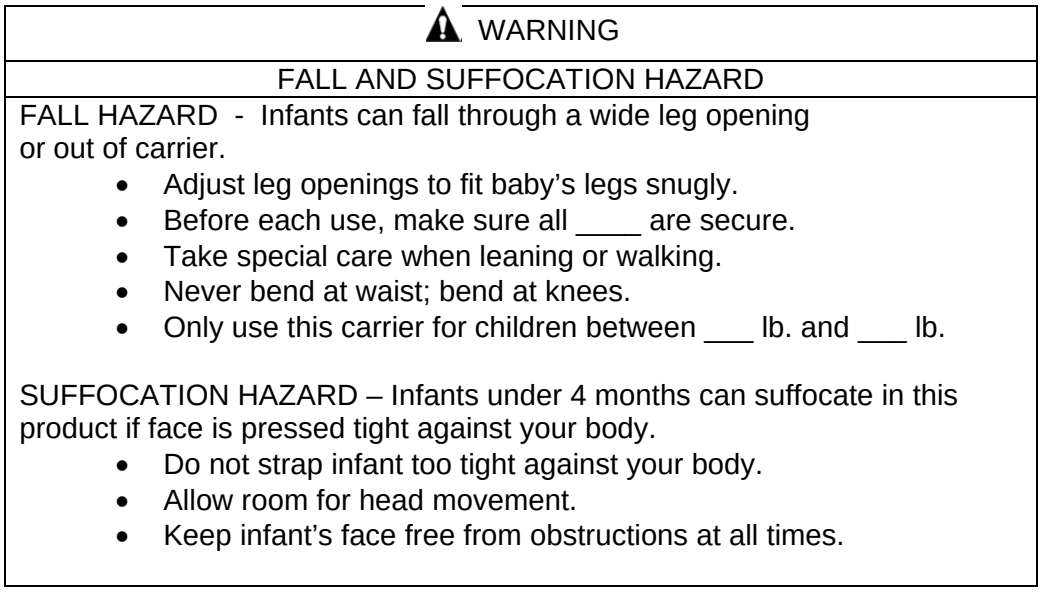


Figure 5. ASTM F2236-13 Warning label.

Third, ASTM F2236-13 modified the flammability requirement. When considering flammability hazards, CPSC staff considers soft infant carriers to be items of wearing apparel. Therefore, the foreseeable flammability hazard associated with these products is addressed, most appropriately,[5] by the inclined surface flame impingement test requirements of CPSC's wearing apparel standard, 16 CFR part 1610, rather than the flammability of solids requirement of 16 CFR § 1500.3 (c)(6)(vi).

2. Other Soft Infant and Toddler Carrier Standards

CPSC staff is aware of one international standard that covers SITC product safety, EN13209-2:2005 *Child Use and Care Articles – Baby Carriers – Safety Requirements and Test Methods – Part 2: Soft Carrier*.[6] Staff evaluated requirements in ASTM F2236-13 and EN13209-2:2005 and determined the requirements in ASTM F2236-13 are more stringent and address the incidents seen in the data and reduce the risk of injury from these products (Tab A). The few EN13209-2:2005 requirements without an ASTM F2236-13 counterpart address hazard patterns not found in the incident reports considered for this draft proposed rule.

[5] CPSC staff considers soft infant carriers to be items of wearing apparel, and therefore, subject to 16 CFR part 1610.
[6] BS EN13209-2005 *Child use and care articles – Baby carriers – Safety requirements and test methods - Part 2: Soft carrier*, British Standards Institution (27 September 2005).

III. DISCUSSION

A. Stakeholder Input

ASTM holds subcommittee meetings for SITC twice a year, typically in spring and fall. Over the past year, there have been two additional SITC subcommittee meetings to streamline the process for incorporating changes into the voluntary standard. Attendees included: representatives from manufacturers, retailers, JPMA, third party testing laboratories, consumer advocacy groups, Health Canada, independent juvenile product technical consultants, and interested members of the public and press corps. CPSC technical staff consistently attended these meetings. Staff supplied the subcommittee with incident data (redacted in-depth investigation reports (IDIs) or summary spreadsheets) demonstrating that the primary hazard with SITCs related to falls from the carrier.

On October 7, 2011, staff updated the subcommittee on the progress of the CPSC SITC rulemaking project. The presentation concluded with staff requesting that the subcommittee form a task group to develop requirements addressing two issues:

- Expansion of the scope, to include products for toddlers up to 45 lbm.; and
- Fastener and strap adjustment mechanism structural integrity.

Additionally, during spring 2012, staff recommended changes to the ASTM subcommittee regarding two additional issues:

- Warnings and product instructions; and
- Updated flammability requirements.

ASTM has since balloted and published new requirements addressing all four of these issues; they are now included in the latest version of the SITC standard, ASTM F2236-13.

B. Recent Compliance Activity (Tab B)

Since 1999, the CPSC has issued seven recalls of more than 650,000 soft infant and toddler carriers. All of these recalls were for product defects that created a substantial product hazard. The recalled products posed a fall hazard to the occupant due to leg opening size, fastener failures, or strap slippage (Tab B). The recalls are listed below[7]:

[7] Details of each of these recalls can be found in the Recall section on the CPSC.gov website by clicking on the links provided.

- CPSC, Baby Swede, LLC Announce Recall to Repair "Baby Bjorn" Infant Carrier (January 21, 1999; revised May 18, 2005) CPSC.gov link;
- CPSC, Evenflo Company, Inc. and Hufco-Delaware, Inc. Announce Recall to Replace Soft Infant Carriers (June 24, 1999) CPSC.gov link;
- CPSC, Baby Swede, LLC Announce Recall to Repair "Baby Björn" Infant Carriers (September 14, 2004; Revised May 18, 2005) CPSC.gov link;
- CPSC, Playtex Products Inc., Announce Recall of Hip Hammock Child Carriers (February 22, 2005) CPSC.gov link;
- Beco Baby Carrier Recalls "Beco Butterfly" Infant Carriers (April 22, 2008) CPSC.gov link;
- Optave Inc. Recalls Action Baby Carriers Due to Fall Hazard (September 3, 2008) CPSC.gov link;
- Regal Lager Recalls Infant Carriers Due to Fall Hazard (June 17, 2010) CPSC.gov link;

C. Incident Characterization (Tab C)

Staff from the Directorate for Epidemiology, Division of Hazard Analysis, characterized the number of deaths and injuries and the types of hazards related to SITCs. Staff is aware of a total of 93 incidents related to SITCs—reported over a period of nearly 13 years—beginning in January 1999 through early September 2012. Two incidents involved fatalities and 91 incidents were nonfatal. These characterizations are based on incident reports received by CPSC staff.

1. Incident Data

Staff could not directly attribute the two reported fatalities to product design or mechanical failure. However, both fatalities were suffocations. The first involved a 5-week-old male who fell asleep in the soft carrier after a feeding. About 20 minutes later, he appeared unresponsive. The official cause of death was listed as positional asphyxia. The second fatal incident occurred when a 2-month-old female fell asleep in a SITC worn by her parent. The parent lay down to sleep for the night on a couch while still wearing the carrier with the infant inside and awoke the next morning to find the child unresponsive with her face pressed into the parent's chest.

Approximately 33 percent (30) of the 91 nonfatal incidents involved reports of an injury to an infant during use of the SITC. A majority of these injuries resulted from falls from the carrier. All of the injuries in which the age of the victim was given reportedly were sustained by infants from 1 month to 13 months old. However, most of the incidents involved infants 6 months and younger. Although the remaining 61 nonfatal incidents reported that no injury had occurred, many of the descriptions indicated the potential for a serious injury or death.

Five SITC-related injuries reportedly required hospitalization, all for skull fractures suffered from a fall. Three other incidents reported skull fractures due to falls from the product, but they did not mention any hospitalization. Some of the remaining injuries reported included: collarbone and limb fractures, contusions, abrasions, blisters, and scratches.

2. Hazard Pattern Identification

Staff classified the reported incidents by the product feature, design element, or failure that may have played a role in the incident (Table 1). Six mechanical categories were identified. Reports in the "Other" category lacked information sufficiently detailed to determine the exact nature of the product's contribution to the incident. Reports that only contained comments and complaints regarding SITC, but no incident information, were separated from the others.

Table 1. Distribution of Reported Incidents by Hazard Patterns Associated with SITC
Reporting Period: January 1, 1999–September 10, 2012

Issues	***Total Reports***		***Deaths***		***Injuries***	
	Count	*Percentage*	*Count*	*Percentage*	*Count*	*Percentage*
Mechanical Issues	**77**	**83**	**0**	**0**	**26**	**87**
Fasteners	*25*	*27*	*0*	*0*	*6*	*20*
Structure, fit, and position	*14*	*15*	*0*	*0*	*10*	*33*
Large leg openings	*12*	*13*	*0*	*0*	*7 (3 hosp.)*	*23*
Stitching/seams	*10*	*11*	*0*	*0*	*1*	*3*
Design and finish	*8*	*9*	*0*	*0*	*2*	*7*
Straps	*8*	*9*	*0*	*0*	*0*	*0*
Other	**11**	**12**	**2**	**100**	**4** *(2 hosp.)*	**13**
Consumer Comments	**5**	**5**	**0**	**0**	**0**	**0**
Total	**93**	**100**	**2**	**100**	**30**	**100**

Source: U.S. Consumer Product Safety Commission's epidemiological databases IPII, INDP, and DTHS.
Note: The percentages have been rounded to the nearest integer. Subtotals do not necessarily add to heading totals.

3. National Injury Estimates

Staff estimates a total of 1,400 injuries that were treated in U.S. hospital emergency departments related to soft infant and toddler carriers over the 13-year period from 1999 through 2011. Because CPSC's National Electronic Injury Surveillance System (NEISS) data for 2012 is finalized in spring 2013, partial estimates for 2012 are not available. The injury estimates for individual years are based on very small samples and are not reportable.[8] Moreover, due to the unreliability of the yearly estimates, a trend analysis is not feasible.

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

No fatalities were reported through NEISS. Although data extraction criteria included up to age 4 years, all of the injured children were reported to be less than 2 years of age. Presented below are the most frequently occurring characteristics among the emergency department-treated injuries associated with soft infant and toddler carriers:

- Hazard – Striking the ground while in the carrier when caregiver fell (65%); falling out of the carrier (21%).
- Injured body part – Head (63%); face (11%).
- Injury type – Internal organ injury (48%); contusions/abrasions (19%); and fractures (12%).
- Disposition – Treated and released (79%); hospitalized (10%); and treated and transferred (9%).

D. Hazard Severity Summary/Assessment of ASTM F2236-13 (Tabs A & D)

The data summarized in Table 1 above lists hazard patterns by frequency of incident reports but not necessarily by severity of the hazard. The listing below identifies hazard patterns in order of severity, starting with those requiring hospitalization, followed by injuries not requiring hospitalization. The "Other" category, which includes the fatal incidents and two hospitalizations, will be treated separately because the exact nature of the product's contribution cannot be determined **(bold font** indicates a hazard where fatalities have been reported). Following the list is a discussion regarding each hazard and how it relates to the current voluntary standard, ASTM F2236-13:

1. Large Leg Openings
2. Structure, Fit, and Position
3. Fasteners
4. Design and Finish
5. Stitching/seams
6. Straps
7. **Other**

1. Large Leg Openings

Three of the five hospitalizations and 23 percent of the injuries (7 of 30) were caused when a child fell out of a large leg opening. The last incident occurred in 2005, with a product purchased in 2000. The prevalence of this hazard led to product recalls in 1999 (see section III.B above) and helped justify the creation of ASTM F2236, whose first performance requirement (6.1 and corresponding test 7.1) was developed to limit the size of SITC leg openings. New

reports involving the large leg opening hazard ceased within 2 years of the first version of ASTM F2236 being published in 2003. This, combined with CPSC detailed incident reviews, led staff to determine that the current ASTM standard adequately addresses this hazard scenario.

2. Structure, Fit, and Position

The largest percentage of SITC injuries reported to the CPSC (33%, 10 of 30) was related to the structure of the SITC carrying pouch; fit of the occupant in the SITC; and the position of either the SITC on the wearer, or the position of the child in the carrying pouch. These incidents occurred, for example, when an infant tucked down into the carrier and the caregiver bent at the waist, breaking the child's leg; an infant fell out of the top of the carrier when the caregiver bent forward; abrasions and/or blisters on infants from prolonged rubbing against the carrier while in use; and when an infant suffered leg circulation-related injuries. Staff believes that several of the injuries involving the caregiver bending at the waist could have been mitigated if caregivers had heeded warnings advising against this practice. The new warning label published in ASTM F2236-13 (Fig. 5) and updated warning language in the instructional literature may address many of these hazards if consumers read, understand, and comply with the warnings. The diverse size of potential occupants, the broader range of caregiver sizes and shapes, and the numerous possible motions and activities that could lead to injury cannot be reliably replicated in a laboratory setting, making development of a repeatable test prohibitively difficult. A warning label, however, would likely not address the hazard associated with leg circulation-related injuries because this may be due to a design issue (Tab D). Staff will continue to study incoming reports of these types of injuries, with the goal of determining the appropriate corrective action. No further action is recommended at this time.

3. Fasteners

The six injuries caused by fastener failures (20% of injuries) occurred when a fastener suddenly broke or separated, and the child fell to the ground. Although there were no hospitalizations reported, there were three fractured collarbones, along with contusions and abrasions to heads and faces. Fortunately, the caregiver was able to catch the child and prevent a fall in the majority of the 25 incidents. Fastener failures led to four of the five voluntary product recalls conducted since 2005.

The voluntary standard addresses the hazards posed by fastener failures with a new performance requirement published in ASTM F2236-13 section 6.4 and a new test in section 7.7. New requirements state that all load-bearing fasteners, such as buckles, loops, and snaps, may not break or disengage, nor may their straps slip more than 1 inch, when an 80-pound pull force is applied across the fasteners. An exception is made for adjustable leg opening fasteners which must be subjected to a 45-pound pull force. These fasteners see substantially less load than other

load-bearing fasteners during foreseeable use and abuse, such as those securing shoulder and waist straps. This requirement does not apply to non-load-bearing fasteners that attach accessories to the SITC, such as bibs, rain hoods, and toys. Staff believes the voluntary standard with the inclusion of this new requirement will adequately address fastener failure hazards.

4. Design and Finish

Staff concluded that seven percent of the SITC injuries (2 of 30) were attributable to design and finish issues. Reports of complaints included: inadequate back support, rough fabric, poor air flow in the carrier insert, and one report of high lead levels in a zipper pull. The injuries consisted of a pinched finger and a cut on the nose.

ASTM F2236-13 includes language prohibiting sharp points and edges, but it does not specifically mention pinching. A pinching-shearing-scissoring hazard exists typically in products with rigid parts that move past one another; it does not generally exist with soft products. Staff does not recommend any changes to the voluntary standard at this time for design and finish issues. The limits on lead content in children's products are covered in Section 101 of the CPSIA and need not be included in ASTM F2236. [9,10]

5. Stitching/seams

Ten reports (11 percent) were received describing incidents in which SITC stitching became undone or seams ripped, resulting in other components, like straps, becoming detached. One injury was reported when a seam failed, causing a 4-month-old child to fall and receive minor contusions. The new fastener strength test, and the more stringent static and dynamic tests in the 2013 version of ASTM F2236 (sections 7.7 and 7.2, respectively), all apply loads to SITC seams and sewn attachment points. Staff believes that these incidents are adequately addressed by these new requirements in the voluntary standard and does not recommend any additional changes at this time.

6. Straps

Eight reported incidents (nine percent) involve issues with straps. The problems reported include broken strap length adjustment mechanisms and straps that permit unexpected slippage. No injuries or fatalities were reported in this category. For the same reasons listed above for *Stitching and Seams*, staff believes that these incidents are adequately addressed by new testing requirements in the voluntary standard and does not recommend any further changes at this time.

[9] "Section 101. Children's Products Containing Lead; Lead Paint Rule," U.S. CPSC Web page, accessed November 2012.
[10] "FAQs: Total Lead Content in Children's Products," U.S. CPSC Web page, last updated November 15 2011.

7. Other

Eleven reports (12 percent) were related to issues other than the ones described above. This category includes two fatalities and four injuries, including two requiring hospitalization. The two fatalities discussed above in section III.C.1 and by Human Factors staff in Tab D, are included in this category. In each case, CPSC staff concluded that there were too many confounding factors reported to determine that a specific factor contributed predominantly to the deaths. Without a specific factor, staff cannot recommend corresponding performance requirements to be included in the voluntary standard. Staff did recommend a warning requirement to address suffocation, which has been published in ASTM F2236-13.

E. Potential Small Business Impact (Tab E)

CPSC staff estimates that currently, there are at least 39 suppliers of SITCs to the U.S. market. Thirty-one domestic firms supply SITCs to the U.S. market: 15 are domestic manufacturers, eight are domestic importers, and the supply sources of eight domestic firms are unknown. Five foreign firms supply SITCs to the U.S. market: three are foreign manufacturers; one is a foreign importer; and one firm with an unknown supply source. Insufficient information is available on the remaining three firms to categorize them. Based on U.S. Small Business Administration guidelines, 26 of the 31 domestic suppliers are small firms─12 domestic manufacturers, six domestic importers, and eight firms whose supply source is unknown—likely to be affected by the staff's draft proposed standard, as described in the Directorate for Economic Analysis memo (Tab E).

The direct impact on the seven small manufacturers whose SITCs meet the current voluntary standard is not expected to be significant; nor is the impact on the five small manufacturers whose SITCs are not compliant with the voluntary standard.

The six small importers operating in the U.S. market would need to find an alternate source if their existing supplier does not come into compliance with the requirements of staff's draft proposed rule. They could also discontinue importing any noncomplying SITCs, possibly replacing them with another juvenile product.

As is the case with manufacturers, all importers will be subject to third party testing and certification requirements, and consequently, they will experience the associated costs, if their supplying foreign firm(s) does not perform third party testing. The resulting costs could have a significant impact on a few small importers that must perform the testing themselves if more than one sample per model were required. In addition, the impacts could be higher than those

incurred by domestic manufacturers if importers have to test to each batch imported in the case where the foreign manufacturer does not conduct the testing.

IV. STAFF RECOMMENDATIONS

CPSC staff recommends that the Commission publish an NPR, as drafted by the Office of the General Counsel and submitted under separate cover. This draft NPR incorporates by reference the voluntary standard ASTM F2236-13, *Standard Consumer Safety Specification for Soft Infant and Toddler Carriers*. CPSC staff also recommends an effective date of 6 months after publication of the final rule.

TAB A:

Staff's Review of ASTM F2236-13, *Standard Consumer Safety Specification for Soft Infant and Toddler Carriers*

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

Memorandum

Date: March 11, 2013

TO: Gregory K. Rea
Project Manager for Soft Infant and Toddler Carriers
Director
Division of Mechanical Engineering
Directorate for Laboratory Sciences

THROUGH: George A. Borlase
Associate Executive Director
Directorate for Engineering Sciences

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

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

SUBJECT: Staff's Review of ASTM F2236-13, *Standard Consumer Safety Specification for Soft Infant and Toddler Carriers*

I. INTRODUCTION

In accordance with the Danny Keysar Child Product Safety Notification Act Section 104 of the Consumer Product Safety Improvement Act (CPSIA), *Standards and Consumer Registration of Durable Nursery Products*, this memorandum assesses the effectiveness of ASTM F2236-13, *Standard Consumer Safety Specification for Soft Infant and Toddler Carriers*, and recommends that the Commission propose to incorporate the standard by reference in the draft proposed rule on soft infant and toddler carriers (SITCs).

F2236-13 defines a "SITC" as a product, normally of sewn fabric construction, which is designed to contain a full-term infant to a toddler, generally in an upright position, in close proximity to the caregiver. The SITC may be configured to carry the infant in front of, to the side of, or behind the caregiver, or the SITC may be reconfigured to carry the infant in multiple

positions. The infant may face away from or toward the caregiver. A typical SITC is designed to hold an infant weighing between 7 and 45 lbs. Figure 1 is a typical soft infant and toddler carrier.

Figure 1. Soft Infant and Toddler Carrier

History of ASTM F2236, *Standard Consumer Safety Specification for Soft Infant and Toddler Carriers*

The voluntary standard for SITCs was first approved and published in April 2003, as ASTM F2236-03, *Standard Consumer Safety Performance Specification for Soft Infant Carriers.* The voluntary standard has been revised five times since then. The current version, ASTM F2236-13, was approved on March 1, 2013 and published in March 2013.

ASTM F2236-03 established requirements to address the following issues:

- Sharp points and edges,
- Small parts,
- Lead in paints,
- Wood parts,
- Locking and latching,
- Leg opening size,
- Dynamic load testing,
- Static load testing, and

- Labeling.

ASTM F2236-08 (approved on March 1, 2008):

- Added a definition for unbounded leg opening, and
- Added unbounded leg opening test requirement and methods.

ASTM F2236-08a (approved on November 1, 2008):

- Added requirements for flammable solids, and
- Added requirements for attached toys.

ASTM F2236-09 (approved on April 1, 2009):

- Changed the labeling requirement for child to face caregiver until the child's head can be held upright from being part of the warning label to being an informational statement separate and distinct from the warning label.

ASTM F2236-10 (approved on December 1, 2010):

- Clarified that the informational statement for child to face caregiver until head can be held upright was unnecessary for carriers that only have one use position with the child facing the caregiver.

ASTM F2236-12 (approved on May 1, 2012):

- Modified title and scope to include toddler carriers that hold children up to 45 lbs;
- Added clarification of test samples;
- Clarified test weights and increased dynamic load test weight up to manufacturer's recommended maximum weight limit for each specific carry position;
- Increased static load test weight up to three times manufacturer's recommended maximum weight limit for each specific carry position; and
- Clarified unbounded leg opening test procedure to ensure consistency in how test is performed.

ASTM F2236-13 (approved March 1, 2013):

- Added fastener definition, and fastener strength and strap retention test requirements; and
- Updated warning label format and content and instructional literature.
- Updated flammability requirement.

II. INCIDENT HAZARD REVIEW

According to the Directorate for Epidemiology,[11] a total of 93 incidents were reported, including two fatalities and 91 nonfatal incidents related to SITC reported from January 1, 1999 through September 10, 2012. The children who were injured in the reported incidents were 13 months of age or younger (where age was reported). However, because reporting is ongoing, the number of reported incidents may change.

The following is a list of the hazard patterns identified in incident reports (**bold font** indicates a hazard where fatalities have been reported).

1. Fasteners

Twenty-five cases in the incident data related to SITC fasteners, which includes snaps, buttons, and buckles. Six of these cases reported injuries. The most common scenario involved fasteners breaking or unexpectedly releasing, frequently resulting in the infant falling out of or partially falling out of the SITC.

2. Structure, Fit, and Position

Fourteen incidents related to SITC structure, infant fit, and position on the caregiver. Ten injuries were reported in this category. Typical incidents in this hazard pattern indicated prolonged contact with a part of the SITC seat, resulting in bruises or blisters and poorly fitting SITCs that resulted in the infant falling out when the caregiver bent over. Two infants suffered broken legs when their caregiver bent over to pick up an item and the infant's leg became wedged against the caregiver's hip. Reports also include infants legs "turning blue" from cut-off circulation.

3. Large Leg Openings

Twelve incidents were related to leg openings that were large enough to allow the infant to slip through and fall out. Of the 12, seven reported injuries, including three hospitalizations for skull fractures.

4. Stitching and Seams

Ten incidents related to stitching or seams on the SITC. Several reports involved SITCs that ripped at the seams. In some cases, this resulted in a strap or belt coming loose. In one instance, an infant was slightly bruised as she brushed against the chest strap.

[11] Chowdhury, Risana, "Soft Infant and Toddler Carrier-Related Deaths, Injuries, and Potential Injuries, and NEISS Injury Estimates; 1999–September 10, 2012," March 11, 2013.

5. Design and Finish-Related Issues

Eight of the incidents were related to design or finish (quality) issues. Two reports involved poor back support in the SITC, resulting in the infant almost falling out. Reports were made of SITCs not providing enough air circulation to the infant, which could result in suffocation. Two of the eight incidents reported injuries. One infant got her fingers caught in a plastic adjustment piece on the SITC. Another report involved the inability of the adjustment rings to stay together, which could result in the fabric slipping and the infant falling out.

6. Straps

Eight incidents involved SITC straps. Typical incidents involved straps coming loose from buckles.

7. Other Issues

Eleven reports lacked information sufficiently detailed to determine the exact nature of the product's contribution to the incident. Two fatalities were in this category: one infant died while in a carrier being worn by the parent during a zoo visit; the other died when the parent fell asleep with the infant still in the SITC. There were four injuries, including two hospitalizations, reported among the 11 incidents. The remaining reports were related to unspecified falls and an abrasion caused in an unknown manner.

8. Consumer Comments

Five reports involved consumer-perceived safety issues of the SITC. No incidents were involved.

III. ADEQUACY OF THE CURRENT ASTM F2236-13 REQUIREMENTS

This section discusses how each hazard pattern relates to the current voluntary standard F2236-13. ESME staff believes that F2236-13 addresses many of the general hazards associated with durable nursery products, such as lead in paints, sharp edges/sharp points, small parts, and warning labels. Specific requirements for labeling and restraint systems are also included.

Hazard Patterns 1, 4, and 6 – Fasteners, Stitching and Seams, and *Straps*

The current version of ASTM F2236 increased the maximum dynamic and static test weights to account for heavier occupants and clarified the test procedure for unbounded leg openings. These changes will help ensure that the SITC, as a whole, is capable of handling the intended loads and will highlight deficiencies with straps and stitching/seams.

However, due to the number of fastener failures seen in the reported incidents, staff felt that adding component-level testing of connected fasteners and straps into the ASTM F2236

performance requirements was appropriate. Staff tested the fasteners/straps of several SITCs by conducting quasi-static pull tests to see what loads they could handle. This was done on each fastener of 14 unique products, resulting in more than 100 individual tests. Testing included products recalled for strap/buckle failures. Testing determined that most buckles failed at loads well over 90 lbs., while buckles on recalled products failed at 22 to 55 lbs. Buckles and straps used to adjust leg openings do not see loads as high as the main load-carrying buckles and straps used to support the infant. As a result, staff determined an appropriate test load of 80 lbs. for fasteners supporting the infant's weight and attaching to the caregiver, and 45 lbs. for fasteners used to adjust leg openings. The requirements also address strap slippage, by ensuring that straps will not slip through adjustment buckles by more than 1-inch during the test.

Staff believes that inclusion of the fastener and strap testing, in addition to other changes made in ASTM F2236-13, will reduce the number of incidents involving fasteners, stitching and seams, and straps.

Hazard patterns 2, 3, and 5- Structure, Fit, Position, Leg Openings, and Design Issues
Hazard patterns involving SITC fit and design can be sorted into two categories. The first is the capability of the product to hold the infant adequately, and the second is the ease with which the caregiver can adjust the product to fit the infant. The first can be assessed best by performance testing, the second by adequate labeling.

The two most recent versions of ASTM F2236 made several changes to performance testing that are related to fit and design. The scope of the standard was revised to include testing occupants up to toddler size who are within the recommended weight limits for SITCs on the market. This required increasing the test loads for dynamic and static tests. In addition, the performance test for unbounded leg openings was clarified. The existing version of the standard includes requirements for sharp points and edges.

Warnings are present in the existing standard regarding leg openings to advise the caregiver that small children can fall through a leg opening; and if the SITC has adjustable leg openings, the caregiver should adjust the leg openings to fit the baby's legs snugly. Engineering Sciences Human Factors staff believes that incoming reports of SITC leg constriction-related incidents should continue to be studied with the goal of determining whether additional changes to the standard would be warranted in the future. However, staff has been working with the ASTM task group to modify the labeling requirements in ASTM F2236 to improve caregiver awareness of the consequences of leaning over while wearing the SITC with the infant inside.

Staff is not making any recommendations at this time.

Hazard Patterns 7 and 8 – Other Issues and *Consumer Comments*
At this time, insufficient information exists on the "Other" and "Consumer Comments" hazard patterns to enable staff to recommend performance changes to the existing standard. However, staff believes that the labeling requirement in the standard may address suffocation if consumers read, understand, and comply with the warning.

IV. OTHER STANDARDS

ESME staff compared the performance requirements of ASTM F2236-13 to the performance requirements of other standards. ES staff found one international standard, BS EN13209 *Child Use and Care Articles – Baby Carriers – Safety Requirements and Test Methods – Part 2: Soft Carrier*, which addresses the product category in a fashion similar to ASTM F2236.

Staff believes that the current ASTM F2236-13 standard is the most comprehensive of the standards to address the incident hazards. Some individual requirements in the BS EN13209 standard are more stringent than F2236-13. BS EN13209 includes requirements for surface chemicals, cords/ribbons, graspable components, material shrinkage, filling material, packaging film, and monofilament threads. No hazard patterns exist in the incidents reported to the CPSC that necessitated adding similar requirements to ASTM F2236-13. However, staff will continue to monitor hazard patterns and recommend future changes, if necessary. Appendix A summarizes and compares the requirements of BS EN 13209 to those found in ASTM F2236-13.

V. CONCLUSION

Staff recommends that the Commission approve the draft NPR that proposes to incorporate by reference the voluntary standard ASTM F2236-13, *Standard Consumer Safety Specification for Soft Infant and Toddler Carriers*, as the soft infant and toddler carrier mandatory standard.

Appendix A: Comparison of ASTM F2236 Standard Consumer Safety Performance Specification for Soft Infant and Toddler Carriers to EN 13209

	ASTM F2236-13		EN	Comment
Para		**Para**		
1.0	Title and Scope modified to include toddler carriers up to 45 lbs.			
5.1	No hazardous sharp points or edges		Requirement is not in standard.	
5.2	No small parts	6.2.1	Same	
	Similar requirement for toy accessories only	6.2.3	Graspable components not intended to detach, which detach after torque and tension tests, must not create small parts.	See 1.
	Similar requirement for toy accessories only	6.3	Cords, ribbons, and parts used as ties (excluding restraints) shall have a maximum free length of 220 mm when stretched with a force of 25n.	See 1.
	Requirement not in standard	6.4	Carriers intended for use with children up to 4 months of age shall include support for the child's head. Head support should comprise an adequate means of preventing the head of a child up to 4 months of age from rolling backward, forward, or sideways.	See 2.
	Requirement not in standard	6.5	Caregiver's attachment system shall be adjustable with a minimum of 40 mm width for belts and straps.	See 3.
	Requirement not in standard	6.7	Soft carriers intended for use on a caregiver's back shall not release any filling from the upper edge of the carrier in the direction the child is facing when tested with gripping device.	See 1.
5.3	Comply with 16 CFR 1303 - lead paint	5.1	Similar for lead. EN adds requirements for other elements.	See 1.
5.4	Wood parts smooth & free of splinters		Requirement is not in standard.	
5.5	Locking and latching must remain in manufacturer's recommended use position before and after testing		Requirement is not in standard.	
5.6	Labeling		Similar	
5.6.1	Labeling permanence		Similar	
5.6.2	Non-paper labels shall not liberate small parts		Requirement is not in standard.	

	ASTM F2236-13		EN	Comment
5.7	No Class 2 or 3 fabrics when evaluated against 16 CFR 1610. Evaluate against F963 Annex 5 if necessary.	5.2	Similar	
	Requirement is not in the standard.	5.3	Shrinkage due to washing shall not prevent removable parts from being refitted and shall not impair performance of the product use.	See 1.
	Requirement is not in the standard.	5.4	Monofilament threads shall not be used	See 1.
5.8	Toy accessories must meet F963.		Requirement not in standard	
6.1	Leg Openings - shall not permit the passage of the Leg Opening Test Sphere when tested in accordance with 7.1.	6.1.1	Same	
6.2	Dynamic Load - Carrier shall not create a hazardous condition, such as fastener breaking or disengaging, or seams separating, when tested in accordance with 7.2. Adjustable elements shall not slip more than 1 inch.	6.6	Similar dynamic durability test. EN requirement uses 9 kg and 15 kg weights or up to manufacturer's recommended weight. Entire test torso is moved up and down 120 mm for 50,000 cycles. Slippage must be less than 20 mm after 90 cycles.	See 4.
6.1	Static Load - Carrier shall not create hazardous condition, such as not supporting the test weight, fasteners breaking or disengaging or seams separating when tested in accordance with 7.3. Adjustable elements shall not slip.		Requirement is not in the standard.	
6.3	Unbounded Leg Opening—Leg opening shall not allow complete passage of the truncated test cone when tested according to 7.7.		Requirement is not in the standard.	
6.4	Fastener Strength and Strap Retention (Load testing) – Fasteners shall not break or disengage when tested in accordance with 7.8.1 and 7.8.2.		Requirement is not in the standard	
	Requirement is not in the standard.	7	Requirements for packaging film thickness	See 1.
8	Labeling	8	Similar	
9	Instructional literature	8.5.3	Similar	

Both standards address many of the general hazards associated with durable nursery products, such as lead in paints, sharp edges/sharp points, small parts, and warning labels.

1. EN 13209 includes requirements for graspable components, cords/ribbons, filling material, surface chemicals, shrinkage, monofilaments, and packaging film. There were no hazard patterns noted in the incidents reported to the CPSC that necessitated adding similar requirements to F2236-13. However, staff will continue to monitor these hazard patterns and recommend future changes, if necessary.

2. EN 13209 includes a requirement for SITCs intended for use by children up to 4 months of age to include support for the child's head. Head support should comprise an adequate means of preventing the head of a child up to 4 months of age from rolling backward, forward, or sideways. Staff does not believe that any reported incidents noted in the CPSC data would be addressed by adding such a requirement at this time. F2236 currently includes an informational requirement instructing the caregiver to have the infant face the caregiver until the infant can hold their head upright.

3. EN 13209 includes a requirement for caregiver shoulder straps and waist belts to be adjustable with a minimum 40 mm width. Staff is not aware of any SITCs sold in the United States that do not meet the adjustability requirement. Staff believes that specifying a minimum belt/strap width is unnecessary in lieu of ensuring belts and straps meet retention requirements. Specific load testing of straps and belts was added to F2236 to ensure that they are adequate to carry intended loads, regardless of their physical dimensions.

4. EN 13209 includes a dynamic durability test that may impart higher loads on the SITC than the F2236 dynamic test; however, F2236 also requires the SITC to meet a very rigorous static load not specified EN 13209, as well as conduct component testing of belts, straps, and fasteners. ES staff believes that the combination of the dynamic and static testing in F2236 is adequate to ensure SITCs are capable of handling expected loads.

TAB B:

Durable Nursery Products: Summary of Recalls Involving Soft Infant and Toddler Carrier Products

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

Memorandum

Date: September 18, 2012

TO : Gregory K. Rea
Project Manager for Soft Infant and Toddler Carriers
Director
Division of Mechanical Engineering
Directorate for Laboratory Sciences

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

Mary F. Toro, Director, Division of Regulatory Enforcement

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

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

SUBJECT : Durable Nursery Products: Summary of Recalls Involving Soft Infant and Toddler Carrier Products

PURPOSE

This memorandum provides compliance information relevant to the drafting of a safety standard for soft infant and toddler carriers. Section 104 of the Consumer Product Safety Improvement Act of 2008, Pub. L. 110-314, 122 Stat. 3016 (August 14, 2008) (CPSIA), the Danny Keysar Child Product Safety Notification Act, requires the Commission to study and develop safety standards for infant and toddler products, which includes soft infant carriers. CPSC staff is drafting a proposed rule for soft infant and toddler carriers (SITCs) for Commission consideration. The draft proposed rule addresses the hazards associated with SITCs through performance requirements for fastener strength and strap retention component evaluation, unbounded leg opening test procedures, and enhancements to the clarity and effectiveness of warning labels. This memo summarizes the product safety recalls stemming from manufacturer reports under Section 15 of the Consumer Product Safety Act, defect investigations conducted by the Office of Compliance and Field Operations (Compliance), and the reported incidents and injuries involving soft infant carriers.

Compliance Investigation Information

Staff received 130 incident reports involving SITCs relating to the seven product safety recalls announced between January 1, 1999 and June 17, 2010. During that period, 652,250 SITCs were subject to a recall. At the time the products were recalled, nine infants had been injured significantly in incidents that ranged from bruises to skull fractures.

Soft Infant Carriers CPSIA Rulemaking
Recall Summary

Manufacturer	Model	Year Recalled	Units Recalled	Reason	Incident Reports	Injury Reports
Evenflo Company & Hufco-Delaware, Inc.	Model 070 & 080 Snugli® Front and Back Pack™	1999	327,000	Infant shifts to side & slips through leg opening, falls out.	13	One - fractured skull; two - bruises
Baby Swede, LLC	Baby Bjorn	1999	240,000 (Recall to Repair)	Infants slip through leg openings - fall. Infants < 2 months - highest risk.	9	Six fractured skulls
Baby Swede, LLC	Baby Bjorn Carrier Active	2004	49,000	Back support buckles detach from shoulder straps - pose fall hazard.	93	No injuries reported.
Playtex Products, Inc.	Playtex Hip Hammock	2005	32,000	Shoulder strap detaches from Hammock, posing fall hazard.	2	No injuries reported.
Beco Baby Carrier, Inc.	Beco Baby Carrier Butterfly	2008	2,000	Shoulder strap buckles unexpectedly release tension - straps slip through - pose fall hazard.	8	No injuries reported.
Optave, Inc.	Action Baby Carrier	2008	250	Chest strap can detach from shoulder straps, posing fall hazard to infant.	2	No injuries reported.
Regal Lager, Inc.	CYBEX 2. GO Infant Carriers	2010	2,700 U.S. 400 Canada	Shoulder strap slider buckle can break, posing fall hazard to infant.	3	No injuries reported.

TAB C:

Soft Infant and Toddler Carrier-Related Deaths, Injuries, and Potential Injuries, and NEISS Injury Estimates; 1999–September 10, 2012

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

Memorandum

Date: March 11, 2013

TO : Gregory K. Rea
Project Manager for Soft Infant and Toddler Carriers
Director
Division of Mechanical Engineering
Directorate for Laboratory 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 : Soft Infant and Toddler Carrier-Related Deaths, Injuries, and Potential Injuries, and NEISS Injury Estimates; 1999–September 10, 2012[12]

I. Introduction

This memorandum characterizes the number of deaths and injuries and the types of hazards related to soft infant and toddler carriers (SITCs) over a period of more than 13 years, beginning in January 1999.[13] These characterizations are based on incident reports received by CPSC staff.

[12] 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.
[13] 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.

The memorandum also presents national injury estimates from January 1999 through December 2011.

The ASTM voluntary standard for Soft Infant and Toddler Carriers, F2236-13, addresses safety issues related to soft infant and toddler carriers. According to the ASTM definition, a "soft infant and toddler carrier" is a product, normally of sewn fabric construction, which is designed to contain a full-term infant to a toddler, generally in an upright position, in close proximity to the caregiver. The soft infant and toddler carrier is normally "worn" by the caregiver, with a child positioned in the carrier and the weight of the child and carrier suspended from one or both shoulders of the caregiver. These products may be worn on the front, side, or on the back of the caregiver's body, with the infant either facing toward the caregiver or away from the caregiver. Products generally referred to as "slings" are not considered soft infant and toddler carriers.

The last major revision of the ASTM standard for soft infant and toddler carriers was published in 2003. CPSC staff, however, is of the opinion that the ASTM standard did not adequately address some of the issues already salient in the data around that time. For this regulatory package, staff decided to review CPSC data from 1999 forward to reevaluate the preexisting issues, as well as have enough data points to assess any new issues with the product. The estimates of emergency department-treated injuries associated with soft infant and toddler carriers are presented separately from the rest of the incident data.

II. Incident Data[14]

CPSC staff is aware of a total of 93 incidents (two fatal and 91 nonfatal) that reportedly occurred from January 1, 1999 through September 10, 2012, related to SITCs. For this analysis, the data extraction criteria limited the age range for the infants involved to zero to under 5 years. The zero age group included reports where age was not reported because there was no injury involved or age was unknown. Only injuries that occurred when the child was in the carrier or was being placed into, or taken out of the carrier, are included for the purposes of this memorandum.

[14] 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 are they 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 soft infant and toddler carriers.

Date of extraction for reported incident data was 09/11/12. The incident reports involving carriers do not always specify clearly the type of carrier involved. As such, all data coded under product codes 1527/1548/1549 and the age range 0−4 years were extracted, yielding a very large initial data pool. Upon careful joint review with CPSC's Directorates for Lab Sciences, Engineering Sciences, Economics, and Health Sciences staff, many cases were considered out of scope for the purposes of this memorandum. For example, cases with SIDS or other preexisting medical conditions as the official cause of death, or cases where a child was outside a carrier, playing with it and then injured by it, were excluded. However, all incidents where hazardous environments in and around the soft infant and toddler resulted in fatalities, injuries, or near-injuries were retained. With the exception of incidents occurring in U.S. military bases, all incidents that occurred outside of the United States have been excluded. To prevent any double-counting, when multiple reports of the same incident were identified, they were consolidated and counted as one incident.

Because reporting is ongoing, the number of reported fatalities, nonfatal injuries, and noninjury incidents may change in the future. Table 1 provides the breakdown of the incidents by year. Given that these reports are anecdotal and that reporting is incomplete, CPSC staff strongly discourages drawing any inferences based on the year-to-year increase or decrease shown in the reported data.

Table 1: Soft Infant and Toddler Carrier-Related Reported Incidents 01/01/99 through 09/10/12

Incident Year	***Total Number of Reported Incidents***	***Number of Reported Incidents***	
		Nonfatal	***Fatal***
1999	15	15	
2000	12	11	1
2001	9	9	
2002	2	2	
2003	1	1	
2004	9	9	
2005	4	4	
2006	3	3	
2007	6	5	1
2008	5	5	
2009	5	5	
2010*	8	8	
2011*	4	4	
2012*	10	10	
Total	***93***	***91***	***2***

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

A. *Fatalities*

There were two fatalities associated with the use of a SITC, which reportedly occurred during the time period from January 1, 1999 through September 10, 2012. The first decedent was a 1-month-old who was smothered while being carried in a front-style carrier. The second decedent was a 2-month-old who was asleep in a front-style carrier while the parent, wearing the carrier, slept overnight on a couch; the infant suffocated.

B. *Nonfatal Incidents*

Of the 91 soft infant and toddler carrier-related nonfatal incidents that were reported to have occurred from January 1, 1999 through September 10, 2012, a total of 30 reported an injury to

the infant during use of the product. Age was unreported or unknown for three of the injured; for the rest, the age ranged from 1 month to 13 months.

Among the 30 reported nonfatal injuries, five were hospitalizations for skull fractures from falls. T three additional skull fracture injuries were reported, but no hospitalization was mentioned. The remaining injuries ranged from collarbone and limb fractures to contusions, abrasions, blisters, and scratches. A majority of the injuries resulted from falls from the carrier. The remaining injuries were either due to miscellaneous product-related issues or unknown issues, where the specifics of the circumstances were not reported.

The remaining 61 incidents reported that no injury had occurred or provided no information about any injury. However, many of the descriptions indicated the potential for a serious injury or even death.

III. Hazard Patterns

CPSC staff considered all 93 reported incidents (two fatal and 91 nonfatal) to identify hazard patterns associated with soft infant and toddler carriers. In order of frequency of incident reports, the hazard patterns—mostly product-related—were grouped into the following categories:

- Fastener problems;
- Structure, fit, and position issues;
- Problems with large leg openings;
- Issues with stitching/seams;
- Design and finish-related issues;
- Strap issues;
- Other issues; and
- Consumer comments, no incident involved.

A. Fastener problems: Twenty-five of the 93 incidents (27 percent) were related to fastener problems, such as snaps breaking/unexpectedly releasing, or buckles breaking/detaching/pinching/unexpectedly releasing. Six injuries, but no fatalities, were included among these reports.

B. ***Structure, fit, and position issues:*** Fourteen of the 93 incidents (15 percent) were related to aspects of the leg- and torso-opening design, how the carrier held the infant, and where it was positioned on the caregiver. Examples of scenarios reported include an infant slipping down far into the carrier and suffering an injury when the caregiver went into a

bent position; an infant falling out of the carrier when the caregiver bent forward; and the leg circulation-related injuries. There were 10 injuries reported in this category. No reported fatalities were associated with this issue.

C. ***Problems with large leg openings:*** Twelve of the 93 incidents (13 percent) were related to leg openings that were too large and allowed the infant to slip through completely and fall out of the carrier. While there were no fatalities among these reports, there were seven injuries, three of which were hospitalizations for skull fractures.

D. ***Issues with stitching/seams:*** Ten reports (11 percent) were received about stitching on the carrier coming undone or seams ripping, resulting in other components, like straps, becoming detached. One injury, but no fatality, was included among these reports.

E. ***Design and finish-related issues:*** Eight reports (9 percent) of inadequate back support, rough fabric, poor air flow in the carrier insert, and other design issues were reported. No fatalities, but two injuries, were associated with these issues.

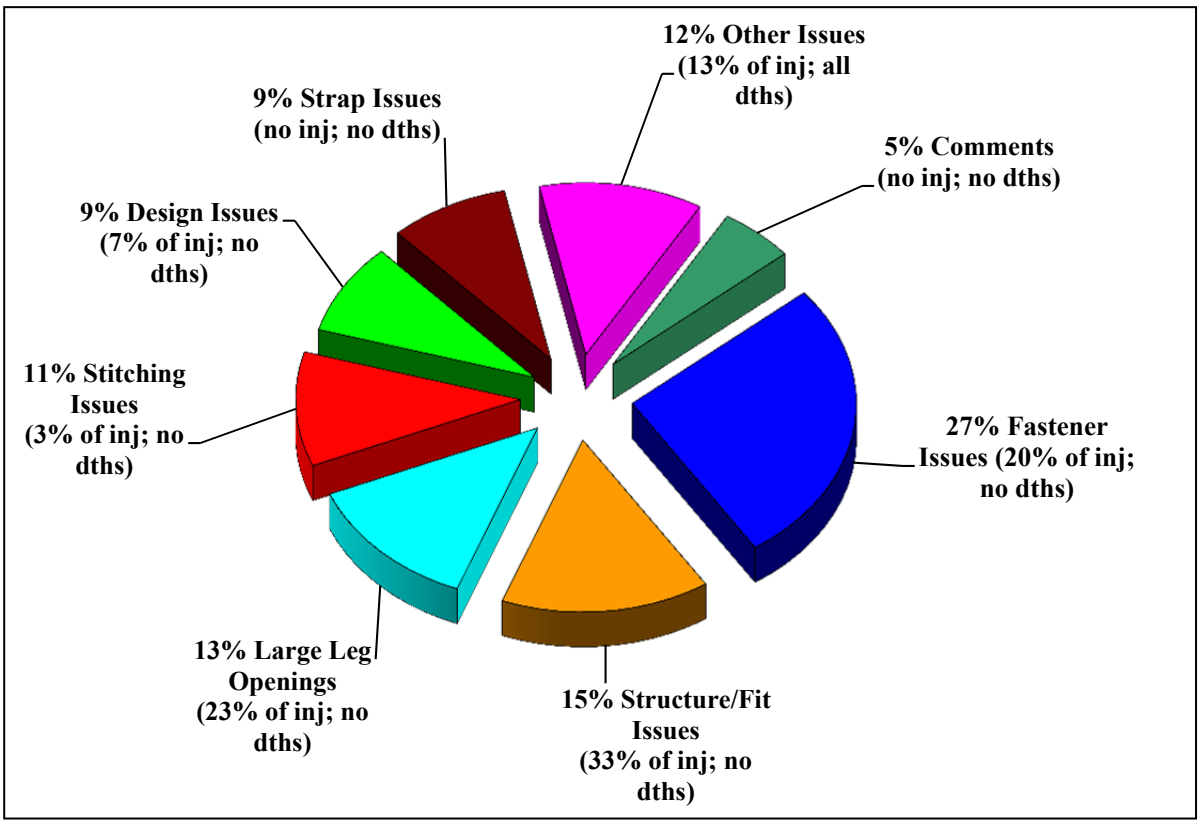
F. ***Strap issues:*** Eight incidents (9 percent) reported issues with straps, mostly about the adjuster breaking or slipping. No injuries or fatalities were reported in this category.

G. ***Other issues:*** Eleven reports (12 percent) were related to issues other than the ones described above. Two fatalities and four injuries, including two hospitalizations, were reported in this category. The two fatalities—one case of a parent falling asleep while wearing the carrier with the infant inside, and the other case of an infant suffering respiratory distress while being carried facing the caregiver—are included in this category. In each case, CPSC staff concluded that there were too many confounding factors reported to determine that a specific factor contributed predominantly to the deaths. The remaining reports were of unspecified falls, an unspecified abrasion injury, and an incidental injury to the infant due to the caregiver falling.

H. ***Consumer comments:*** Five reports (5 percent) involve consumer comments or observations of perceived safety hazards. None of these cases involved an actual incident.

The distribution of the 93 reported incidents by the hazard patterns described above is shown in Fig. 1.

Fig 1: Distribution of Incident Reports Associated with Soft Infant and Toddler Carriers by Hazard Pattern Characterizations 01/01/99−09/10/12



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

IV. National Injury Estimates[15]

Staff estimates a total of 1,400 injuries (sample size=66, coefficient of variation=0.23) related to SITCs that were treated in U.S. hospital emergency departments over the 13-year period 1999−2011. Until NEISS data for 2012 is finalized in spring 2013, partial estimates for 2012 are not available. The injury estimates for individual years are based on very small samples and are not reportable.[16] Moreover, due to the unreliability of the yearly estimates, a trend analysis is not feasible.

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

All data coded under product codes 1527, 1548, and 1549 were extracted. Age was limited to less than 5 years. Certain records were considered out of scope for the purposes of this memorandum. For example, a victim suffering an acute medical episode while sitting in the soft infant and toddler carrier was considered out of scope. These records were excluded prior to deriving the statistical injury estimates.

[16] According to the NEISS publication criteria, an estimate must be 1,200 or greater; the sample size must be 20 or greater; and the coefficient of variation must be 33 percent or smaller.

No fatalities were reported through NEISS. Although data extraction criteria included ages up to 4 years, all of the injured children were reported to be less than 2 years of age. Presented below are the most frequently occurring characteristics among the emergency department-treated injuries associated with soft infant and toddler carriers:

- Hazard – Striking the ground while in the carrier when caregiver fell (65%); falling out of the carrier (21%).
- Injured body part – Head (63%); face (11%).
- Injury type – Internal organ injury (48%); contusions/abrasions (19%); and fractures (12%).
- Disposition – Treated and released (79%); hospitalized (10%); and treated and transferred (9%).

TAB D:

Labeling for Soft Infant and Toddler Carriers

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

Memorandum

Date: December 14, 2012

TO : Gregory K. Rea
Project Manager for Soft Infant and Toddler Carriers
Director
Division of Mechanical Engineering
Directorate for Laboratory Sciences

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

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

FROM : Sharon R. White, Engineering Psychologist
Division of Human Factors
Directorate for Engineering Sciences

SUBJECT : Labeling for Soft Infant and Toddler Carriers

As part of the soft infant carrier Consumer Product Safety Improvement Act (CPSIA) 104 rulemaking activity, staff of the U.S. Consumer Product Safety Commission's (CPSC) Division of Human Factors (ESHF) has prepared this memo in response to a request to review the adequacy of the label in the voluntary standard for soft infant and toddler carriers (SITC) in the draft proposed rule.

I. BACKGROUND

ESHF staff examined various styles and colors of SITCs for this analysis. SITCs are composed of fabric and are worn by a caregiver with the child in the carrier that is suspended from one or both shoulders of the caregiver. Some of the carriers are designed to be worn only on the front of the caretaker. Other carriers are designed to be worn on both the front and back; front, back, and hip; or hip only position. The upper weight limit on these SITCs generally tends to be higher than that of the front carriers only. For example, some are designed for infants from birth up to 32, 35, and 45 pounds, depending upon the brand. Other carriers are designed for

infants who can hold their head upright, with a minimum weight limit of 16 or 18 pounds. All are designed to hold a child in an upright position in close proximity to a caretaker, rather than a curled, semi-reclined position as allowed by a sling.

All but one of the SITCs examined have a warning label affixed. The labels have the signal word "WARNING" and a "FALL HAZARD" statement. The labels also have precautionary statements. The warning label on one of the carriers reads as follows:

The warning labels on other carriers may contain these or similar warning statements. Others may carry additional language [*e.g.*, "child MUST be able to sit upright unassisted to use the backpack position (about 6 months old)"]. Language relevant to age and weight requirements may differ. Some of the precautionary statements are presented in paragraph format as above. Others are presented in a vertical list format.

Originally, ASTM F2236-03 covered soft infant carriers designed for infants weighing between 7 and 25 pounds. This standard established performance requirements and marking and labeling requirements for soft carriers. Given that SITCs are marketed for children up to 45 pounds, CPSC staff recommended to the ASTM Soft Carrier subcommittee that the scope of the standard be expanded to address carriers designed for occupants weighing between 7 and 45 pounds. The updated scope was first published in ASTM F2236-12 and remains in the current version, ASTM F2236-13.

Incident Data

National Electronic Injury Surveillance System (NEISS)

CPSC staff is aware of 66 SITC-related injuries treated in emergency departments of hospitals that are members of the NEISS sample from the years 1999 through 2011. Based on these cases, staff estimated 1,400 emergency department-treated injuries nationally. The majority of the

estimated injuries occurred when a child in the carrier was struck after a caregiver fell (65%), or a child fell out of the carrier (21%). Head injuries accounted for 63 percent of all injuries.

Non-NEISS incidents

Staff also received reports of 93 SITC-related incidents that occurred between January 1, 1999 through September 10, 2012. These incident reports are housed in the CPSC's epidemiological database of in-depth investigations (INDP), injury or potential injury incidents (IPII), and the death certificates (DTHS). The incidents primarily involved infants 6 months and under.

Deaths

Two of the 93 cases involved a suffocation death. In an incident in 2000, the mother was on a field trip at the zoo with her 6-year-old son. She brought along her 5-week-old in an infant carrier. The mother loosened the straps and tilted the victim onto his side to allow him to nurse. She covered him with a light blanket. The mother stated that the infant did not drink much and fell asleep. Noticing the infant was asleep, she repositioned him by tightening the straps so he was held snug against and facing inward toward her body. Within the next 15 to 20 minutes, her 6-year-old son noticed blood coming from the infant's nose. The infant was later pronounced dead due to positional asphyxia. In 2007, the father of the 2-month-old victim placed the child in the carrier facing him and walked around to calm the victim. The father eventually lay down on his back on the couch with the victim still in the carrier. The father awakened the next morning and discovered the victim unresponsive with her face pressed directly into her father's chest. The victim was later pronounced dead.

Nonfatal Incidents

Of the 93 reported incidents, twenty-five (27%) incidents involved buckles or snaps breaking, releasing, or detaching, and buttons coming off. Twelve incidents (13%) occurred when an infant slipped through the leg hole. Ten incidents (11%) involved seams/stitching ripping or coming apart. Nine of the 93 (10%) involved legs/feet "turning purple." Seven (7%) incidents involved the caretaker kneeling or bending down, or leaning forward, causing the occupant to fall out. Seven (8%) incidents involved the strap adjuster breaking, and one (1%) involved the strap breaking. Two incidents (2%) involved a caretaker bending over or squatting, resulting in fractures of a child's limbs. The remaining cases are classified as "miscellaneous." They include fingers caught and a scratched and bruised arm. Others involve falls in which there is insufficient information to determine the cause of the incidents.

Consumer Complaints

Five of the 93 (5%) reports were consumer comments about safety concerns. They included complaints about the product being labeled improperly, wide leg holes, buckle accessibility, and other non-injury-related complaints.

II. DISCUSSION

The Danny Keysar Child Product Safety Notification Act, section 104 of the CPSIA, requires that the CPSC evaluate the existing voluntary standards for durable infant or toddler products and promulgate a mandatory standard substantially the same as, or more stringent than, the applicable voluntary standard. Infant carriers are among the durable products named in the Danny Keysar Child Product Safety Notification Act. Staff from the Directorate of Laboratory Sciences (LS) requested staff from HF to analyze, and strengthen if appropriate, the labeling requirements in the previous version of the standard in response to the direction provided in section 104 of the CPSIA. Staff analyzed the injury data because these provide important opportunities to identify and understand the hazards (Laughery and Hammond, 1999) as well as for determining which behaviors to warn against and how to do so. At the request of LS staff, HF also reviewed applicable labeling language from other standards such as Standard Consumer Specification for Frame Child Carriers, F 2549-06; Standard Consumer Safety Specification for Hand-Held Infant Carriers, F 2050-09; and Standard Consumer Safety Specification for Sling Carriers, ASTM F 2907-12 to update the standard consistent with other similar durable infant and product standards. Based on HF staff's review of the injury data and other sources, staff determined that the labeling requirements could be improved in content and format. Therefore, HF staff proposed a label that was balloted and will be published in ASTM F2236-13 in March, 2013 (Fig.1).

The new warning label is intended to address the incidents mentioned previously with the exception of incidents related to leg circulation-related injuries. HF staff did not recommend labeling requirements to address these incidents because labeling would not be an appropriate measure for hazard control. HF staff suggests that incoming incidents continue to be examined to determine whether changes to the ASTM standard would be needed in the future.

⚠ WARNING
FALL AND SUFFOCATION HAZARD
FALL HAZARD - Infants can fall through a wide leg opening or out of carrier. • Adjust leg openings to fit baby's legs snugly. • Before each use, make sure all ____ are secure. • Take special care when leaning or walking. • Never bend at waist; bend at knees. • Only use this carrier for children between ___ lb and ___ lb. SUFFOCATION HAZARD – Infants under 4 months can suffocate in this product if face is pressed tight against your body. • Do not strap infant too tight against your body. • Allow room for head movement. • Keep infant's face free from obstructions at all times.

Figure 1

The label contains components that HF staff believes are important for a label. It contains the signal word "WARNING," a statement of hazard and consequences, and what to do to avoid the hazard. Guidelines for warning labels recommend focusing on the most likely and most serious risks. Warnings about low probability events (*e.g.*, "Never leave child unattended"), such as addressed in the labeling requirements for standard Consumer Safety Specification for Hand-Held Carriers, ASTM F 2050-09 were omitted because these may dilute the effectiveness of language concerning events more likely to occur. Events that have a low likelihood of occurring are more appropriately addressed in other warning systems (Laughery and Hammond, 1999; Wogalter, 2006) such as product instructions. Therefore, hazards having the highest priority (i.e., most likely to occur, most serious consequences, etc.) fall and suffocation, respectively, are prominently and conspicuously displayed on the product label. A description of the consequences as well as precautionary statements is also prominently displayed to draw consumers' attention. Additionally, the format of the warning is presented in a list format for visual appeal. This may increase the likelihood that consumers will read, understand, and comply with the warning. Warnings presented in a paragraph format, as is the current practice of many manufacturers of SITCs, may reduce the likelihood that consumers will read the warnings. If consumers do read the warnings, they may only skim the label and miss warnings.

Effectiveness of Labeling

Infant and toddler carriers are designed for strapping a child close to an adult caretaker's body while freeing a caretaker's hands for other tasks. The carriers provide a soft and warm enclosure for an infant, and the rhythmic movements of a caretaker can calm and soothe a distressed child. Consumers are likely to perceive such an environment as safe for a child. Research indicates that consumers are not likely to look for or read warnings on products perceived as safe (Godfrey et al, 1983). Second, consumers frequently use these products with their young children. Research demonstrates quite clearly that users who are more familiar or experienced with a product or a similar product are less likely to look for warnings (Godfrey et al, 1983; Godfrey and Laughery, 1984; Wogalter, Desaulniers, Brelsford, Jr., 1986; Sanders and McCormick, 1993; and Wogalter and Laughery, 2006), read (Otsubo, 1988), and comply with warnings (Wogalter and Murphy, 1995). Although ESHF staff made suggestions to improve the warning for soft carriers, repeated exposure to such a warning over time may result in its attracting less attention (Dejoy, 1999); this is especially so, due to the perceived hazard and familiarity effect. Therefore, ESHF staff believes that, due to the perception of a low hazard associated with, and high familiarity with this product or a similar product, labeling is likely to have limited effectiveness.

III. CONCLUSION

As part of the SITC CPSIA 104 rulemaking activity, HF staff proposed a label that was balloted and is now published in ASTM F2236-13. Staff proposed this warning at the request of staff from the Directorate of Laboratory Sciences (LS) to improve the labeling requirements in the previous version of the standard. In developing the label, staff analyzed the injury data and, at the request of LS staff, also reviewed applicable labeling language from other standards to update the standard consistent with other similar durable infant and product standards. Based on the injury data, ESHF identified multiple hazards associated with soft carriers. They include suffocation; and infant falls from the SITC when the user (caretaker) fell; fasteners breaking or detaching; users leaning and/or bending over, resulting in fractures of a child's limbs or a child falling out of the carrier, and infants slipping through a leg hole. Other hazards include leg circulation-related injuries.

The new warning label is intended to address these incidents with the exception of incidents related to leg circulation-related injuries. HF staff did not recommend labeling requirements to address these incidents because labeling would not be an appropriate measure for hazard control. HF staff suggests that incoming incidents continue to be examined to determine what, if any, future changes should be made to the ASTM standard for SITCs.

The requirements for content and format of the label are much improved over those in the previous version of the standard. HF staff believes that the new warning label may motivate consumers to read, understand, and comply with the warning. Therefore, HF staff recommends adopting the voluntary standard for SITCs as a mandatory standard, without any changes to the labeling provisions.

Although HF staff recommends adopting the voluntary standard for SITCs as a mandatory standard, without any changes to the labeling provisions, staff believes that repeated exposure to such a warning over time may result in its attracting less attention and especially so due to the perceived hazard and familiarity effect. Therefore, ESHF staff believes that due to the low perception of hazard associated with and high familiarity with this product or similar product, labeling is likely to have limited effectiveness.

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TAB E:

Initial Regulatory Flexibility Analysis of Staff-Recommended Proposed Standard for Soft Infant and Toddler Carriers

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

Memorandum

Date: March 11, 2013

TO : Gregory K. Rea
Project Manager, Soft Infant and Toddler Carriers
Director
Division of Mechanical Engineering
Directorate for Laboratory 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 : Samantha Li
Economist
Directorate for Economic Analysis

SUBJECT : Initial Regulatory Flexibility Analysis of Staff-Recommended Proposed Standard for Soft Infant and Toddler Carriers

Introduction

On August 14, 2008, the Consumer Product Safety Improvement Act (CPSIA) was enacted. Among its provisions, section 104, the Danny Keysar Child Product Safety Notification Act, requires that the U.S. Consumer Product Safety Commission (CPSC) evaluate the existing voluntary standards for durable infant or toddler products and promulgate a mandatory standard substantially the same as, or more stringent than, the applicable voluntary standard. Infant carriers are among the durable products specifically named in the Danny Keysar Child Product Safety Notification Act. Upon review, CPSC staff recommends that the Commission adopt the voluntary ASTM International (or ASTM, formerly known as the American Society for Testing and Materials) standard for soft infant and toddler carriers (F2236–13) *Standard Consumer Safety Specification for Soft Infant and Toddler Carriers* with no modifications.

The Regulatory Flexibility Act (RFA) requires that proposed rules be reviewed for their potential economic impact on small entities, including small businesses. Section 603 of the RFA requires that CPSC staff prepare an initial regulatory flexibility analysis and make it available to the public for comment when the general notice of proposed rulemaking is published. The initial regulatory flexibility analysis must describe the impact of the proposed rule on small entities and identify any alternatives that may reduce the impact. Specifically, the initial regulatory flexibility analysis must contain:

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

The Product

As specified in the current ASTM standard (F2236-13), a soft infant and toddler carrier (SITC) is a product, normally of sewn fabric construction, designed to contain a full term infant up to a toddler, generally in an upright position, in close proximity to the caregiver. These products are intended for infants and toddlers between the weight of 7 lbs. and 45 lbs. A SITC is worn by the caregiver, and the infant is suspended from one or both shoulders of the caregiver, with the infant either facing toward the caregiver or away from the caregiver. This includes SITCs that can be worn on the front, side, or back of the caregiver's body. Slings or sling carriers, which are infant carriers of fabric or sewn fabric construction where the occupant can be carried in a reclined position, are not included.

The Market for Soft Infant and Toddler Carriers

SITCs are generally produced and/or marketed by juvenile product manufacturers and distributors. Several of these firms focus exclusively on SITCs, as well as substitute products such as slings. CPSC staff believes there are at least 39 suppliers to the U.S. market. Thirty-one domestic firms supply SITCs to the U.S. market: 15 are domestic manufacturers; eight are domestic importers; and the supply sources of eight domestic firms are unknown. Five foreign

firms supply SITCs to the U.S. market: three are foreign manufacturers; one is a foreign importer; and one firm with an unknown supply source. Insufficient information is available on the remaining three firms to categorize them.[17]

According to a 2005 survey conducted by the American Baby Group (*2006 Baby Products Tracking Study*), 51 percent of new mothers own SITCs.[18] Approximately 30 percent of SITCs were handed down or purchased second-hand.[19] Thus, about 70 percent of SITCs were acquired new. This suggests that approximately 1.5 million SITCs are sold to households annually (.51 x .70 x 4.1 million births per year).[20]

Many SITCs have expanded their maximum weight limits in recent years to accommodate older children. However, staff believes that most adult users would not be comfortable carrying older, heavier children in SITCs, and this is supported by a lack of incident data with children over 2 years old.[21] It appears that SITCs are used during a child's first year, with some caregivers continuing to use these products into the second year. We do not know the proportion that continues use of these products into the second year, so we estimate risk under the assumption that approximately 25−50 percent will do so. Based on data from the *2006 Baby Products Tracking Study*, approximately 2.1 million SITCs are owned by new mothers. Therefore, approximately 2.6−3.2 million households have SITCs available for use annually. Based on Epidemiology staff's estimate of 1,400 injuries treated nationally in emergency departments from 1999 to 2011, it is estimated that an average of 108 emergency department-treated injuries involving children under age 2 related to SITCs are treated annually.[22] Therefore, about 0.34−0.40 emergency department-treated injuries may occur annually for every 10,000 SITCs available for use in the households of new (and second year) mothers.

[17] Staff made these determinations using information from Dun & Bradstreet and Reference USAGov, as well as firm websites.
[18] 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, since the most recent survey information is from 2005, it may not reflect the current market.
[19] The data on secondhand products for new mothers was not available. Instead, data for new mothers and experienced mothers was combined and broken down into first-time mothers and experienced mothers. Data for first-time mothers and experienced mothers have been averaged to calculate the approximate percentage that were handed down or purchased secondhand.
[20] U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), National Center for Health Statistics, National Vital Statistics System, "Births: Final Data for 2009," *National Vital Statistics Reports* Volume 60, Number 1 (November 2011): Table I. Number of live births in 2009 is rounded from 4,130,665.
[21] Memorandum from Risana Chowdhury, Directorate of Epidemiology, Dated March 11, 2013, Subject: Soft Infant and Toddler Carrier-Related Deaths, Injuries, and Potential Injuries, and NEISS Injury Estimates; 1999− September 10, 2012.
[22] Ibid.

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

The Danny Keysar Child Product Safety Notification Act, section 104 of the CPSIA, requires the CPSC to promulgate mandatory standards for nursery products that are substantially the same as, or more stringent than, the voluntary standard. CPSC staff worked closely with ASTM to develop the new requirements and test procedures that have been incorporated into ASTM F2236-13, which forms the basis of the draft proposed rule.

Compliance Requirements of the Draft Proposed Rule

Staff recommends that the Commission adopt the current voluntary standard with no revision as its proposed rule. Some of the more significant requirements of the current voluntary standard for soft infant and toddler carriers (ASTM F2236–13) include: [23]

- Dynamic and static load– intended to ensure structural integrity of the soft carrier;
- Leg openings – intended to prevent occupant from falling out; and
- Fastener strength and strap retention – intended to ensure the structural integrity of the fastening systems.

The voluntary standard also includes: (1) requirements for several features to prevent cuts (hazardous sharp points or edges, small parts, and wood parts); (2) requirements for locking and latching; (3) marking and labeling requirements; (4) flammability requirements; (5) requirements for the permanency and adhesion of labels; (6) requirements for instructional literature; and (7) toy accessories requirements.

The current voluntary standard revised several test procedures, warning label statements, and instructional literature to provide greater clarification. The dynamic and static tests were revised to require testing for each carrying position. The fabric used in SITCs must pass the flammability test for clothing or items worn on the body (16 C.F.R. part 1610). The revised test harmonizes the flammability requirement with that of slings. The unbounded leg opening requirement was clarified to require: (1) placement of a SITC on the front of the caregiver's torso, and (2) use of a test cone to test for possible bounded leg openings. The updated warning statements provide additional details of the fall and suffocation hazards. Changes to warning labels are not expected to have a significant impact on suppliers. Typically, warning labels that are placed on fabric, as is the case here, are less costly than those used on plastic or metal.

[23] Memorandum from Vincent Amodeo, Division of Mechanical Engineering, Directorate for Engineering Sciences, dated: March 11, 2013, Subject: Incorporation of ASTM F2236-13, Standard Consumer Safety Specification for Soft Infant and Toddler Carriers, into Staff's Draft Proposed Rule.

The fastener requirement will help address some of the incidents caused by fastener problems, issues with stitching/seams and straps, as well as some incidents involving recalled products.[24] The requirement applies to loadbearing fasteners only, where the failure to support a child's weight could result in injury. Staff testing found all SITCs that had not been subject to a recall for strap/fastener problems could meet the requirement without product modifications. If a modification is required, it is likely to be minor and inexpensive (stronger material used for straps or for sewing seams, stronger or different materials used for the fasteners, etc.).

Other Federal Rules

Section 14(a)(2) of the Consumer Product Safety Act (CPSA) requires every manufacturer and private labeler of a children's product that is subject to a children's product safety rule to certify, based on third party testing conducted by a CPSC-accepted laboratory, that the product complies with all applicable children's product safety rules. Section 14(i)(2) of the CPSA requires the Commission to establish protocols and standards by rule for, among other things, ensuring that a children's product is tested periodically and where there has been a material change in the product, and safeguarding against the exercise of undue influence on a conformity assessment body by a manufacturer or private labeler. A final rule implementing sections 14(a)(2) and 14(i)(2) of CPSA, *Testing and Labeling Pertaining to Product Certification*, 16 CFR part 1107, became effective on February 13, 2013 (the 1107 rule).

SITCs will be subject to a mandatory children's product safety rule, so they will also be subject to the third party testing requirements of section 14 of the CPSA and the 1107 rule when the final rule and the notice of requirements become effective.

Impact on Small Businesses

Under U.S. Small Business Administration (SBA) guidelines, a manufacturer of SITCs 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, 26 of the 31 domestic firms supplying SITCs to the U.S. market are small firms —12 manufacturers, six importers, and eight firms whose supply source is unknown. Additional unknown small soft infant and toddler carrier suppliers may operate in the U.S. market as well.

[24] Memorandum from David Whiting, Compliance Officer, Regulatory Enforcement Division, Mechanical Hazards Team, dated September 18, 2012, Subject: Durable Nursery Products: Summary of Recalls Involving Soft Infant and Toddler Carrier Products.

Small Manufacturers

The expected impact of the staff-recommended draft proposed rule on small manufacturers will differ, based on whether their soft infant and toddler carriers are already compliant with F2236-10. Although ASTM F2236-12 was published in December 2012, and ASTM F2236-13 was published in March 2013, new standards are not in effect until six months after publication. Accordingly, firms are likely still testing to ASTM F2236-10.

In general, firms whose SITCs meet the requirements of F2236-10 are likely to continue to comply with the voluntary standard as new versions are published. In addition, they are likely to meet any new standard within 6 months, because this is the amount of time JPMA allows for products in their certification program to shift to a new standard. Many of these firms are active in the ASTM standard development process and compliance with the voluntary standard is part of an established business practice.

The impact on seven of 12 domestic manufacturers that comply with ASTM F2236-10 is expected to be small. Firms already in compliance with F2236-10 may require slight, if any, modifications, in order to bring their product into compliance with the current voluntary standard. Any strap/fastener modifications are expected to incur minimal costs, as are changes to the warning label.

Meeting ASTM F2236-13's requirements could necessitate some product redesign for five of the 12 domestic manufacturers not believed to be compliant with F2236-10. These redesigns would likely involve adding or changing straps, fasteners, or fabrics and are generally less expensive than complete redesign, based on past discussions with manufacturers. For the types of changes that might be required of these products, staff does not believe that complete redesigns (including engineering time, prototype development, tooling, etc.) would be required for any known products. Therefore, in most cases, the impact of the draft proposed rule is not expected to have a significant effect on products not believed to be compliant with F2236-10.

It is possible that some firms whose SITCs are neither certified as compliant nor claim compliance with F2236-10 (or a similar standard), in fact, are compliant with the standard. CPSC staff has identified many such cases with other infant and toddler products. To the extent that some of these firms may supply compliant SITCs, and have developed a pattern of compliance with the voluntary standard, the direct impact of the draft proposed rule will be less significant than described above.

There are eight small firms with unknown supply sources, three of which appear to be compliant with F2236-10. If these firms are manufacturers, they will be affected as described above. If

these firms are distributers or wholesalers, the impact will be similar to the impact on importers, as discussed below.

In addition to the direct impact of the draft proposed rule, there are indirect impacts. These impacts are considered indirect because they do not arise directly as a consequence of the proposed rule's requirements. Once the rule becomes final and the notice of requirements is in effect, all manufacturers will be subject to the additional costs associated with the third party testing and certification requirements. This will include any physical and mechanical test requirements specified in the final rule; lead and phthalates testing is already required, and hence, they are not included in this discussion.

Staff estimates that testing to the ASTM voluntary standard could cost around $500−$600 per model sample. On average, each small domestic manufacturer supplies two different models of soft infant and toddler 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−$1,200 annually. Based on a review of firms' revenues, the impact of third party testing to ASTM F2236-13 is unlikely to be significant if only one soft carrier sample per model is required. However, these costs could be more significant if multiple models are needed for testing.

Small Importers

Most importers would not experience significant impacts as a result of the draft proposed rule. Five of the six small importers are believed to be compliant with the voluntary standard. In the absence of regulation, these firms would likely continue to comply with the voluntary standard as it evolves and would likely comply with the final mandatory standard as well.

The remaining importer might need to find an alternate source of SITCs if its existing supplier does not come into compliance with the requirements of the draft proposed rule. Alternatively, the firm may discontinue importing SITCs altogether and perhaps substitute another product.

As is the case with manufacturers, all importers will be subject to third party testing and certification requirements, and consequently, they will experience the associated costs, if their supplying foreign firm(s) does not perform third party testing. The resulting costs could have a significant impact on a few small importers that must perform the testing themselves if more than one sample per model were required. In addition, the impacts could be higher than those incurred by domestic manufacturers if importers have to test to each batch imported in the case where the foreign manufacturer does not conduct the testing.

Alternatives

Under the Danny Keysar Child Product Safety Notification Act, section 104 of the CPSIA, one alternative would be to set an effective date later than the staff-recommended six months, which is generally considered sufficient time for suppliers to come into compliance with a proposed durable infant and toddler product rule. Setting a later effective date would allow suppliers additional time to modify and/or develop compliant soft infant and toddler carriers and spread the associated costs over a longer period of time.

TAB F:

Regulatory Flexibility Analysis of the Accreditation Requirements for Conformity Assessment Bodies for Testing Conformance to the Soft Infant and Toddler Carrier Standard

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

Memorandum

Date: March 11, 2013

TO : Gregory K. Rea
Project Manager, Soft Infant and Toddler Carriers
Director
Division of Mechanical Engineering
Directorate for Laboratory Sciences

THROUGH: Gregory Rodgers
Associate Executive Director
Directorate for Economic Analysis

Deborah V. Aiken
Senior Staff Coordinator
Directorate for Economic Analysis

FROM : Robert Franklin
Economist
Directorate for Economic Analysis

SUBJECT : Regulatory Flexibility Analysis of the Accreditation Requirements for Conformity Assessment Bodies for Testing Conformance to the Soft Infant and Toddler Carrier Standard

In accordance with section 14 of the Consumer Product Safety Act (CPSA), children's products that are subject to a children's product safety rule must be tested by an accredited conformity assessment body for compliance with the product safety rule. Staff is proposing an amendment to 16 CFR part 1112 that would establish the requirements for the laboratory acceptance of the accreditation of a conformity assessment body to test for compliance with the soft infant and toddler carrier proposed rule. This memorandum assesses the impact of the amendment on the small laboratories.

Section 14(a)(3) of the CPSA requires the Commission to publish a notice of requirements (NOR) for the accreditation of third party conformity assessment bodies (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 Fed. Reg. 15836 (March 12, 2013), which codifies part 1112. 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. The final rule also codifies all of the NORs that the CPSC has published to date. All new NORs, such as the soft infant and toddler carrier standard, require an amendment to this rule.

On May 24, 2012, staff conducted an analysis of the potential impacts on small entities of the proposed rule establishing accreditation requirements, 77 Fed. Reg. 31086, 31123-26, as required by the Regulatory Flexibility Act and prepared an Initial Regulatory Flexibility Analysis (IRFA). Briefly, the IRFA 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 rule to include the NOR for the soft infant and toddler carrier standard would not have a significant adverse impact on small laboratories. Moreover, based upon the number of laboratories in the United States that have applied for CPSC acceptance of the accreditation to test for conformance to other juvenile product standards, we expect that only a few laboratories will seek CPSC acceptance of their accreditation to test for conformance with the soft infant and toddler carrier standard. Most of these laboratories will have already been accredited to test for conformance to other juvenile product standards and the only costs to them would be the cost of adding the soft infant and toddler carrier standard to their scope of accreditation. As a consequence, the Commission could certify that the proposed notice requirements for the soft infant and toddler carrier standard will not have a significant impact on a substantial number of small entities.