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

DATE: March 22, 2017

BALLOT VOTE SHEET:

TO: The Commission
Todd A. Stevenson, Secretary

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

FROM: Patricia M. Pollitzer, Assistant General Counsel
Matthew T. Mercier, Attorney, OGC

SUBJECT: Proposed Rule: Safety Standard for Infant Inclined Sleep Products

BALLOT VOTE DUE - Tuesday, March 28, 2017

The Office of the General Counsel is providing for Commission consideration the attached draft notice of proposed rulemaking for publication in the *Federal Register*. The draft proposed rule would incorporate by reference the voluntary safety standard for infant inclined sleep products pursuant to the Danny Keysar Child Product Safety Notification Act, section 104 of the Consumer Product Safety Improvement Act of 2008. In addition, the draft proposed rule proposes to: amend the definition of "durable infant or toddler product" in the consumer registration rule to clarify that inclined sleep products fall within the category of "durable infant or toddler product," and amend 16 C.F.R. part 1112 to include the mandatory standard for inclined sleep products in the list of notices of requirements.

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.)

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_____ _____

(Signature) (Date)

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

_____ _____

(Signature) (Date)

IV. Take other action. (Please specify.)

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_____ _____

(Signature) (Date)

Attachment: Draft *Federal Register* Notice: Proposed Rule to Establish a Safety Standard for Infant Inclined Sleep Products

Billing Code 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1112, 1130, and 1235

[CPSC Docket No. 2017-XXXX]

Safety Standard for Infant Inclined Sleep Products

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 infant inclined sleep products (inclined sleep products) in response to the direction under section 104(b) of the CPSIA. In addition, the Commission is proposing an amendment to include inclined sleep products in the list of notice of requirements (NORs) issued by the Commission. The Commission is also proposing to explicitly identify infant inclined sleep products as a durable infant or toddler product subject to CPSC's consumer registration requirements.

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 requirements of the proposed mandatory standard for

inclined sleep products should be directed to the Office of Information and Regulatory Affairs, the Office of Management and Budget, Attn: CPSC Desk Officer, FAX: 202-395-6974, or e-mailed to oira_submission@omb.eop.gov.

Other comments, identified by Docket No. CPSC-2017-XXXX, 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 by mail/hand delivery/courier 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-2017-XXXX, into the "Search" box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Celestine T. Kish, Project Manager, Directorate for Engineering, U.S. Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone: (301) 987-2547; email: *ckish@cpsc.gov*.

SUPPLEMENTARY INFORMATION:

I. Background and Statutory Authority

The CPSIA was enacted on August 14, 2008. Section 104(b) of the CPSIA, part of the Danny Keysar Child Product Safety Notification Act, requires the Commission to: (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 or toddler products. Standards issued under section 104 are to be "substantially the same as" the applicable voluntary standards, or more stringent than the voluntary standard if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product.

Section 104(f)(1) of the CPSIA defines the term "durable infant or toddler product" as "a durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years." The definition lists examples of several categories of durable infant or toddler products, including bassinets and cradles. Staff initially considered inclined sleep products to fall within the scope of the bassinet/cradle standard, but as work progressed on that standard, it became evident that one rule could not effectively address all products. Accordingly, the Commission directed staff to separate inclined sleep products into a separate rulemaking effort. Thus, the inclined sleep products safety standard is an outgrowth of the bassinet/cradle safety standard, addressing products with an incline greater than 10 degrees from horizontal.

ASTM simultaneously began work on developing a voluntary standard for inclined sleep products. ASTM published the resulting infant inclined sleep products standard in May 2015, and most recently revised the standard in January of 2017.

This proposed rule would establish a standard for inclined sleep products as a type of durable infant or toddler product under section 104 of the CPSIA. Because the inclined sleep product standard is an outgrowth of the bassinet/cradle standard, a category that the statutory definition of "durable infant or toddler product" explicitly lists, inclined sleep products could be considered a type of bassinet. Section 104(f). Thus, to avoid possible confusion about inclined sleep products being a durable infant or toddler product, the Commission proposes to amend the definition of "durable infant or toddler product" in the consumer registration rule to explicitly include "infant inclined sleep products."

Pursuant to section 104(b)(1)(A) of the CPSIA, the Commission consulted with manufacturers, retailers, trade organizations, laboratories, consumer advocacy groups, consultants, and members of the public in the development of this notice of proposed rulemaking (NPR), largely through the ASTM process.

Based on a briefing package prepared by CPSC staff, the NPR would incorporate by reference the most recent voluntary standard developed by ASTM International, ASTM F3118-17, *Standard Consumer Safety Specification for Inclined Sleep Products*, with a modification to the standard's definition of "accessory." [INSERT link to briefing package] If finalized, the ASTM standard, as modified, would be a mandatory safety rule under the Consumer Product Safety Act (CPSA).

The testing and certification requirements of section 14(a) of the CPSA apply to the standards promulgated under section 104 of the CPSIA. Section 14(a)(3) of the CPSA requires

the Commission to publish an NOR for the accreditation of third party conformity assessment bodies (test laboratories) to assess conformity with a children's product safety rule to which a children's product is subject. The proposed rule for inclined sleep products, if issued as a final rule, would be a children's product safety rule that requires the issuance of an NOR. To meet the requirement that the Commission issue an NOR for the inclined sleep products standard, this NPR also proposes to amend 16 CFR part 1112 to include 16 CFR part 1235, the CFR section where the inclined sleep products standard will be codified, if the standard becomes final.

II. Product Description

A. Infant Inclined Sleep Products, Generally

There are many different styles of infant inclined sleep products available for infants and newborns. These can be categorized as:

- **Hammocks** (typically constructed of fabric and suspended from one or two points, either above or on either side; constructed of various materials; generally conform to the shape of the child when placed in the product; can either be supported by a frame or other structure, such as a ceiling);
- **Newborn or infant frame type** (intended to be placed on the floor; self-supporting; typically use a metal frame with a rigid or semi-rigid sleeping surface; base may be stationary or allow side to side rocking; may be intended for use by either newborns or infants, or both, depending on the size);
- **Compact** (freestanding with the bottom of the seat a maximum of 6 inches above the floor; generally constructed of foam with a fixed seat back angle between 10° and 30°; intended to be used on the floor); and

- **Newborn or infant inclined sleep product accessories** (intended to provide sleeping accommodations and are attached to or supported in some way by another product; a rigid frame product that has either a stationary or fixed base and in some cases may be removed and used independently; products intended for newborn use have a seat back less than 17 inches).

Products intended for use with newborns are generally similar in design to products intended for infants, except that products intended for use with newborns have a seat back length of 17 inches or less.

B. Definition of "Infant Inclined Sleep Product"

An "infant inclined sleep product," as defined by ASTM F3118-17, includes three key components:

- Age of intended product occupant: the product must be intended for infants up to five months old (3 months for certain smaller products). The product may additionally be intended for older children, possibly in a different configuration, provided that its intended use also includes children up to five months.
- Sleep: the product must be primarily intended and marketed to provide sleeping accommodations.
- Surface incline: the product must have at least one inclined sleep surface position that is greater than 10 degrees, but less than or equal to 30 degrees.

In sum, the inclined sleep products standard covers "a free standing product with an inclined sleep surface primarily intended and marketed to provide sleeping accommodations for an infant up to 5 months old or when the infant begins to roll over or pull up on sides, whichever comes first."

The ASTM standard also covers newborn inclined sleep products, compact inclined sleep products, and inclined sleep product accessories. According to the ASTM standard, a newborn inclined sleep product is a "smaller product intended for newborns up to 3 months old or when newborn begins to wiggle out of position or turn over in the product or weighs more than 15 lb (6.8 kg), whichever comes first." A compact inclined sleep product is "a free standing infant or newborn inclined sleep product having a distance of 6.0 in. or less between the underside of the lowest point on the seat bottom and the support surface (floor)." The ASTM standard defines "infant and newborn inclined sleep product accessories" as products "which are attached to, or supported by, another product with the same age or abilities, or both, as the free standing products." The ASTM standard currently limits inclined sleep product accessories to rigidly framed products, but the Commission proposes to modify the definition in ASTM F3118-17 of "infant and newborn inclined sleep product accessories" to remove the phrase "rigidly framed" so that the standard will include recently-identified soft-sided products that attach to cribs and play yards.

The scope section of ASTM F3118-17 further provides that if the inclined sleep product can be converted into a product for which another ASTM standard consumer safety specification exists, the product shall meet the applicable requirements of that standard, in addition to those of ASTM F3118-17.

CPSC and ASTM recognize that the scope section of the standard as currently written may contain some ambiguity about the meaning of "intended and marketed to provide sleeping accommodations." CPSC and ASTM staff continue to work to reduce this ambiguity to provide greater clarity for inclined sleep product suppliers to determine whether their products fall within the scope of the ASTM standard. One option would be for the standard to clarify "intended . . .

to provide sleeping accommodations." ASTM and CPSC recognize that infants sleep in many products, some of which are designed specifically for sleep, while others are designed for other purposes (i.e., infant swings). CPSC requests comments on the need to define "intended or marketed to provide sleeping accommodations," along with potential definitions of that term, as well as whether and the extent to which clarification regarding which products constitute multi-use inclined sleep products is needed.

III. Incident Data

The Commission is aware of a total of 657 incidents (14 fatal and 643 nonfatal) related to infant inclined sleep products, reported to have occurred between January 1, 2005 and September 30, 2016. Information on 40 percent (261 out of 657) of the incidents was based solely on reports submitted to CPSC by manufacturers and retailers through CPSC's "Retailer Reporting System." Various sources, such as hotlines, internet reports, newspaper clippings, medical examiners, and other state and local authorities provided the CPSC with the remaining incident reports. Because reporting is ongoing, the number of reported fatalities, nonfatal injuries, and non-injury incidents may change in the future.

A. Fatalities

CPSC has reports of 14 fatalities associated with the use of an infant inclined sleep product, which occurred between January 1, 2005 and September 30, 2016.

- Eight of the 14 deaths involved rocker-like inclined sleep products.
    - In three cases, the unstrapped decedent was found to have rolled over into a face-down position.
    - In two additional cases, the decedent reportedly rolled over into a face down position, but no information was available on the use of a restraint.

- For the remaining three cases, there was insufficient information about the cause or manner of the deaths.

- Four of the 14 deaths involved reclined infant seat-type products.
  - In three cases, the products were placed inside cribs and the decedents (two with restraints, one without restraints) were found to have rolled over the edge of the products into the bedding in the cribs.
  - In the remaining one case, restraints were not used and the decedent was found to have rolled over into a face-down position.
- Two of the 14 deaths involved infant hammocks.
  - In one case, the decedent had rolled over on her stomach—restraint-use not mentioned—and was found face down on a foam mattress.
  - In the one remaining case, the decedent was trapped in the head down position, with face pressed against bedding material after product straps were not assembled correctly, allowing the product to tip out of position.

B. Nonfatalities

CPSC has reports of 643 inclined sleep product-related nonfatal incidents that were reported to have occurred between January 1, 2005 and September 30, 2016. Of the 643 incidents, 301 involved an injury to the infant during use of the product. The majority of the injured (256 out of 301) were between 1 month and 8 months of age. Age was reported to be over 8 months for 16 of the injured infants, and was not reported for 29 of the injured infants.

The severity of the injury types among the 301 reported injuries were as follows:

- 20 required hospital admissions (17 for respiratory problems suffered due to mold on the sleep product, 2 for treatment of a head injury due to a fall, and 1 for observation of an infant who had stopped breathing for unspecified reasons).
- 27 were treated and released from emergency departments. These infants were treated for respiratory problems, head injuries (such as a skull fracture or a *closed-head injury*), contusions/bruises, and, in one case, foreign objects (namely, metal shavings from the product) that entered the infant's eye.
- 151 required treatment for *plagiocephaly* (flat head syndrome), *torticollis* (twisted neck syndrome), or both conditions, associated with the use of the inclined sleep product.
- 90 were treated for mostly respiratory and some skin problems associated with mold on the product.
- Seven infants suffered minor bumps/bruises/lacerations due to falls or near-falls.
- Three suffered a combination of respiratory problems along with flat head syndrome or fall injuries.
- One eye-burn injury, one thermal burn due to electrical overheating, and one abnormal back curvature condition attributed to the use of an inclined sleep product.

The remaining 342 incident reports stated 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.

C. Hazard Pattern Identification

CPSC staff considered all 657 reported incidents to identify hazard patterns associated with inclined sleep products. ASTM F3118-17 covers a variety of products. Some, like

hammocks, are suspended in air, while other seat-like products are meant to be placed on a level floor (although incident reports indicate they often were not). Yet others sit as attachments on larger nursery products.

Because inclined sleep products include a variety of product types, staff identified different hazard patterns depending on which product was involved and how it was used. CPSC staff identified the following hazard patterns associated with inclined sleep products:

1. ***Design Problems*** *(75%)*: 492 incidents fell within this category. Staff identified two major design issues: (1) infants reportedly developed respiratory and/or skin ailments due to the growth of mold on the product; and (2) infants reportedly developed physical deformations such as *plagiocephaly* (flat head syndrome) and/or *torticollis* (twisted neck syndrome) from extended use of the product. Although this category does not include any deaths, this category includes 17 hospitalizations and 13 emergency department (ED) visits, all for treating respiratory problems associated with the use of the inclined sleep product. This category also includes an additional 244 non-hospitalized, non-ED injuries.

2. ***Compromised Structural integrity*** *(5%)*: 36 incident reports noted some level of failure of the product or its components. These failures included buckles or straps breaking, pads/seats/liners tearing, hardware coming loose, and metal stands/bars and other unspecified components breaking. No injuries or fatalities were reported in this category.

3. ***Inadequate restraints*** *(5%)*: 35 incidents reportedly occurred when the restraint failed to adequately confine the infant in position. These incidents include two deaths when an infant, although restrained, rolled over, out of position, and ended up with

face buried in nearby soft bedding. Three of the nine injuries in this category were treated in emergency departments and resulted from a strapped-in infant falling out of the product entirely.

4. ***Electrical issues*** *(3%)*: 22 incidents involved overheating or melting of components such as the vibrating unit, battery cover, switch, or motor. One incident resulted in a thermal burn.

5. ***Non-product-related/unknown issues*** *(3%)*: In 18 incidents either the manner in which the product was used led to an incident or not enough information was available to determine how the incident occurred. This category includes 10 fatalities and four injuries. User error contributed to six asphyxiation fatalities in this category; all decedents were left unstrapped and later found in a prone position. Two additional fatalities occurred when an infant rolled out of position while in the product; it was unknown if a restraint was used. The incident reports did not indicate clearly the circumstances that led to the remaining two fatalities. Of the four injuries, staff attributed two to user error; staff has very little information about the circumstances leading to the remaining two injury incidents.

6. ***Infant positioning during use*** *(2%)*: In 13 reported incidents the infant moved into a compromised position. Most of the incidents involved hammock-like products, which shifted into a non-level rest position as the infant moved. Two infants ended up trapped in a corner with face in the fabric/bedding of the product. In two other reports, consumers complained of difficulty in preventing the infant from getting into a head-to-chin position.

7. ***Miscellaneous product-related issues*** *(1%)*: Nine incident reports noted a

variety of product-related issues. These included: complaints of poor finish (metal shavings, sharp edges, a threaded needle left in the product), instability (product, suspended mid-air, flipping over, or product, sitting on floor, tipping over), incomplete packaging (missing parts and instructions), and noxious odor. In addition, one incident reported both restraint inadequacy and mold growth, indicating a design problem. Two injuries were reported in this category, including one treated and released from a hospital emergency department.

8. ***Unspecified falls*** *(1%)*: In nine incidents, an infant fell from the inclined sleep product, but very little information was available on the circumstances surrounding the falls. All of the incidents were reported through hospital emergency departments and were reports of head injuries (skull fracture or *closed-head injury*) or face contusion. One infant was hospitalized while others were treated and released.

9. ***Consumer comments*** *(4%)*: 23 incidents fall in this category. The reports consisted of consumer comments/observations of perceived safety hazards or complaints about unauthorized sale of infant inclined sleep products. None of these reports indicated that any incident actually occurred.

D. Product Recalls

Compliance staff reviewed recalls of infant inclined sleep products from May 10, 2000 to March 1, 2016. During that time, there were nine consumer-level recalls involving infant inclined sleep products. The recalls were conducted to resolve issues involving mold, structural stability, entrapment, suffocation, falls, and strangulation. Three recalls involved inclined sleep products and six recalls involved infant hammocks (which are within the scope of F3118-17).

One recall for mold affected 800,000 units of infant inclined sleep products. Two recalls for entrapment and suffocation affected 195,000 units of inclined sleep products. The six additional recalls were the result of potential suffocation, strangulation, structural stability, entrapment, and fall hazards. Those recalls collectively affected 25,368 hammock units.

IV. International Standards for Inclined Sleep Products

Other standards include infant inclined sleep products within their scope, but these standards are intended primarily to address hazards associated with products having flat sleeping surfaces, such as bassinets and cradles. These include:

- *The Cribs, Cradles, and Bassinets regulation included in the Canada Consumer Product Safety Act*: The Canadian regulation has similar requirements to ASTM F3118, such as warnings, labels, and general performance requirements (e.g. lead content, small parts, openings). The Canadian regulation has additional requirements for slat strength, mesh material, structural integrity, and mattress supports. Upon review, CPSC staff determined that the Canadian regulation provides similar performance requirements, but does not provide the comprehensive product assessment of the specific hazards identified in CPSC incident data that the ASTM standard does.
- *The European standard (SS-EN 1130: Furniture, Cribs, and Cradles Safety Requirements)*: EN 1130 covers only inclined sleep products with a body and frame. The European standard would not include hammocks or similar products that are suspended from ceilings or other structures. EN 1130 includes requirements for construction and materials similar to the general ASTM F3118 requirements. Additional requirements include labeling, use instructions, packaging, and stability. EN 1130 is intended primarily to address hazards associated with bassinets and cradles and not the unique hazards

associated with inclined sleep products. Based on evaluation, CPSC staff believes the ASTM standard is more inclusive because it includes all hammock styles and provides a more comprehensive assessment of potential hazards associated with inclined sleep products.

- *The Australian standard (AS/NZS 4385 Infants' rocking cradles --Safety requirements)*: AS/NZS 4385 is intended for rocking cradles that swing, rock, or tilt, but specifically excludes hammocks that do not have this feature. It is unclear if tilt means incline, thereby including in the Australian standard inclined sleep products as defined in ASTM F3118. AS/NZS 4385 contains requirements for construction, toxicology, and flammability. There are also other general provisions such as those for included toys. AS/NZS 4385 has some similar performance requirements, but is not as comprehensive as ASTM F3118 in assessing the potential hazards associated with inclined sleep products.

V. Voluntary Standard–ASTM F3118

A. History of ASTM F3118

Section 104(b)(1)(A) of the CPSIA requires the Commission to consult representatives of "consumer groups, juvenile product manufacturers, and independent child product engineers and experts" to "examine and assess the effectiveness of any voluntary consumer product safety standards for durable infant or toddler products." As a result of incidents arising from inclined sleep products, CPSC staff requested that ASTM develop voluntary requirements to address the hazard patterns related to the use of inclined sleep products. ASTM first approved ASTM F3118 on April 1, 2015, and published it in May 2015. Through the ASTM process, CPSC staff consulted with manufacturers, retailers, trade organizations, laboratories, consumer advocacy

groups, consultants, and members of the public. The current standard, ASTM F3118-17, was approved on January 1, 2017, and published in March of 2017. This is the third revision to the standard since it was first published in May 2015.

B. Description of the Current Voluntary Standard–ASTM F3118-17

ASTM F3118-17 includes the following key provisions: scope, terminology, general requirements, performance requirements, test methods, marking and labeling, and instructional literature.

Scope. This section states the scope of the standard, detailing what constitutes an infant inclined sleep product. As stated in section II.A. of this preamble, the Scope section describes an inclined sleep product as "a free standing product with an inclined sleep surface primarily intended and marketed to provide sleeping accommodations for an infant up to 5 months old or when the infant begins to roll over or pull up on sides, whichever comes first." This section also states that the standard covers newborn inclined sleep products, compact inclined sleep products, and inclined sleep products accessories. This section further explains that if the inclined sleep product can be converted into a product for which another ASTM standard consumer safety specification exists, the product shall meet the applicable requirements of that standard, in addition to those of ASTM F3118-17.

Terminology. This section provides definitions of terms specific to this standard.

General Requirements. This section addresses numerous hazards with several general requirements, most of which are also found in the other ASTM juvenile product standards. The general requirements included in this section are:

- Lead in paint;
- Sharp edges or points;

- Small parts;
- Wood parts;
- Scissoring, shearing, and pinching;
- Openings;
- Exposed coil springs;
- Protective components;
- Labeling; and
- Toys.

Performance Requirements and Test Methods. These sections contain performance requirements specific to inclined sleep products (discussed here) and the test methods that must be used to assess conformity with such requirements.

- **Stability**: This requirement is intended to prevent inclined sleep products from tipping over while in use.
- **Unintentional folding**: This requirement is intended to prevent unintentional folding of the product while it is in use, regardless of type of lock/latch the product uses (if any).
- **Restraint systems**: This requirement is intended to ensure the integrity and effectiveness of restraint systems, which (when present) must include both a waist and crotch restraint, but not shoulder straps. Additionally, the inclined sleep product's restraint system must be designed so that the crotch restraint has to be used whenever the restraint system is used. The restraint system must be attached to the product in one of the manufacturer's recommended use positions at the time of shipment.
- **Side height**: This requirement is intended to prevent falls, in conjunction with head, foot, and side containment requirements.

- **Head, foot, and side containment**: This requirement is intended to prevent falls, in conjunction with side height requirements.
- **Side to side surface containment**: This requirement is intended to ensure a seat back shape that prevents children from rotating into a sideways position.
- **Seat back length**: This requirement is intended to prevent older children from being placed in inclined sleep products intended for younger users by restricting the head containment area available on the seat back.
- **Structural integrity**: This requirement is intended to ensure that the inclined sleep product remains cohesive after both dynamic and static load testing. It is also intended to ensure that the product can support the intended user's weight when a safety margin is factored in.

Marking and Labeling. This section contains various requirements relating to warnings, labeling, and required markings for inclined sleep products. This section prescribes various substance, format, and prominence requirements for such information.

Instructional Literature. This section requires that instructions be provided with inclined sleep products and be easy to read and understand. Additionally, the section contains requirements relating to instructional literature contents and format.

VI. Assessment of the Voluntary Standard ASTM F3118-17

CPSC staff identified 657 incidents (including 14 deaths) related to the use of inclined sleep products. CPSC staff examined the incident data, identified hazard patterns in the data, and worked with ASTM to develop the performance requirements in ASTM F3118. The incident data and identified hazard patterns served as the basis for the development of ASTM F3118-15 and F3118-17 by ASTM with CPSC staff support throughout the process.

CPSC believes that the current voluntary standard, ASTM F3118-17, addresses the primary hazard patterns identified in the incident data, with one modification to the standard's definition of "accessory." CPSC concludes that more stringent requirements relating to the standard's definition of "accessory" would further reduce the risk of injury associated with inclined sleep products.

The following section discusses how each of the identified product-related issues or hazard patterns listed in section III.C. of this preamble is addressed by the current voluntary standard, ASTM F3118-17, and discusses the proposed more stringent requirement where appropriate:

A. Design Problems

Incident reports indicate that 75 percent of reported incidents were associated with the design of the inclined sleep product. Staff identified two major design issues: infant respiratory and/or skin ailments due to mold growth on the product, and (2) infant physical deformations such as *plagiocephaly* (flat head syndrome) and/or *torticollis* (twisted neck syndrome) from extended product use.

In the reported cases of mold that resulted in respiratory problems for infants using the product, all cases were related to one particular manufacturer's inclined sleep product. CPSC conducted a recall of that product in 2013. Infants who use an inclined sleep product that is known to develop visible mold can be at risk of developing health effects such as allergies, asthma, mycosis, and effects of mycotoxins. However, because the mold growth was restricted to one manufacturer's product and that product was recalled, the Commission is not proposing any modifications to address potential hazards associated with mold.

Plagiocephaly, cranial deformity or asymmetry (commonly known as flat head) is a condition that may exist at birth due to mechanical constraint of fetal head movement in the womb, birth-related injuries during assisted delivery, or as a result of increased likelihood of skull deformity as a consequence of premature birth. Muscular torticollis (twisted neck) is a known risk factor associated with plagiocephaly caused by constraint of head and neck movement. Although incident data indicate that consumers believe use of an inclined sleep product is the cause for their child's plagiocephaly/torticollis, there is no evidence to support this belief. The increase in the number of children with plagiocephaly may actually be attributed to the American Academy of Pediatrics' (AAP) recommendation to place infants to sleep on their backs to decrease the risk of sudden infant death syndrome (SIDS). Because the development of plagiocephaly and torticollis is not exclusively attributable to the use of infant inclined sleep products, the conditions are not addressable with performance standards. The Commission is not proposing any modifications to the voluntary standard to address these issues.

B. Inadequate restraints

ASTM F3118-17 does not require the inclusion of any type of restraint system. However, for products that do include restraints, the ASTM standard includes performance requirements to address restraint operation and function. Two deaths occurred in an inclined sleep product that was recalled during the development of the ASTM voluntary standard. The ASTM standards subcommittee developed the restraint requirements and containment requirements to address these deaths and injuries. The Commission believes that these restraint performance requirements adequately address this hazard pattern, and notes that these are similar requirements used in other juvenile product safety standards.

C. Compromised structural integrity

The incidents included in this category consisted of complaints related to buckles/straps breaking, pads/seats/liners tearing, hardware coming loose, and metal stands/bars and other unspecified components breaking. The static and dynamic load tests included in F3118-17 address structural integrity in a similar manner to other ASTM juvenile product standards. Following evaluation of these tests, the Commission believes that these requirements adequately address this hazard pattern.

D. Infant positioning during use

Most infant position incidents involved hammock-like products, which shifted into a non-level rest position as the infants moved, resulting in the infants becoming trapped in a corner with their face in the fabric/bedding of the product. Two fatalities occurred in this manner. Hazardous positioning involves multiple factors, such as the fabric or material used on the product's side, inclusion of a mat or mattress, and the infant's ability to reposition in the product. As the factors involved in these incidents are complex and not easily addressable, ASTM F3118-17 does not include specific performance requirements to directly address this scenario at this time. The voluntary standard addresses instability with a performance test; however, the intent of that test is to address incidents such as siblings pulling on the side and tipping the inclined sleep product. CPSC will continue to monitor incident data and could consider changes to the standard in the future if needed.

E. Non-product-related/unknown

There were ten fatalities and four injuries in this category. User error contributed to six of the asphyxiation fatalities. All decedents were left unstrapped and later found in a prone position. ASTM F3118-17 has requirements for restraints (where the product includes restraints) and side containment to prevent infants from moving out of position. In addition, CPSC staff has worked

with the ASTM subcommittee on the warnings and instructions to provide consumers with adequate information to use the product correctly.

F. Miscellaneous product-related issues

CPSC considers incidents in this category (involving such hazards as stray objects, incomplete packaging, missing parts, and noxious odors) to present manufacturing quality control issues, not safety-related issues. Therefore, these incidents are not addressable by this standard. Requirements relating to other miscellaneous product-related issues, such as prevention of rough finishes, sharp edges, and points are included in the general requirements of ASTM F3118-17. The voluntary standard also includes performance requirements for the stability of infant, newborn, and compact inclined sleep products. CPSC evaluated these requirements and concludes that they are adequate to address this hazard pattern.

G. Electrical issues

Since CPSC staff began monitoring the incident reports for inclined sleep products, incidents involving electrical issues have risen from 1 percent to 3 percent of the total reported incidents. One thermal burn injury was reported in this category. CPSC staff recently shared this new data with the ASTM subcommittee and suggested that electrical requirements similar to those in other juvenile products be added to F3118. The Commission requests comments regarding inclusion of electrical requirements to prevent further additional incidents, such as overheating, melting battery compartments, and thermal burns.

H. Unspecified falls

There were eight reports of falls from the product with little detail on the incidents that led to the injury. Without details, it is unclear how the incident occurred or if it would be addressed by any performance standard. However, ASTM F3118-17 includes stability and

containment requirements, as described in earlier sections, which address known hazard patterns that could result in falls.

I. Consumer comments

This category contained 23 reports from consumers about perceived product hazards that did not result in incidents. CPSC staff reviewed the reports and determined that the information did not describe a hazardous situation or a situation not already addressed in the ASTM standard.

VII. Proposed Standard for Infant Inclined Sleep Products

As discussed in the previous section, most of the requirements of ASTM F3118-17 are sufficient to reduce the risk of injury posed by inclined sleep products. However, CPSC concludes that the accessory definition should be modified by removing "rigid frame" from the definition to further reduce the risk of injury associated with product use. ASTM F3118-17 defines "accessory inclined sleep product" as "a rigid framed inclined sleep product that is intended to provide sleeping accommodations for infants or newborns and attaches to or is supported by another product." During 2016 ASTM subcommittee meetings, CPSC staff became aware of a new product that ASTM subcommittee members agreed should be classified as an accessory inclined sleep product, except for the fact that the product did not have a "rigid frame." The subcommittee members agreed that "rigid frame" should be removed from the accessory definition. CPSC agrees with this approach and therefore proposes to incorporate by reference ASTM F3118-17 with a modification that would remove the phrase "rigid frame" from the definition of "accessory inclined sleep product."

VIII. Proposed Amendment to 16 CFR part 1112 to Include NOR for Infant Inclined Sleep Products

The CPSA establishes certain requirements for product certification and testing. Products

subject to a consumer product safety rule under the CPSA, or to a similar rule, ban, standard or regulation under any other act enforced by the Commission, must be certified as complying with all applicable CPSC-enforced requirements. 15 U.S.C. 2063(a). Certification of children's products subject to a children's product safety rule must be based on testing conducted by a CPSC-accepted third party conformity assessment body. *Id*. 2063(a)(2). The Commission must publish an NOR for the accreditation of third party conformity assessment bodies to assess conformity with a children's product safety rule to which a children's product is subject. *Id.* 2063(a)(3). Thus, the proposed rule for 16 CFR part 1235, *Standard Consumer Safety Specification for Infant Inclined Sleep Products*, if issued as a final rule, would be a children's product safety rule that requires the issuance of an NOR.

The Commission published a final rule, *Requirements Pertaining to Third Party Conformity Assessment Bodies*, 78 FR 15836 (March 12, 2013), codified at 16 CFR part 1112 ("part 1112") and effective on June 10, 2013, which establishes requirements for accreditation of third party conformity assessment bodies to test for conformity with a children's product safety rule in accordance with section 14(a)(2) of the CPSA. Part 1112 also codifies all of the NORs issued previously by the Commission.

All new NORs for new children's product safety rules, such as the inclined sleep products standard, require an amendment to part 1112. To meet the requirement that the Commission issue an NOR for the inclined sleep products standard, as part of this NPR, the Commission proposes to amend the existing rule that codifies the list of all NORs issued by the Commission to add inclined sleep products to the list of children's product safety rules for which the CPSC has issued an NOR.

Test laboratories applying for acceptance as a CPSC-accepted third party conformity assessment body to test to the new standard for inclined sleep products 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, the laboratory can apply to the CPSC to have 16 CFR part 1235, *Standard Consumer Safety Specification for Infant Inclined Sleep Products,* included in the laboratory's scope of accreditation of CPSC safety rules listed for the laboratory on the CPSC website at: www.cpsc.gov/labsearch.

IX. Proposed Amendment to Definitions in Consumer Registration Rule

The statutory definition of "durable infant or toddler product" in section 104(f) applies to all of section 104 of the CPSIA. In addition to requiring the Commission to issue safety standards for durable infant or toddler products, section 104 of the CPSIA also directed the Commission to issue a rule requiring that manufacturers of durable infant or toddler products establish a program for consumer registration of those products. Pub. L. 110-314, section 104(d).

Section 104(f) of the CPSIA defines the term "durable infant or toddler product" and lists examples of such products:

> (f) DEFINITION OF DURABLE INFANT OR TODDLER PRODUCT. As used in this section, the term "durable infant or toddler product" –
>
> (1) means a durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years; and
>
> (2) includes –
>
> (A) full-size cribs and nonfull-size cribs;

(B) toddler beds;

(C) high chairs; booster chairs, and hook-on-chairs;

(D) bath seats;

(E) gates and other enclosures for confining a child;

(F) play yards;

(G) stationary activity centers;

(H) infant carriers;

(I) strollers;

(J) walkers;

(K) swings; and

(L) bassinets and cradles.

Pub. L. 110-314, section 104(f).

The infant inclined sleep products safety standard is an outgrowth of the bassinet safety standard. When considering the bassinet standard, the Commission stated that a separate standard targeted specifically to inclined sleep products would more effectively address the hazards associated with those products. 77 FR 64055, 64059 (Oct. 18, 2012). Therefore, CPSC staff began working with ASTM to develop a voluntary standard that would cover the wide array of products on the market that provide infants and toddlers with inclined sleeping environments. Inclined sleep products, like bassinets, are thus durable products within the meaning of section 104 of the CPSIA.

Because the inclined sleep product standard is an outgrowth of the bassinet standard, inclined sleep products may be considered a sub-category of bassinets. To provide greater clarity

that inclined sleep products are durable infant or toddler products, the Commission proposes to amend the Commission's consumer registration rule to explicitly include inclined sleep products.

In 2009, the Commission issued a rule implementing the consumer registration requirement. 16 CFR part 1130. As the CPSIA directs, the consumer registration rule requires each manufacturer of a durable infant or toddler product to: provide a postage-paid consumer registration form with each product; keep records of consumers who register their products with the manufacturer; and permanently place the manufacturer's name and certain other identifying information on the product. When the Commission issued the consumer registration rule, the Commission identified six additional products as "durable infant or toddler products":

- children's folding chairs
- changing tables;
- infant bouncers;
- infant bathtubs;
- bed rails; and
- infant slings.

16 CFR 1130.2. The Commission stated that the specified statutory categories were not exclusive, but that the Commission should explicitly identify the product categories that are covered. The preamble to the 2009 final consumer registration rule states: "Because the statute has a broad definition of a durable infant or toddler product but also includes 12 specific product categories, additional items can and should be included in the definition, but should also be specifically listed in the rule." 74 FR 68668, 68669 (Dec. 29, 2009).

In this document, the Commission proposes to amend the definition of "durable infant or toddler product" in the consumer registration rule to clarify that inclined sleep products fall

within the term "durable infant or toddler product" as used in the product registration card rule and section 104 of the CPSIA.

X. Incorporation by Reference

The Commission proposes to incorporate by reference ASTM F3118-17, with one modification to the standard, discussed above. The Office of the Federal Register (OFR) has regulations concerning incorporation by reference. 1 CFR part 51. For a proposed rule, agencies must discuss in the preamble of the NPR ways that the materials the agency proposes to incorporate by reference are reasonably available to interested persons or how the agency worked to make the materials reasonably available. In addition, the preamble of the proposed rule must summarize the material. 1 CFR 51.5(a).

In accordance with the OFR's requirements, section V.B. of this preamble summarizes the provisions of ASTM F3118-17 that the Commission proposes to incorporate by reference. ASTM F3118-17 is copyrighted. By permission of ASTM, the standard can be viewed as a read-only document during the comment period on this NPR, at: http://www.astm.org/cpsc.htm. Interested persons may also purchase a copy of ASTM F3118-17 from ASTM International, 100 Bar Harbor Drive, P.O. Box 0700, West Conshohocken, PA 19428; http://www.astm.org/cpsc.htm. One may also inspect a copy at CPSC's Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone 301-504-7923.

XI. Effective Date

The Administrative Procedure Act (APA) generally requires that the effective date of a rule be at least 30 days after publication of the final rule. 5 U.S.C. 553(d). ASTM F3118-17 is a new voluntary standard that covers a variety of products whose manufacturers may not be aware

that their product must comply. The Commission is proposing to incorporate by reference ASTM F3118-17, with one modification. To allow time for infant inclined sleep product manufacturers to bring their products into compliance after a final rule is issued, the Commission is proposing an effective date of 12 months after publication of the final rule in the Federal Register for products manufactured or imported on or after that date. The Commission believes that most firms should be able to comply with the 12-month timeframe, but asks for comments on the proposed 12-month effective date. We also propose a 12-month effective date for the amendments to parts 1112 and 1130.

XII. Regulatory Flexibility Act

A. Introduction

The Regulatory Flexibility Act (RFA) requires that agencies review a proposed rule for the rule's potential economic impact on small entities, including small businesses. Section 603 of the RFA generally requires that agencies prepare an initial regulatory flexibility analysis (IRFA) and make the analysis available to the public for comment when the agency publishes an NPR. 5 U.S. C. 603. Section 605 of the RFA provides that an IRFA is not required if the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. Staff could not rule out a significant economic impact for six of the 10 known small suppliers of inclined sleep products to the U.S. market. Accordingly, staff prepared an IRFA and poses several questions for public comment to help staff assess the rule's potential impact on small businesses.

The IRFA must describe the impact of the proposed rule on small entities and identify significant alternatives that accomplish the statutory objectives and minimize any significant economic impact of the proposed rule on small entities. Specifically, the IRFA must contain:

- 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, and where feasible, an estimate of the number of small entities to which the proposed rule will apply;
- a description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities subject to the requirements and the type of professional skills necessary for the preparation of reports or records; and
- identification, to the extent possible, of all relevant federal rules that may duplicate, overlap, or conflict with the proposed rule; and

  In addition, the IRFA must describe any significant alternatives to the proposed rule that accomplish the stated objectives of applicable statutes and minimize any significant economic impact of the proposed rule on small entities.

B. Market Description

The Commission has identified 25 firms supplying inclined sleep products to the U.S. market. Sixteen of these firms produce infant hammocks. The majority of the 25 known firms (including 12 manufacturers and five importers) are domestic. The remaining eight firms (seven manufacturers and one retailer) are foreign.

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

As discussed in section I. of this preamble, section 104 of the CPSIA requires the CPSC to promulgate consumer product safety standards for durable infant or toddler products that are substantially the same as, or more stringent than, the relevant voluntary standard. As explained in section IX of this preamble, ASTM's standard for infant inclined sleep products developed out of

CPSC's efforts on bassinets. CPSC and ASTM determined that a separate standard was necessary for these products.

D. Impact of Proposed 16 CFR Part 1235 on Small Businesses

CPSC staff is aware of approximately 25 firms currently marketing inclined sleep products in the United States, 17 of which are domestic. Under U.S. Small Business Administration (SBA) guidelines, a manufacturer of inclined sleep products is considered small if it has 500 or fewer employees; and importers and wholesalers are considered small if they have 100 or fewer employees. Staff limited its analysis to domestic firms because SBA guidelines and definitions pertain to U.S.-based entities. Based on these guidelines, 14 of the 17 domestic firms are small—10 manufacturers and four importers. Additional unknown small domestic inclined product suppliers may be operating in the U.S. market.

1. Small Manufacturers

i. Small Manufacturers with Compliant Inclined Sleep Products

Of the ten small manufacturers, three produce inclined sleep products that are likely to comply with ASTM F3118-17 which is in effect for testing purposes under the Juvenile Product Manufactures Association (JPMA) certification program. Although only one large firm is currently listed on the JPMA website as having certified inclined sleep products, we expect the products of these three small manufacturers to comply because the firms were involved in the standard's development. In general, staff expects that small manufacturers whose inclined sleep products comply with the current voluntary standard will remain compliant with the voluntary standard as it evolves, because they follow and, in this case, actively participate in the standard development process. Therefore, compliance with the voluntary standard is part of an established business practice. ASTM F3118-17 is the version of the voluntary standard upon which the staff-

recommended mandatory standard is based; therefore, we expect these firms are already in compliance.

In light of the expectation that these firms will already be complying with ASTM F3118-17 by the time it becomes effective, and that none would be impacted by the proposed change to the definition of an "accessory inclined sleep product," the economic impact of the proposed rule should be small for the three small domestic manufacturers supplying compliant inclined sleep products to the U.S. market.

ii. Small Manufacturers with Noncompliant Inclined Sleep Products

Seven small manufacturers (two of which would only be included due to the proposed change to the definition of an "accessory inclined sleep product") produce inclined sleep products that do not comply with the voluntary standard. CPSC cannot rule out a significant economic impact for six small manufacturers, but was able to rule out a significant impact for one small manufacturer (one of the manufacturers that the standard covers only as a result of CPSC's proposed modification). These firms may not be aware of the ASTM voluntary standard or may believe that their product falls outside the scope of the standard. All six firms are likely to require modifications, some of which may be significant, to meet the base requirements of the voluntary standard. Four of these firms (two of which would be covered by the standard as a result of the proposed modification to the standard) may not currently have warning labels or instruction manuals for their products, and therefore may be required to make modifications to comply with the ASTM standard.

The extent and cost of the changes that these firms would be required to make to comply with the standard cannot be determined and, therefore, staff cannot rule out a significant economic impact. Additionally, the four firms that do not currently have warning labels or

instruction manuals for their products appear to very small, supplying very few products in very low quantities. The cost of developing warning labels and instruction manuals is, therefore, more likely to have a significant economic impact on these firms, as their resources may be more limited.

Additionally, staff believes that as many as five of the seven firms with noncompliant inclined sleep products may not be aware of the inclined sleep products voluntary standard, which could increase the time period required for firms to come into compliance. The Commission proposes a longer than usual effective date of 12 months to give firms time to familiarize themselves with the scope of the new standard and develop new/modified products if needed.

The Commission requests information on the changes that may be required to meet the voluntary standard ASTM F3118-17, in particular whether redesign or retrofitting would be necessary, as well as the associated costs and time frame for the changes. *Third Party Testing Costs for Small Manufacturers*

Under section 14 of the CPSA, when new inclined sleep product requirements become effective, all manufacturers will be subject to the third party testing and certification requirements under the 1107 rule. Third party testing will include any physical and mechanical test requirements specified in the final inclined sleep products rule. Manufacturers and importers should already be conducting required lead testing for inclined sleep products. Third party testing costs are in addition to the direct costs of meeting the inclined sleep product standard.

Three of the small inclined sleep product manufacturers are already testing their products to verify compliance with the ASTM standard, though not necessarily by a third party. For these manufacturers, the impact to testing costs would be limited to the difference between the cost of

third party tests and the cost of current testing regimes. Staff contacted manufacturers of inclined sleep products. They estimate that third party testing inclined sleep products to the ASTM voluntary standard would cost about $300 to $1,000 per model sample. For the three small manufacturers that are already testing, the incremental costs are unlikely to be economically significant, and informal discussions with several firms actively participating in the ASTM voluntary standard development process suggest such.

For the seven small manufacturers that are not currently testing their products to verify compliance with the ASTM standard, the impact of third party testing, by itself, could result in significant costs for one firm. Staff made this determination based on an examination of firm revenues from recent Dun & Bradstreet or ReferenceUSAGov reports. Although staff does not know how many samples will be needed to meet the "high degree of assurance" criterion required in the 1107 rule, testing costs could exceed one percent of gross revenue with as few as four samples tested for this firm (assuming high-end testing costs of $1,000 per model sample). Revenue information was not available for the four small manufacturers and, therefore, no impact evaluation could be made. All four firms are very small, however, so staff cannot rule out a significant impact.

The Commission welcomes comments regarding overall testing costs and incremental costs due to third party testing (*i.e.,* how much does moving from a voluntary to a mandatory third party testing regime add to testing costs, in total and on a per test basis). In addition, the Commission welcomes comments regarding the number of inclined sleep product units that typically need to be tested to provide a "high degree of assurance."

2. Small Importers

Four small importers supply inclined sleep products to the U.S. market (two of which are multi-use products that the clarified scope is meant to address); none of their products comply with the ASTM voluntary standard. Staff has insufficient information to rule out a significant impact for these firms, particularly given the lack of sales revenue data. Whether there is a significant economic impact will depend upon the extent of the changes required to come into compliance and the response of their supplying firms. Manufacturers may pass onto importers any increase in production costs that manufacturers incur as a result of changes made to meet the mandatory standard. These costs would include those associated with coming into compliance with the voluntary standard, as well as those associated with the proposed modification to the voluntary standard.

Two of the four known importers are tied directly to their foreign suppliers. Therefore, finding an alternative supply source would not be a viable alternative. However, the foreign suppliers to these firms may have an incentive to work with their U.S. distributors to maintain an American market presence. Discontinuing the sale of inclined sleep products would likely have a significant impact on one of these firms because their entire product line consists of inclined sleep products and accessory products. The remaining two small importers do not supply many other products, and as a result, discontinuing the sale of inclined sleep products could have a significant impact on those firms as well.

As with manufacturers, importers will be subject to third party testing and certification requirements, and consequently, will be subject to costs similar to those for manufacturers if their supplying foreign firm(s) does not perform third party testing. The four known small importers do not currently test their products to verify compliance with the ASTM standard. Therefore, the full extent of third party testing costs would be due to these small importers

having to comply with a mandatory standard (and not related to CPSC's proposed modification to the standard). Based on the revenue data available, it does not appear that third party testing will have a significant impact on one of the four small importers. However, there was no revenue data available for the remaining three small importers of inclined sleep products not believed to comply with the voluntary ASTM standard. Therefore, we had no basis for evaluating the size of the impact on that firm.

3. Summary

In summary, based upon current information, we cannot rule out a significant economic impact for six of the ten firms operating in the U.S. market for inclined sleep products. The 12-month proposed effective date would help to spread costs over a longer time-frame.

4. Alternatives

At least three alternatives are available to minimize the economic impact on small entities supplying inclined sleep products while also meeting the statutory objectives:

i. Adopt ASTM F3118-17 with no modifications

Section 104 of the CPSIA requires that the Commission promulgate a standard that is either substantially the same as the voluntary standard or more stringent if the Commission determines that more stringent standards would further reduce the risk of injury. Therefore, adopting ASTM F3118-17 with no modifications is the least stringent rule that could be promulgated for inclined sleep products. Although it would not reduce the testing costs triggered by the rule, this alternative would eliminate any economic impact on the two firms that would be subject to the rule as a result of the proposed modification to the definition of "accessory inclined sleep product." However, adopting ASTM F3118-17 with no modifications would not address the risk of injuries and death in what are clearly inclined sleep product accessories except that

they do not have rigid frames. Additionally, the impact on one of these firms would be limited to warning label and instructional literature changes.

ii. Allow a later effective date.

The Commission could reduce the proposed rule's impact on small businesses by setting a later effective date. A later effective date would reduce the economic impact on firms in two ways. Firms would be less likely to experience a lapse in production/importation, which could result if they are unable to bring their products into compliance and certify compliance based on third party tests within the required timeframe. Also, firms could spread the costs of developing compliant products over a longer time period, thereby reducing their annual costs, as well as the present value of their total costs (*i.e.,* they could time their spending to better accommodate their individual circumstances). The Commission believes that the proposed 12-month effective date would allow firms that may not be aware of the ASTM voluntary standard or may believe that their product falls outside the scope of the standard time to make this determination and bring their products into compliance. However, an even later effective date would further reduce these costs.

iii. Time the effective date for warning labels and instruction manuals to coincide with the timing of model changes in the durable nursery product market

The Commission could time the effective date for warning labels and instruction manuals to coincide with the timing of model changes in the durable nursery product market. This alternative may reduce the impact on all of the known small businesses supplying inclined sleep products to the U.S. market. In particular, this timing could reduce costs associated with inventory issues that may result from changes that companies may need to make to warning

labels and instruction manuals that are keyed to model and SKU numbers. The Commission requests comments on the extent of cost savings that may result from timing the effective date of the rule to coincide with the timing of model changes within the industry.

E. Impact of Proposed 16 CFR Part 1112 Amendment on Small Businesses

This proposed rule would also amend part 1112 to add inclined sleep products to the list of children's products for which the Commission has issued an NOR. As required by the RFA, staff conducted a Final Regulatory Flexibility Analysis (FRFA) when the Commission issued the part 1112 rule (78 FR 15836, 15855-58). The FRFA concluded that the accreditation requirements would not have a significant adverse impact on a substantial number of small testing laboratories because no requirements were imposed on test laboratories that did not intend to provide third party testing services. The only test laboratories that were expected to provide such services were those that anticipated receiving sufficient revenue from the mandated testing to justify accepting the requirements as a business decision.

Based on similar reasoning, amending 16 CFR part 1112 to include the NOR for the infant inclined sleep product standard will not have a significant adverse impact on small test laboratories. Moreover, based upon the number of test laboratories in the United States that have applied for CPSC acceptance of accreditation to test for conformance to other mandatory juvenile product standards, we expect that only a few test laboratories will seek CPSC acceptance of their accreditation to test for conformance with the infant inclined sleep product standard. Most of these test laboratories will have already been accredited to test for conformance to other mandatory juvenile product standards, and the only costs to them would be the cost of adding the infant inclined sleep product standard to their scope of accreditation. As a consequence, the Commission certifies that the proposed NOR amending 16 CFR part 1112 to

include the infant inclined sleep products standard will not have a significant impact on a substantial number of small entities.

F. Impact of Product Registration Rule, 16 CFR Part 1130, on Small Businesses

As discussed above in Sections I and IX, the Commission proposes to amend the definition of "durable infant or toddler product" in the consumer registration rule to reduce any uncertainty as to whether inclined sleep products are "durable infant or toddler products." The product registration rule requires that firms provide consumers with a postage-paid consumer registration card with each product, although firms may also maintain on-line registration pages as well. The information supplied on the cards (but not necessarily the cards themselves) must be maintained for a minimum of six years.

Of the 14 small domestic firms identified by staff as supplying inclined sleep products to the U.S. market, it is likely that six will not be significantly impacted by the requirements of the product registration rule. Four of the six firms supply combination products, such as play yards with accessory inclined sleep products that are already covered under the product registration rule. All six firms have other products that are already subject to the product registration rule, as well as on-line product registration sites. Therefore, these firms likely already have the infrastructure to maintain the records and would, at most, require cards to be printed for, and shipped with, their inclined sleep products.

To comply with the product registration rule, the remaining eight firms (most of which produce only infant hammocks on a very small scale) would need to develop a postage-paid product registration card for their inclined sleep products, include the card with their other packaged materials, and develop/maintain a system to store the information collected. Each model would require a unique registration card that clearly identifies the product (e.g., model

name, model number, product identification number, or other identifier typically used by the firm). For many of the components that would make up the cost for firms that supply inclined sleep products to comply with product registration card requirements, cost would depend on the number of products an inclined sleep products supplier sells annually. Such cost components include card design, paper supplies, cutting and printing, postage, card attachment to product, and data entry, storage, and maintenance for returned cards. The Directorate for Economic Analysis's memorandum at Tab F of the staff's briefing package provides detailed information on the range of costs for individual elements of inclined sleep product suppliers complying with product registration card requirements. [INSERT link to briefing package]. The prices for the inclined sleep products supplied by the eight firms likely to be impacted by the product registration rule range from $30 to $250. Firms selling inclined sleep products on the high end of that range may be able to easily absorb these costs if they sell a larger volume (for example, a $1.10 per product cost increase represents about 0.004% of a $250 inclined sleep product), while it may be more difficult for a company selling their inclined sleep products for $30 to absorb or pass on their cost increase even if they are a relatively high volume firm (a $1.10 per product cost increase represents about 0.037% of a $30 inclined sleep product).

XIII. Environmental Considerations

The Commission's regulations address whether the agency is required to prepare an environmental assessment or an environmental impact statement. Under these regulations, certain categories of CPSC actions normally have "little or no potential for affecting the human environment," and therefore do not require an environmental assessment or an environmental impact statement. Safety standards providing requirements for products come under this

categorical exclusion. 16 CFR 1021.5(c)(1). The proposed rule falls within the categorical exclusion.

XIV. Paperwork Reduction Act

This proposed rule contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (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 Infant Inclined Sleep Products

Description: The proposed rule would require each inclined sleep product to comply with ASTM F3118-17, *Standard Consumer Safety Specification for Infant Inclined Sleep Products,* with one modification. Sections 8 and 9 of ASTM F3118-17 contain requirements for marking, labeling, and instructional literature. These requirements fall within the definition of "collection of information," as defined in 44 U.S.C. 3502(3).

Description of Respondents: Persons who manufacture or import infant inclined sleep products.

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
1235	25	2	50	1	50

Our estimate is based on the following:

Twenty-five known entities supply inclined sleep products to the U.S. market may need to make some modifications to their existing warning labels. We estimate that the time required to make these modifications is about 1 hour per model. Based on an evaluation of supplier product lines, each entity supplies an average of 2 models of inclined sleep products; therefore, the estimated burden associated with labels is 1 hour per model x 25 entities x 2 models per entity = 50 hours. We estimate the hourly compensation for the time required to create and update labels is $33.30 (U.S. Bureau of Labor Statistics, "Employer Costs for Employee Compensation," September 2016, 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 $1,665 ($33.30 per hour x 50 hours = $1,665). No operating, maintenance, or capital costs are associated with the collection.

Section 9.1 of ASTM F3118-17 requires instructions to be supplied with the product. 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." We are unaware of inclined sleep products that generally require use instructions but lack such

instructions. However, it is possible that some firms selling homemade infant hammocks on a very small scale may not supply instruction manuals as part of their "normal course of activities." Based on information collected for the infant slings rulemaking, staff tentatively estimates that each small entity supplying homemade infant hammocks might require 50 hours to develop an instruction manual to accompany their products. It is uncertain how many homemade infant hammock suppliers are in operation at any point in time, but based on staff's review of the marketplace, 50 firms seems like a reasonable outside bound. These firms typically supply only one infant hammock model. Therefore, the costs of designing an instruction manual for these firms could be as high as $82,550 (50 hours per model x 50 entities x 1 models per entity = 2,500 hours x $33.02 per hour = $82,550). Not all firms would incur these costs every year, but new firms that enter the market would and this is a highly fluctuating market. Other firms are estimated to have no burden hours associated with section 9.1 of ASTM F3118-17 because any burden associated with supplying instructions with inclined sleep products would be "usual and customary" and not within the definition of "burden" under the OMB's regulations.

Based on this analysis, staff estimates that the proposed standard for inclined sleep products would impose a burden to industry of 2,550 hours at a cost of $84,915 annually.

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 the OMB for review. Interested persons are requested to submit comments regarding information collection by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**, to the Office of Information and Regulatory Affairs, OMB (see the ADDRESSES section at the beginning of this notice).

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

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

XV. Preemption

Section 26(a) of the CPSA, 15 U.S.C. 2075(a), provides that when a consumer product safety standard is in effect and applies to a product, no state or political subdivision of a state may either establish or continue in effect a standard or regulation that prescribes requirements for the performance, composition, contents, design, finish, construction, packaging, or labeling of such product dealing with the same risk of injury unless the state requirement is identical to the federal standard. Section 26(c) of the CPSA also provides that states or political subdivisions of states may apply to the Commission for an exemption from this preemption under certain circumstances. Section 104(b) of the CPSIA refers to the rules to be issued under that section as "consumer product safety rules." Therefore, the preemption provision of section 26(a) of the CPSA would apply to a rule issued under section 104.

XVI. Request for Comments

This NPR begins a rulemaking proceeding under section 104(b) of the CPSIA to issue a consumer product safety standard for inclined sleep products, to amend part 1112 to add inclined sleep products to the list of children's product safety rules for which the CPSC has issued an NOR, and to amend part 1130 to identify inclined sleep products as a durable infant or toddler product subject to CPSC consumer registration requirements. We invite all interested persons to submit comments on any aspect of this proposal. In addition to requests for specific comments elsewhere in this NPR, the Commission requests comments on the standard's scope language, the proposed effective date, and the costs of compliance with, and testing to, the proposed inclined sleep products safety standard. During the comment period, the ASTM F3118-17 Standard Consumer Safety Specification for Infant Inclined Sleep Products, is available as a read-only document at: http://www.astm.org/cpsc.htm.

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 1130

Administrative practice and procedure, Business and industry, Consumer protection, Reporting and recordkeeping requirements.

16 CFR Part 1235

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

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

PART 1112—REQUIREMENTS PERTAINING TO THIRD PARTY CONFORMITY ASSESSMENT BODIES

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

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

2. Amend § 1112.15 by adding paragraph (b)(45) 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) * * *

(45) 16 CFR part 1235, Safety Standard for Infant Inclined Sleep Products.

* * * * *

3. The authority citation for part 1130 continues to read as follows:

Authority: 15 U.S.C. 2056a, 2056(b).

4. Amend § 1130.2 by revising paragraph (a)(12) to read as follows:

PART 1130—REQUIREMENTS FOR CONSUMER REGISTRATION OF DURABLE INFANT OR TODDLER PRODUCTS

§ 1130.2 Definitions.

***** ***** ***** ***** *****

(a) * * *

(19) Infant inclined sleep products.

* * * * *

5. Add part 1235 to read as follows:

PART 1235-SAFETY STANDARD FOR INFANT INCLINED SLEEP PRODUCTS

Sec.

1235.1 Scope.

1235.2 Requirements for infant inclined sleep products.

Authority: Sec. 104, Pub. L. 110-314, 122 Stat. 3016 (August 14, 2008); Sec. 3, Pub. L. 112-28, 125 Stat. 273 (August 12, 2011).

§ 1235.1 Scope.

This part establishes a consumer product safety standard for infant inclined sleep products, including newborn inclined sleep products, compact inclined sleep products, and accessory inclined sleep products.

§ 1235.2 Requirements for infant inclined sleep products.

(a) Except as provided in paragraph (b) of this section, each infant inclined sleep product must comply with all applicable provisions of ASTM F3118-17, Standard Consumer Safety Specification for Infant Inclined Sleep Products (approved on January 1, 2017). The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from ASTM International, 100 Bar Harbor Drive, P.O. Box 0700, West Conshohocken, PA 19428; http://www.astm.org/cpsc.htm. You may inspect a copy at the Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone 301-504-7923, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal regulations/ibr_locations.html.

(b) Instead of complying with section 3.1.1 of ASTM F3118-17, comply with the following:

(1) 3.1.1 accessory inclined sleep product, n— an inclined sleep product that is intended to provide sleeping accommodations for infants or newborns and attaches to or is supported by another product.

(2) [Reserved]

Dated: _____

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

Staff Briefing Package

Draft Notice of Proposed Rulemaking for Infant Inclined Sleep Products under the Danny Keysar Child Product Safety Notification Act

March 2017

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Briefing Memorandum

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

This document has been electronically approved and signed.

Memorandum

DATE: March 22, 2017

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Mary T. Boyle, General Counsel

Patricia H. Adkins, Executive Director

DeWane Ray, Deputy Executive Director for Safety Operations

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

Celestine T. Kish, Project Manager
Division of Human Factors, Directorate for Engineering Sciences

SUBJECT: Notice of Proposed Rulemaking for Infant Inclined Sleep Products

I. INTRODUCTION

Section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA) is the Danny Keysar Child Product Safety Notification Act. This Act requires the U.S. Consumer Product Safety Commission (CPSC, or 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. Section 104(f) of the CPSIA defines "durable infant or toddler products" as "durable products intended for use, or that may be reasonably expected to be used, by children under the age of 5 years." The list of products in section 104(f) does not specifically include infant inclined sleep products. However, when considering a standard for bassinets and cradles, the Commission determined that hammocks and other inclined sleep products[1]

[1] 77 Fed. Reg. 64055, 64059 (October 18, 2012) (16 C.F.R. § 1218).

should be addressed separately from bassinets and cradles, which are specifically identified as "durable infant or toddler products."[2] Staff recommends that, in addition to proposing a standard establishing requirements for inclined sleep products, the Commission also should propose to amend 16 C.F.R. part 1130, Requirements for Consumer Registration of Durable Infant or Toddler Products, to clarify that infant inclined sleep products are a subset of bassinets/cradles.

Section 104 of the CPSIA also requires the Commission to consult with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts to examine and assess the effectiveness of the relevant voluntary standards. CPSC staff regularly participates in the juvenile products subcommittee meetings of ASTM International (ASTM). ASTM subcommittees consist of members who represent producers, users, consumers, government, and academia.[3] The consultation process for this rulemaking commenced in 2011, when ASTM began developing a new voluntary standard to address hammocks and inclined sleep products. Staff has been actively participating in the development of the new standard since.

This briefing package pertains to products that are included within the scope of the current voluntary standard, ASTM F3118-17, *Standard Consumer Safety Specification for Infant Inclined Sleep Products.* Under the ASTM standard, the infant inclined sleep products category covers sleep products with an inclined angle between 10° and 30° for use by infants up to about 5 months of age. The briefing package reviews the relevant incident data and assesses the standard's effectiveness. In addition, the briefing package discusses the potential impact of staff's recommendations on small businesses, reviews recent recalls associated with infant inclined sleep products, and provides staff's recommendations to the Commission. Additionally, the draft NPR includes a notice of requirements (NOR), which explains how test laboratories could become CPSC-accepted third party conformity assessment bodies to test infant inclined sleep products to the new safety standard.

II. BACKGROUND

A. ASTM Voluntary Standard Overview

ASTM F3118, *Standard Consumer Safety Specification for Infant Inclined Sleep Products,* is the voluntary standard that was developed to address the identified hazard patterns associated with the use of infant inclined sleep products. The current standard was approved on January 1, 2017, and published in March 2017. This is the third revision since the standard was first published in May 2015.

The ASTM standard contains both general and product-specific performance requirements, and it references CPSC requirements for lead in paint, sharp edges or points, and small parts. There are also mechanical requirements for scissoring, shearing, and pinching. The performance requirements relate to stability, unintentional folding, restraints, side height, containment, incline, structural integrity, dynamic load, static

[2] 74 Fed. Reg. 68668 (December 29, 2009) (16 C.F.R. § 1130.2(a)(16)).
[3] ASTM International website: www.astm.org, About ASTM International.

load, and newborn products' seat back length. The scope of the standard encompasses a wide variety of products that offer not only an inclined sleep position, but also other uses while the child is awake. Due to the variety of products that are covered by this standard, there are multiple warning labels to choose from to address the different combinations of product features.

B. Products

Staff began work on hammocks and inclined sleep products as a part of Section 104 work for bassinets and cradles. "Bassinets/cradles" are defined as providing sleep accommodations with an inclined surface 10° to flat. As work progressed, it became evident that one rule could not effectively address all products without banning hammocks as a class. Accordingly, the Commission directed staff to begin a separate rulemaking for the subset of hammock/inclined sleep products.[4] At the same time, ASTM began work on developing a voluntary standard for these products.

ASTM F3118-17 defines an "infant inclined sleep product" as "a freestanding product, intended to provide a sleeping accommodations (sic) for an infant up to approximately 5 months of age, that is generally supported by a stationary or rocker base with one or more inclined sleep surface positions for the seat back that are greater than 10° and do not exceed 30° from the horizontal." The standard also covers a smaller product intended for newborns up to 3 months old, or when the newborn begins to wiggle out of position or turn over in the product or weighs more than 15 lb (6.8 kg), whichever comes first." Some infant inclined sleep products are also identified as compact and accessory products because of their smaller size and attachment to play yards or cribs. Hammocks are considered infant inclined sleep products because of their sleep incline between 10° and 30° angle.

The scope specifically states: "1.3 This consumer safety performance specification covers a free standing product with an inclined sleep surface *primarily intended and marketed* (emphasis added) to provide sleeping accommodations for an infant up to 5 months old or when the infant begins to roll over or pull up on sides, whichever comes first."

The standard was developed in response to incident data supplied by CPSC staff to address: *(1)* fall hazards, *(2)* positional asphyxiation, and *(3)* obstruction of nose and mouth by bedding.

C. Juvenile Products Manufacturers Association Certification[5]

The Juvenile Products Manufacturers Association (JPMA) has a certification program for a variety of juvenile products, including infant inclined sleep products. To obtain JPMA certification, manufacturers submit their products to an independent test laboratory for conformance testing to the most current ASTM voluntary standard. Currently, one manufacturer supplies JPMA-certified infant inclined sleep products. It

[4] https://www.regulations.gov/docket?D=CPSC-2010-0028.
[5] Certification JPMA. Juvenile Product Manufacturers Association. (n.d.). Retrieved on April 29, 2016, from: http://jpma.org/content/certification/overview.

should be noted that a lack of participation in the JPMA certification program does not mean that the products are not compliant with, or tested to, the ASTM standard. ASTM F3118-16 is currently in effect for testing purposes under the JPMA certification program. Typically, there is a 6-month period between ASTM standard publication and its adoption for purposes of JPMA certification. ASTM F3118-17, the version of the voluntary standard upon which the staff-recommended proposed mandatory standard is based, was published in March 2017, and that version would be in effect by the time a mandatory standard became final.

D. Incident Data

The memorandum from the Directorate for Epidemiology staff (Tab A) discusses 657 incidents (14 fatal and 643 nonfatal) related to infant inclined sleep products that reportedly occurred from January 1, 2005 through September 30, 2016. Retailers and manufacturers submitted 40 percent of the reports (261 out of 657) through CPSC's Retailer Reporting Program. Various sources, such as hotlines, Internet reports, newspaper clippings, medical examiners, and other state/local authorities provided the remaining incident reports to CPSC. Reporting is ongoing, and therefore, the number of reported fatalities, nonfatal injuries, and non-injury incidents may change in the future.

1. Fatalities

Fourteen fatalities associated with the use of an infant inclined sleep product reportedly occurred from January 1, 2005 through September 30, 2016. When age was known, the victims were 2-month-olds to 8-month-olds; one reported death did not provide age of victim.

Eight of the 14 deaths involved rocker-like inclined sleep products; in three cases, the unstrapped decedent reportedly rolled over into a face-down position. Two additional cases also reported a rollover into a face-down position, but no information was available on the use of a restraint. There was insufficient information about the cause or manner of death for the three remaining deaths.

Four of the 14 deaths involved reclined infant seat-type products. In three of these cases, the products were placed inside cribs and the decedents—two with restraints on, and one without restraints—were found to have rolled over the edge of the products into the bedding in the cribs. In the remaining death, restraints were not used and the decedent was found to have rolled over into a face-down position.

Two of the 14 deaths involved infant hammocks. One decedent had rolled over onto her stomach—restraint-use not mentioned—and was found face-down on a foam mattress. The second decedent was trapped in the head down position, with the decedent's face pressed against bedding material after product straps were not assembled correctly, which allowed the product to tip out of position.

2. Nonfatal Injuries

Three hundred and one of the 643 inclined sleep product-related nonfatal incidents that reportedly occurred from January 1, 2005 through September 30, 2016, involved an injury to the infant during product use. The

majority of the injured (256 out of 301) were between 1 month and 8 months of age; age was reported to be over 8 months or unreported for 16 and 29 of the injured infants, respectively.

The severity of the injury types among the 301 reported injuries were as follows:

- Twenty required hospital admissions. Seventeen of the hospitalizations were for respiratory problems suffered due to mold on the sleep product, two were for treatment of head injuries due to a fall, and one was for observation of an infant who had stopped breathing for unspecified reasons.
- Twenty-seven were treated and released from emergency departments (EDs). These infants were treated for respiratory problems for exposure to mold, head injuries (such as a skull fracture or a closed-head injury[6]), contusions/bruises from falls or near-falls, and temporary cessation of breathing by the infant in a chin-to-chest position in an inclined sleep product. In one incident, metal shavings from the product had to be removed from an infant's eye.
- Among the remaining 254 injuries, 151 required treatment for plagiocephaly (flat head syndrome), torticollis (twisted neck syndrome), or both conditions, which were associated with the use of the inclined sleep product; 90 were treated for mostly respiratory and some skin problems associated with mold on the product; seven infants suffered minor bumps/bruises/lacerations due to falls or near-falls; three suffered a combination of respiratory problems along with flat head syndrome or fall injuries. Finally, there was one eye-burn injury, one thermal burn due to electrical overheating, and one abnormal back curvature condition attributed to the use of an inclined sleep product.

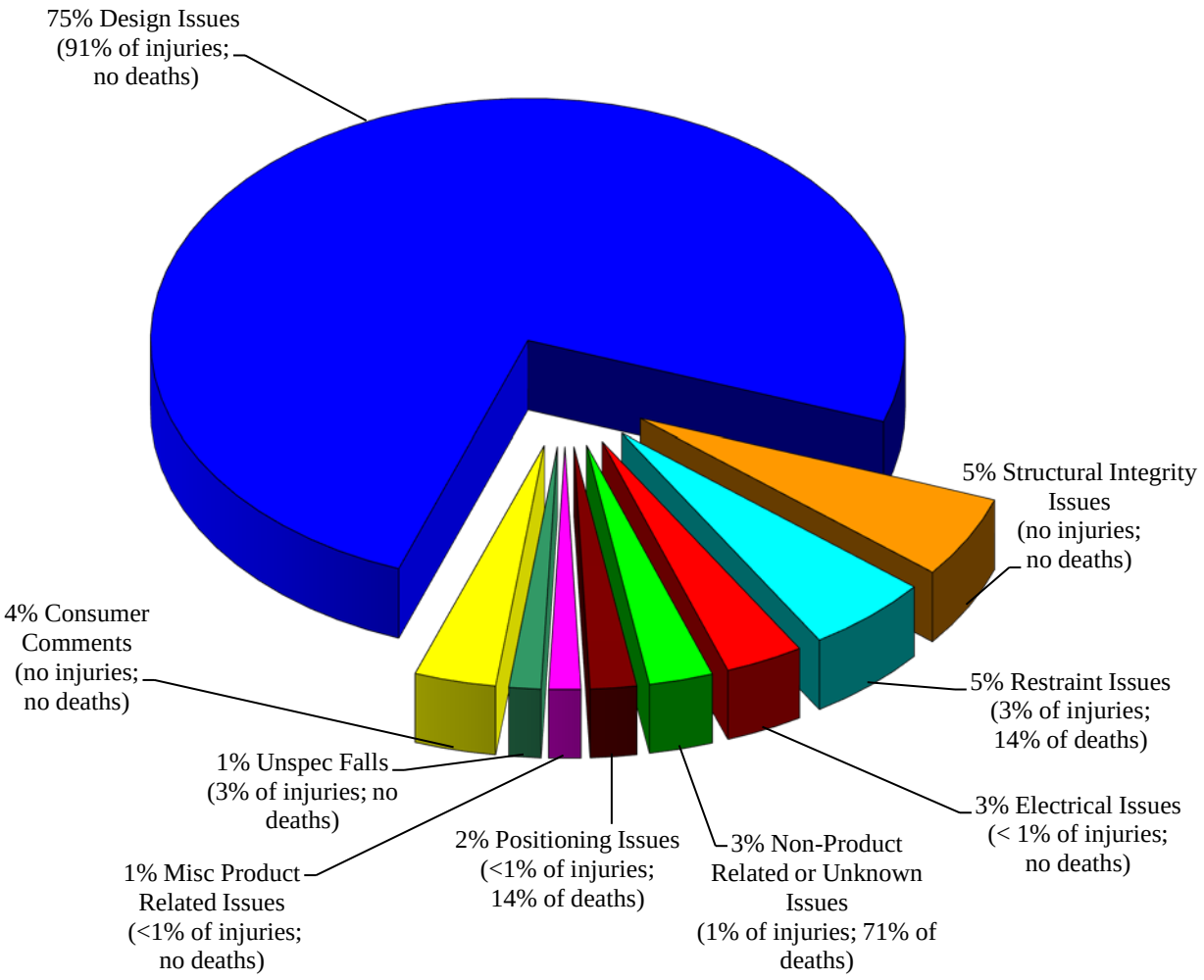
The remaining 342 incidents reported that no injury had occurred or provided no information about any injury. However, many of the descriptions indicated the potential for a serious injury, or even death, similar to those reported in the incident data.

E. Hazard Pattern Characterization Based on Incident Data

This section summarizes the hazard pattern characterizations based on the incident data. Figure 1 shows the distribution of hazard patterns by frequency.

[6] According to staff from the Directorate for Health Sciences, a closed-head injury is a head injury where the skull remained intact, but the injury can range in severity from a minor bump to a severe life-threatening traumatic brain injury.

Figure 1: Distribution of Incident Reports Associated with Infant Inclined Sleep Products by Hazard Pattern Characterizations January 1, 2005 - September 30, 2016



Source: CPSC epidemiological databases CPSRMS and NEISS. Note: Percentages do not always add to 100 due to rounding.

1. Problems with the ***design*** of the infant inclined sleep product: Four hundred and ninety-two of the 657 reported incidents (75 percent) were in this category. Two major issues were identified. One, infants reportedly developed respiratory and/or skin ailments due to the growth of mold on the product. Two, infants also reportedly developed physical deformations, such as *plagiocephaly* (flat head syndrome) and/or *torticollis* (twisted neck syndrome), from extended use of the product. Although no deaths were reported, this category includes 17 hospitalizations and 13 ED visits, all for treating respiratory problems associated with the use of the inclined sleep product. An additional 244 non-hospitalized, non-ED injuries were also reported in this category.

2. Lack of ***structural integrity***: Thirty-six of the 657 incidents (5 percent) reported some sort of failure of the product or its components. These included complaints of buckles/straps breaking, pads/seats/liners tearing, hardware coming loose, and metal stands/bars and other unspecified components breaking. No injuries or fatalities were reported in this category.

3. ***Inadequate restraints***: Thirty-five of the 657 incidents (5 percent) reportedly occurred when the restraint failed to confine the infant in position. One of the 35 reports also mentioned a mold problem on the product. Two deaths occurred when infants, although restrained, managed to roll over out of position, and ended up burying their face in nearby soft bedding. Three of the nine injuries in this category, treated in EDs, resulted from a strapped-in infant falling out of the product entirely.

4. ***Electrical*** issues: Twenty-two of the 657 incident reports (3 percent) reported overheating or melting of components, such as the vibrating unit, battery cover, switch, or motor. One thermal burn injury was reported in this category.

5. ***Non-product-related*** or ***unknown*** issues: Eighteen of the 657 incident reports (3 percent) indicated that either the manner in which the product was used led to an incident, or there was not enough information available to determine how the incident occurred. There were 10 fatalities and four injuries in this category. User error contributed to six asphyxiation fatalities; all decedents were left unstrapped and later found in a prone position. Two more fatalities occurred when an infant rolled out of position while in the product; it was unknown if a restraint was used. The circumstances leading to the remaining two fatalities were unknown. Many of these fatalites reported the presence of extra soft bedding in the product. Among the four injuries, two of which required hospitalization, user error was attributed in two cases. Very little information was available for the remaining two injuries.

6. Difficulty with correct ***positioning*** during use: There were 13 reported incidents (2 percent) in this category. Most of the incidents involved hammock-like products, which shifted into a unlevel rest position as the infant moved. Two infants ended up trapped in a corner with their face in the fabric/bedding of the product and suffocated. In two other reports, consumers complained of difficulty preventing their infant from getting into a chin-to-chest position; both of these infants, who had stopped breathing, were treated at a hospital ED.

7. ***Miscellaneous product-related*** issues: Nine of the 657 (1 percent) incidents reported a variety of other product-related issues not listed above. There were complaints of poor finish (metal shavings, sharp edges, a threaded needle left in the product); instability (product suspended mid-air, flipping over, or product, sitting on floor, tipping over); incomplete packaging (missing parts and instructions); and noxious odor. In addition, one incident reported both restraint inadequacy and mold growth, indicating a design problem. Two injuries were reported in this category, including one who was treated and released from a hospital ED.

8. ***Unspecified falls***: Nine of the 657 incidents (1 percent) reported an infant falling from the product but provided very little information on the circumstances leading up to the falls. All of the incidents were reported through hospital EDs as head injuries (skull fracture or closed-head injury) or face contusions. One infant was hospitalized, while others were treated and released.

9. ***Consumer comments***: Twenty-three of the 657 reports (4 percent) fall in this category. The reports consisted of consumer comments/observations about perceived safety hazards or complaints about unauthorized sale of recalled infant inclined sleep products. None of these reports indicated that any incident actually occurred, and none identified a hazard pattern not covered in the above.

III. DISCUSSION

A. Adequacy of F3118 Requirements

Based on the incident data discussed above, staff assessed the adequacy of ASTM F3118-17; see Tabs B, C, D and E.

Product design
As shown through the data, 75 percent of the incidents/injuries were reportedly associated with the design of the inclined sleep product.

a. In the cases reporting mold, which resulted in respiratory problems for infants using the product, all cases involved one manufacturer's inclined sleep product. CPSC recalled that product in 2013. According to staff of the Directorate for Health Sciences (see Tab C), molds are ubiquitous in the environment and can grow in many places where they have access to moisture and nutrients. Infants who use an inclined sleep product that develops visible mold can be at risk of developing health effects, such as allergies, asthma, mycosis, and effects of mycotoxins. Because the mold growth was restricted to one manufacturer's product and that product was recalled, staff is not recommending any modifications to address potential hazards associated with mold.
b. Plagiocephaly, cranial deformity or asymmetry (commonly known as flat head) is a condition that may exist at birth due to mechanical constraint of fetal head movement in the womb, mainly due to crowding in the womb in cases of multiple births. It may also be the result of birth-related injuries during assisted delivery, such as the use of forceps that might cause strenuous pressure on the skull. Plagiocephaly may also develop after birth, especially in infants born prematurely. These infants are at greater risk for skull deformity attributable to head molding in the first few months of life. Occipital flattening and other uncommon shapes of the head may also be due to the birth defect, craniosynostosis. Although the flattened appearance of an infant's head can be shocking to parents, there is no scientific evidence to show that plagiocephaly interferes with brain development or function. This condition appears to be preventable and reversible when treated; the only lasting effect is on the physical shape/deformity of the head. See Tab D.

c. Muscular torticollis (twisted neck) is a known risk factor associated with plagiocephaly caused by constraint of head and neck movement.

Although the incident data indicate that consumers believe using an inclined sleep product caused their child's plagiocephaly/torticollis, there is no evidence to support this belief. The increase in the number of children with plagiocephaly may actually be attributed to the American Academy of Pediatrics' (AAP) recommendation to place infants to sleep on their backs to decrease the risk of sudden infant death syndrome (SIDS). In the first few months of life, infants spend most of their awake and sleep time on their back. The weight and pressure of their head facing up, causes the back of the head to flatten, regardless of the product the child is using. To help prevent the development of flat head, and to promote the upper shoulder muscle strength necessary for healthy growth, AAP currrently recommends a certain amount of prone positioning, or "tummy time," while the infant is awake and under parental supervision. Therefore, the development of plagiocephaly and torticollis is not exclusively attributable to the use of infant inclined sleep products, and the conditions are not addressable with performance standards. Staff is not recommending any modifications to the voluntary standard to address these issues.

Inadequate restraints

This standard does not require including any type of restraint system. However, for products that do include restraints, performance requirements are included to address their operation and function. Two deaths occurred in an infant inclined sleep product that was recalled during the development of the ASTM voluntary standard. The standard's subcommittee developed restraint and containment requirements to address these deaths and injuries. ASTM F3118-17 requires that restraints on inclined sleep products meet test requirements to prevent breaking and/or separation, and specify that crotch component use is mandatory when the restraint is used. The performance requirements in this standard have been developed to test the inclined sleep product's ability to maintain the child, within the manufacturer's specified age range, in a safe position during normal use without the need for additional restraint systems. However, certain types of restraints are allowed to be used even though not considered necessary for the safe use of the product. Staff agrees with these restraint requirements for products that do include restraints and notes these are similar to requirements used in other juvenile product safety standards.

Structural integrity

The incidents included in this category consisted of complaints related to buckles/straps breaking, pads/seats/liners tearing, hardware coming loose, and metal stands/bars and other unspecified components breaking. The static and dynamic load tests included in F3118-17 address structural integrity in a similar manner to other ASTM juvenile product standards. Any breakage of seams, materials, or changes in adjustments that could affect the product's ability to support the child is considered a failure. After evaluation by staff, staff concludes that the tests satisfactorily address the type of incidents that have been identified for inclined sleep products.

Positioning

Most of the incidents involved hammock-like products that shifted into a non-level rest position as the infants moved and the infants ended up trapped in a corner with their face in the fabric/bedding of the product. Two fatalities occurred in this manner. Hazardous positioning involves multiple factors, such as the fabric or material used on the product's side, inclusion of a mat or mattress, and the infant's ability to reposition in the product. Because the factors involved in these incidents are complex and not easily addressable, ASTM F3118-17 does not include specific performance requirements to directly address this scenario at this time. The voluntary standard addresses instability with a performance test; however, the intent of that test is to address incidents such as siblings pulling on the side and tipping the inclined sleep product. Staff will continue to monitor incident data and recommend changes to the standard in the future, if needed.

Non-product-related/unknown

There were ten fatalities and four injuries in this category. User error contributed to six of the asphyxiation fatalities. All decedents were left unstrapped and later found in a prone position. ASTM F3118-17 has requirements for restraints (where the product includes restraints) and side containment to prevent infants from moving out of position. In addition, CPSC staff has worked with the ASTM subcommittee on the warnings and instructions to ensure that consumers are given adequate information to use the product correctly.

Miscellaneous product-related issues

Incidents included in this category, such as stray objects, incomplete packaging, missing parts, and noxious odors are considered manufacturing quality control issues, not safety-related issues; they are not addressable by this standard. Eliminating rough finishes, sharp edges, and points are included in the general requirements of ASTM F3118-17. The voluntary standard also includes performance requirements for the stability of infant, newborn, and compact inclined sleep products. Staff evaluated these requirements and determined them to be adequate to address incidents of this type.

Electrical issues

Since staff began monitoring the incident reports for infant inclined sleep products, incidents involving electrical issues have risen from 1 percent to 3 percent of the total reported incidents. One thermal burn injury was reported in this category. CPSC staff recently shared this new data with the ASTM subcommittee and suggested that electrical requirements similar to those in other juvenile products be added to F3118. Staff recommends that the NPR include a request for public comment regarding inclusion of electrical requirements to prevent additional incidents, including overheating, melting battery compartments, and thermal burns.

Unspecified falls

There were few details in the reports of falls from the product that led to injury. Without details, we do not know how the incident occurred or whether the incident could be addressed by any performance

standard. However, the new ASTM standard includes stability and containment requirements, as described in earlier sections, which address known hazard patterns that could result in falls.

Consumer comments

This category contained 23 reports from consumers about perceived product hazards that were not associated with incidents. Staff reviewed the reports and determined that the information did not describe a hazardous situation or a circumstance that is not already addressed in the ASTM standard. Based on this evaluation, staff believes that no action is required to address these reports at this time.

Warnings

Division of Human Factors staff (ESHF) (see Tab E) has been actively engaged in the development process of F3118. Due to the variety of products covered in the scope of this voluntary standard, developing the warning labels involved extensive work. While staff and subcommittee members were focused on the wording of the warning labels, ASTM formed an Ad Hoc Warnings subcommittee to create a guidance document for the formatting of warning labels for juvenile products. The guidance document was approved in May 2016. F3118-17 incorporated the formatting recommendations. Staff supports the current warning language and format provisions in ASTM F3118-17 that reflect the recommendations of the Ad Hoc Warnings subcommittee. Staff does not recommend any warning changes to the standard.

ESHF staff also raised an issue with the ASTM subcommittee regarding the placement of the warning labels. ESHF staff found several currently marketed inclined sleep products with warnings wrapped around the side and underside of the product or obscured by the frame of the stand. ESHF staff recommended that the warnings be located either on a vertical or top surface, with no obscurement from the product frame or components. The subcommittee decided to change the definition of "conspicuous" to ensure that the warnings are fully visible; the new definition is in F3118-17. Staff does not recommend any changes to the new definition.

Scope

The scope of F3118-17 states:

> "1.3 This consumer safety performance specification covers a free standing product with an inclined sleep surface primarily intended and marketed to provide sleeping accommodations for an infant up to 5 months old or when the infant begins to roll over or pull up on sides, whichever comes first. It also covers a smaller product intended for newborns up to 3 months old or when newborn begins to wiggle out of position or turn over in the product or weighs more than 15 lb (6.8 kg), whichever comes first. It also covers infant and newborn inclined sleep product accessories, which are attached to, or supported by, another product with the same age or abilities, or both, as the free standing products. If the inclined sleep product can be converted into a product for which another ASTM standard consumer safety specification exists, the product shall meet the applicable requirements of that standard. For example, an inclined sleep product that can have the recline

angle adjusted below 10° shall also comply with the applicable requirements of Consumer Safety Specification F2194.

After the initial infant inclined sleep products standard was published in 2015 (F3118-15), a small number of products was identified that staff, as well as ASTM members, felt should fall within the scope of the standard, but that could mistakenly be determined to be outside the scope of the standard. The confusion primarily entailed what was meant by "intended for sleep." Consequently, CPSC staff worked with ASTM members to clarify the scope to eliminate this confusion, by presenting the scope in outline format to distinguish the various classifications, explain when multiple-use products should be included, and define "intended or marketed" as: "3.1.X *intended or marketed to provide sleeping accommodations, adj.* - includes products marketed for prolonged and/or overnight sleep, as well as products with seat back positions that can be inclined greater than 10° and less than or equal to 30° from the horizontal."

ASTM balloted the new definition along with the reformatted presentation of the scope; however, the ballot received persuasive negative votes. The subcommittee continues to work on acceptable language to adequately convey what is meant by the terms "intended or marketed for sleep." Staff does not believe that the clarified scope, by way of the definition, will have any impact on these products or their suppliers because these products would always have been considered in-scope, and the clarified language merely reduces any uncertainty about that.

The balloted scope also clarified that products whose primary purpose is not inclined sleep (*e.g.*, a bouncer), but can be converted into an inclined sleep product, would fall within the scope of the inclined sleep product standard:

> "1.4 If a product can be converted to an infant or newborn inclined sleep product as defined in 3.1.7 and 3.1.10, it shall be included in the scope of this standard when it is in the infant or newborn inclined sleep product use mode. Note: nursing pillows are excluded from the scope of this standard."

Requirements for mulitple use products are common across ASTM nursery product standards. Essentially, multiuse products need to meet all relevant standards. There are two known firms with a multiuse product that can be converted into an inclined sleep product (specifically bouncers with an inclined sleep position). Again, because of the customary treatment of multiuse products across ASTM voluntary nursery product standards, staff believes that these products were always covered by the inclined sleep product standard and that the clarified scope will not impact their suppliers.

Because the ASTM subcommittee is still trying to achieve agreement on the clarification of the scope, staff does not recommend any changes in the NPR, but requests comments on: (1) the need to define "intended or marketed for sleep," and possible suggestions for that definition; (2) if more clarification is needed as related to multiple use products, as well as input (particularly from those involved in

developing the modified language for the ASTM standard) on the degree to which any changes are clarifications rather than expansions of scope.

Accessory Definition

In the current version of F3118-17, "accessory" is defined as "a rigid framed inclined sleep product that is intended to provide sleeping accommodations for infants or newborns and attaches to or is supported by another product." During the ASTM subcommittee meetings in September 2016, a member brought to the subcommittee's attention a new product that members agreed should be classified as an accessory inclined sleep product, except for the fact that the product does not have a "rigid frame." The subcommittee members agreed that "rigid frame" should be removed from the definition. The ASTM subcommittee chair is planning to ballot new definition of "accessory" without the use of "rigid frame" in spring 2017. Staff agrees with this approach and is recommending that the NPR reflect the suggested change to the definition.

Based on the incident data and review of the voluntary standard above, staff recommends incorporating by reference ASTM F3118-17, with a modification to the "accessory" definition. Specifically, staff recommends removing "rigid frame" from the accessory definition. Staff also recommends including specific requests for public comment regarding the scope of the standard and inclusion of electrical performance and testing requirements.

B. Product Registration Rule Amendment

The statutory definition of "durable infant or toddler product" in section 104(f) applies to all of section 104 of the CPSIA. In addition to requiring the Commission to issue safety standards for durable infant or toddler products, section 104 of the CPSIA also directed the Commission to issue a rule requiring that manufacturers of durable infant or toddler products establish a program for consumer registration of those products.

Section 104(f) of the CPSIA defines the term "durable infant or toddler product" and lists examples of such products:

(f) DEFINITION OF DURABLE INFANT OR TODDLER PRODUCT. As used in this section, the term "durable infant or toddler product" –
(1) means a durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years; and
(2) includes –
(A) full-size cribs and nonfull-size cribs;
(B) toddler beds;
(C) high chairs; booster chairs, and hook-on-chairs;
(D) bath seats;
(E) gates and other enclosures for confining a child;
(F) play yards;

(G) stationary activity centers;
(H) infant carriers;
(I) strollers;
(J) walkers;
(K) swings; and
(L) bassinets and cradles.

Inclined sleep products could be considered a subset of the bassinet category listed in section 104(f). The infant inclined sleep products safety standard developed out of the bassinet safety standard. Inclined sleep products, like bassinets, are durable products intended for use by children under the age of 5 years. Including inclined sleep products in the scope of the bassinet standard, however, would have effectively banned most inclined sleep products on the market. According to the bassinet/cradle standard, such products are "intended to have a sleep surface less than 10 degrees from horizontal," and products with an incline greater than 10 degrees therefore do not fall within the scope of the bassinet/cradle standard. Furthermore, when considering the bassinet standard, the Commission stated that a separate standard targeted specifically to inclined sleep products would more effectively address the hazards associated with those products. 77 FR 64055, 64059 (Oct. 18, 2012). Therefore, CPSC staff began working with ASTM to develop a voluntary standard that would cover the wide array of products on the market that provide infants and toddlers with inclined sleeping environments.

However, it is not entirely clear that inclined sleep products would be considered a sub-category of bassinets. As noted, by definition, products intended to have an incline greater than 10 degrees from horizontal are not covered by ASTM's (or the Commission's) bassinet standard. To provide greater clarity, staff recommends the Commission amend the Commission's consumer registration rule.

In 2009, the Commission issued a rule implementing the consumer registration requirement, 16 CFR part 1130. As the CPSIA directs, the consumer registration rule requires each manufacturer of a durable infant or toddler product to: provide a postage-paid consumer registration form with each product; keep records of consumers who register their products with the manufacturer; and permanently place the manufacturer's name and certain other identifying information on the product. When the Commission issued the consumer registration rule, the Commission identified six additional products as "durable infant or toddler products":

- children's folding chairs
- changing tables;
- infant bouncers;
- infant bathtubs;
- bed rails; and
- infant slings.

The Commission stated that the specified statutory categories were not exclusive, but that the Commission should explicitly identify the product categories that are covered. The preamble to the 2009 final consumer registration rule states: "Because the statute has a broad definition of a durable infant or toddler product but also includes 12 specific product categories, additional items can and should be included in the definition,

but should also be specifically listed in the rule." 74 FR 68668, 68669 (Dec. 29, 2009).

Staff recomments the Commission amend the definition of "durable infant or toddler product" in the consumer registration rule to reduce any uncertainty as to whether inclined sleep products fall within the term "durable infant or toddler product" as used in the product registration card rule and section 104 of the CPSIA.

C. Potential Small Business Impact

As discussed in the memorandum from the Directorate for Economic Analysis (Tab F), staff identified 25 firms supplying inclined sleep products to the U.S. market. More than half of these firms (16 firms) produce infant hammocks. Staff expects that the inclined sleep products of six of these firms are already compliant with ASTM F3118 because the firms either: (1) have their inclined sleep products certified by the Juvenile Products Manufacturers Association (JPMA) (one firm); or (2) claim compliance with the voluntary standard (five firms). Based on U.S. Small Business Administration guidelines, 14 of the 25 firms are small domestic businesses, including 10 manufacturers and four importers. Additional firms not identified by CPSC staff may manufacture or sell inclined sleep products on a very small scale via online marketplaces, such as Etsy, for hand-crafted products.

As described in Tab F, the costs of the rule include costs necessary to bring products into conformance with the requirements of the rule and the third party testing costs that would be triggered with a final rule. The economic impact of the staff-recommended proposed rule is expected to be small for all three small domestic manufacturers supplying compliant inclined sleep products to the U.S. market, as well as one of the small manufacturers supplying noncompliant inclined sleep products. However, staff cannot rule out the possibility that the cost of redesigning and manufacturing their products to comply with the requirements of the staff-recommended proposed rule could be significant for 10 of the 14 (71 percent) known small suppliers (6 manufacturers and 4 importers) of inclined sleep products to the U.S. market that do not currently comply. Accordingly, staff prepared an Initial Reglatory Flexibility Analysis (IRFA).

Staff is recommending an effective date of 1 year to give firms time to familiarize themselves with the scope of the standard and develop new/modified products, if needed. This could help to reduce the impact of the proposed rule on small firms, although these firms may still experience significant economic effects.

D. Compliance Recall Information

Compliance staff reviewed recalls of infant inclined sleep products from May 10, 2000 to March 1, 2016. During that period, there were nine consumer-level recalls involving infant inclined sleep products. The recalls were conducted to resolve risk issues involving mold, structural stability, entrapment, suffocation, falls, and strangulation. Three recalls involved an infant inclined sleep product and six recalls involved infant hammocks, which are covered under the scope of F3118-17.

There was one recall for mold, affecting 800,000 units of infant inclined sleep products. There were two recalls for entrapment and suffocation, affecting 195,000 units of inclined sleep products. The six additional

recalls were the result of potential suffocation, strangulation, structural stability, entrapment, and fall hazards. Those recalls affected 25,368 hammock units.

IV. NOTICE OF REQUIREMENTS

Section 14(a) of the CPSA requires that any children's product subject to a consumer product safety rule under the CPSA must be certified as complying with all applicable CPSC-enforced requirements. The children's product certification must be based on testing conducted by a CPSC-accepted third party conformity assessment body (test laboratory). The CPSA requires the Commission to publish a notice of requirements (NOR) for the accreditation of third party test laboratories to determine compliance with a children's product safety rule to which a children's product is subject. A proposed rule for infant inclined sleep products, if issued as a final rule, would be a children's product safety rule that requires issuing an NOR.

The Commission published a final rule, *Requirements Pertaining to Third Party Conformity Assessment Bodies*, 16 C.F.R. part 1112 (78 Fed. Reg. 15836 (March 12, 2013)) (referred to here as part 1112). This rule took effect on June 10, 2013. Part 1112 establishes the requirements for accreditation of third party testing laboratories to test for compliance with a children's product safety rule. The final rule also codifies all of the NORs that the CPSC has published, to date, for children's product safety rules. All new children's product safety rules, such as the proposed rule for infant inclined sleep products, would require an amendment to part 1112 to create an NOR. Therefore, staff recommends that the Commission propose to amend part 1112 to include infant inclined sleep products in the list of children's product safety rules for which the CPSC has issued NORs.

V. RECOMMENDED EFFECTIVE DATE

ASTM F3118-17 is a new voluntary standard with a scope that covers a variety of products for which some manufacturers may not be aware that their product must comply. To allow time for infant inclined sleep product manufacturers to bring their products into compliance after a final rule is issued, staff recommends an effective date of 12 months after publication of a final rule for products manufactured or imported on or after that date. Staff is recommending incorporating by reference ASTM F3118-17 with one modification to the accessory definition; therefore, staff believes that most firms should be able to comply within the 12-month timeframe.

VI. STAFF RECOMMENDATIONS

CPSC staff recommends that the Commission propose to incorporate by reference the voluntary standard, ASTM F3118-17, *Standard Consumer Safety Specification for Infant Inclined Sleep Products*, with one change to the "accessory" definition. Specifically, staff recommends that the Commission publish the draft NPR incorporating by reference the current standard, with a modification that would define "accessory" without the

phrase “rigidly framed.” Staff also recommends requesting public comment regarding the scope of the standard and possible inclusion of performance and testing requirements for electrical components. Because infant inclined sleep products were not specifically mentioned as a durable infant or toddler product in section 104(f)(2), staff also recommends an amendment to 16 C.F.R. part 1130 to clarify that infant inclined sleep products are a durable infant or toddler product as a subset of bassinets/cradles.

TAB A: Infant Inclined Sleep Product-Related Deaths, Injuries, and Potential Injuries; January 1, 2005 – September 30, 2016

TAB A

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

Memorandum

Date: October 28, 2016

TO : Celestine Kish
Infant Inclined Sleep Products Project Manager
Division of Human Factors
Directorate for Engineering Sciences

THROUGH: Kathleen Stralka
Associate Executive Director
Directorate for Epidemiology

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

FROM : Risana Chowdhury
Division of Hazard Analysis
Directorate for Epidemiology

SUBJECT : Infant Inclined Sleep Product-Related Deaths, Injuries, and Potential Injuries; January 1, 2005 – September 30, 2016[1]

I. Introduction

This memorandum characterizes the number of deaths and injuries and the types of hazards related to infant inclined sleep products over a period of nearly 12 years from January 1, 2005 through September 30, 2016.[2] These characterizations are based on incident reports received by CPSC staff. The number of emergency department-treated injuries associated with infant inclined sleep products, for the period covered, was insufficient to derive any reportable national estimates.[3] Hence, injury estimates are not

[1] 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.
[2] 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 ED-treated injuries.
[3]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.

presented in this memorandum. However, the ED-treated injuries are included in the total count of reported incidents presented here.

ASTM F3118-17, *Standard Consumer Safety Specifications for Infant Inclined Sleep Products*, addresses safety issues related to infant inclined sleep products. According to the ASTM standard, an "infant inclined sleep product" is "a freestanding product, intended to provide sleeping accommodations for an infant up to approximately 5 months of age, that is supported by a stationary or rocker base with one or more inclined sleep surface adjustment positions for the seat back (head-to-toe) that are greater than 10° and do not exceed 30° from the horizontal." This standard also covers infant inclined sleep product accessories, which are attached to or supported by another product, with the same developmental limits as the freestanding products. As such, a wide range of products falls within the definition of an "infant inclined sleep product." Infant hammocks, infant recliner seats, and nappers (which are play yard accessories), as well as many rocker- and bouncer-like products, are some of the products covered by this standard.

ASTM F3118-17 is the current voluntary standard for infant inclined sleep products; the first standard was published in 2015, and was developed primarily based on incident data since 2005, provided by CPSC staff. This memorandum discusses the data from the year 2005, through most of the year 2016.

II. Incident Data[4]

CPSC staff is aware of 657 incidents (14 fatal and 643 nonfatal) related to infant inclined sleep products that reportedly occurred from January 1, 2005 through September 30, 2016. Information on almost 40 percent (261 out of 657) of the incidents was based solely on reports submitted to CPSC by manufacturers and retailers through CPSC's "Retailer Reporting Program." Because reporting is ongoing, the number of reported fatalities, nonfatal injuries, and non-injury incidents may change in the future. Table 1 provides the breakdown of the incidents by year. Given that many of these reports are anecdotal and that reporting is incomplete, CPSC staff strongly discourages drawing any inferences from the year-to-year increase or decrease shown in the reported data.

[4] The CPSC databases searched were the Consumer Product Safety Risk Management System (CPSRMS) and the National Electronic Injury Surveillance System (NEISS). These reported deaths and incidents do not provide a complete count of all that occurred during this time. However, they do provide a minimum number of deaths and incidents occurring during this time and illustrate the circumstances involved in the incidents related to infant inclined sleep products.

Date of extraction for reported incident data was 12/16/15. All data coded under product codes 5037 (hammocks), 1537 (bassinets/cradles), 1513 (playpens), 1529 (portable cribs), 1542 (baby mattresses or pads), 1553 (portable baby swings), and 1558 (baby bouncer seats) was extracted, and keyword searches were used to identify the potentially in-scope cases. Upon careful joint review with CPSC's Directorates for 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 pre-existing medical conditions as the official cause of death, or cases where there was limited information about the product, but the infant using the product was much older than the recommended age, were excluded from this analysis. However, all incidents where hazardous environments in and around the infant inclined sleep product resulted in fatalities, injuries, or near-injuries were retained. With the exception of incidents occurring on U.S. military bases, all incidents that occurred outside of the United States have been excluded. To prevent any double counting, when multiple reports of the same incident were identified, they were consolidated and counted as one incident.

Table 1: Infant Inclined Sleep Product-Related Reported Incidents
01/01/05 – 09/30/16

Incident Year	***Number of Reported Incidents***		
	Total	***Injuries (Hospitalizations)***	***Fatal***
2005	3	2(0)	0
2006	1	1(1)	0
2007	1	1(0)	0
2008	2	1(0)	0
2009	13	1(0)	2
2010	38	15(0)	2
2011	68	48(0)	0
2012	148	85(6)	1
2013	129	72(7)	2
2014*	126	44(3)	2
2015*	79	20(1)	4
2016*(through Sep 30th)	49	11(2)	1
Total	***657***	***301(20)***	***14***

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

Age was not reported in 202 incidents because no injury was involved, or age was unknown. Among the 455 incidents where age was reported, 329 reported ages 5 months old or younger, and 103 reported ages between 6 months and 8 months old; the remaining 23 incidents reported ages between 9 months and 2 years and 5 months. Table 2 provides the age breakdown, as reported in the 657 incidents.

Table 2: Age Distribution as Reported in Infant Incline Sleep Product-Related Incidents
01/01/05 – 09/30/16

Age of Child	***All Incidents***		***Fatal and Nonfatal Injuries***	
	Frequency	***Percentage***	***Frequency***	***Percentage***
Unreported*	202	31	30	10
One – Five Months	329	50	208	66
Six – Eight Months	103	16	61	19
Nine – Twelve Months	14	2	8	3
Over One Year	9	1	8	3
Total	***657***	***100***	***315***	***100***

Source: CPSC epidemiological databases CPSRMS and NEISS.
Note: Percentages do not always add to 100 due to rounding. * : Age was unknown or the incident reported no injury.

A. Fatalities

Fourteen fatalities associated with the use of an infant inclined sleep product reportedly occurred during the period January 1, 2005 through September 30, 2016.

Eight of the 14 deaths involved rocker-like inclined sleep products; in three cases, the unstrapped decedent rolled over into a facedown position. Two additional cases also reported a rollover into a facedown

position, but no information was available on the use of a restraint. There was insufficient information about the cause or manner of the three remaining deaths.

Four of the 14 deaths involved reclined infant seat-type products. In three of these cases, caregivers placed the products inside cribs and the decedents—two with restraints on and one without restraints on—rolled over the edge of the products into the bedding in the cribs. In the remaining death, caregivers did not use restraints, and the decedent rolled over into a facedown position.

Two of the 14 deaths involved an infant hammock. One decedent had rolled over onto her stomach—restraint-use was not mentioned—and was found facedown on a foam mattress. The second decedent was trapped in the head-down position, with face pressed against bedding material when the misinstalled inclined sleep product tipped to an unlevel position.

B. Nonfatal Incidents

Three hundred and one of the 643 inclined sleep product-related nonfatal incidents that reportedly occurred from January 1, 2005 through September 30, 2016 reported an injury to the infant during use of the product.

The severity of the injury type among the 301 reported injuries were as follows:

- Twenty required hospital admissions. Seventeen of the hospitalizations were for respiratory problems suffered due to mold on the sleep product, two were for treatment of head injuries due to a fall, and one was for observation of an infant who had stopped breathing for unspecified reasons.
- Twenty-seven were treated and released from EDs. These infants were treated for respiratory problems due to exposure to mold, head injuries (*e.g.*, a skull fracture or a *closed-head injury*[5]) and contusions/bruises from falls or near-falls, and temporary cessation of breathing by infant due to chin-to-chest position while in an inclined sleep product. One infant needed metal shavings fom the product removed from his eye.
- Among the remaining 254 injuries, 151 required treatment for *plagiocephaly* (flat head syndrome), *torticollis* (twisted neck syndrome), or both conditions, which were associated with the use of the inclined sleep product; 90 were treated for mostly respiratory issues and some skin problems associated with mold on the product; seven infants suffered minor bumps/bruises/lacerations due to falls or near-falls; three suffered a combination of respiratory problems along with flat head syndrome or fall injuries. Finally, there was one eye-burn injury, one thermal burn due to electrical overheating, and one abnormal back curvature condition attributed to the use of an inclined sleep product.

The remaining 342 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, similar to those reported in the incident data.

[5] According to staff from the Directorate for Health Sciences, a closed-head injury is a head injury where the skull remained intact, but the injury could range in severity from a minor bump to a severe life-threatening traumatic brain injury.

III. Hazard Patterns

CPSC staff considered all 657 reported incidents (14 fatal and 643 nonfatal) to identify hazard patterns associated with infant inclined sleep products. As indicated in the Introduction section, ASTM F3118-17 includes a variety of products. Some, like hammocks, are suspended in air. Although other seat-like products are meant to be placed on a level floor, incident reports indicate that often they were not. Yet others sit as attachments on larger nursery products. The hazard patterns identified were quite different, depending on which product was involved and how it was used. In order of frequency of incident reports, the hazard patterns were grouped into the following categories:

A. ***Design*** of the infant inclined sleep product: Four hundred and ninety-two of the 657 reported incidents (75 percent) were in this category. Two major issues were identified: infants were reported to have developed respiratory and/or skin ailments due to the growth of mold on the product; infants were also reported to have developed physical deformations, such as *plagiocephaly* (flat head syndrome) and/or *torticollis* (twisted neck syndrome) from extended use of the product. Although no deaths were reported, this category includes 17 hospitalizations and 13 ED visits, all for treating respiratory problems associated with the use of the inclined sleep product. An additional 244 non-hospitalized, non-ED injuries were also reported in this category.

B. Lack of ***structural integrity***: Thirty-six of the 657 incidents (5 percent) reported some sort of failure of the product or its components. These included complaints of buckle/straps breaking, pads/seats/liners tearing, hardware coming loose, and metal stands/bars and other unspecified components breaking. None of the incidents in this category reported any injuries or deaths.

C. ***Inadequate restraints***: Thirty-five of the 657 incidents (5 percent) reportedly occurred when the restraint failed to confine the infant in position. One of the 35 reports also mentioned a mold problem on the product. Two deaths occurred when infants, although restrained, managed to roll over, out of position, and ended up burying their face in nearby soft bedding. Three of the nine injuries in this category, treated in EDs, resulted from a strapped-in infant falling out of the product entirely.

D. ***Electrical*** issues: Twenty-two of the 657 incident reports (3 percent) reported overheating or melting of components, such as the vibrating unit, battery cover, switch, or motor. One thermal burn injury was reported in this category.

E. ***Non-product-related*** or ***unknown*** issues: Eighteen of the 657 incident reports (3 percent) indicated that either the manner in which the product was used led to an incident, or there was not enough information available to determine how the incident occurred. There were 10 fatalities and four injuries in this category. User error contributed to six asphyxiation fatalities; all decedents were left unstrapped and later found in a prone position. Two more fatalities occurred when an infant rolled out of position while in the product; it was unknown if a restraint was used. The circumstances leading to the remaining two fatalities were unknown. Many of these fatalities reported the presence of extra soft bedding in the product. Among the four injuries, two requiring hospitalization, user error was attributed in two cases. Very little information was available for the remaining two injuries.

F. Difficulty with correct ***positioning*** during use: There were 13 reported incidents (2 percent) in this category. Most of the incidents involved hammock-like products, which shifted into a non-level rest position as the infant moved. Two infants ended up trapped in a corner with their face in the fabric/bedding of the product and suffocated. In two other reports, consumers complained of difficulty preventing their infant from getting into a chin-to-chest position; both of these infants, who had stopped breathing, were treated at a hospital ED.

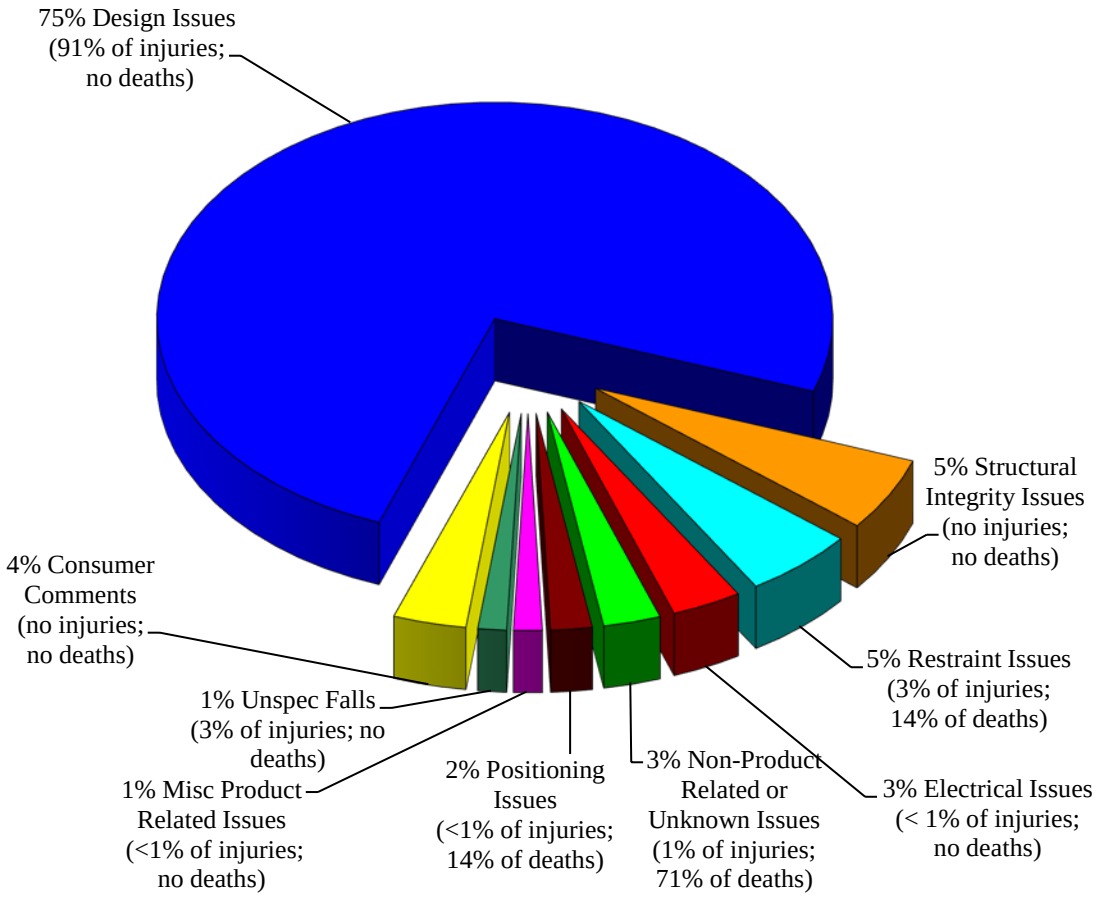
G. ***Miscellaneous product-related*** issues: Nine of the 657 (1 percent) incidents reported a variety of other product-related issues, not listed above. There were complaints of poor finish (metal shavings, sharp edges, a threaded needle left in the product); instability (product while suspended mid-air, flipped over, or product while sitting on floor, tipped over); incomplete packaging (missing parts and instructions); and noxious odor. Two injuries were reported in this category, including one treated and released from a hospital ED.

H. ***Unspecified falls***: Nine of the 657 incidents (1 percent) reported an infant falling from the product but provided very little information on the circumstances leading up to the falls. All of the incidents were reported through hospital EDs and were reports of head injuries (skull fracture or *closed-head injury*) or face contusion. One infant was hospitalized, while others were treated and released.

I. ***Consumer comments***: Twenty-three of the 657 reports (4 percent) fall in this category. The reports consisted of consumer comments/observations of perceived safety hazards or complaints about unauthorized sale of recalled infant inclined sleep products. None of these reports indicated that any incident actually occurred.

The distribution of the 657 reported incidents by the hazard patterns described above are shown in Figure 1.

Figure 1: Distribution of Incident Reports Associated with Infant Inclined Sleep Products by Hazard Pattern Characterizations January 1, 2005 - September 30, 2016



Source: CPSC epidemiological databases CPSRMS and NEISS.
Note: Percentages do not always add to 100 due to rounding.

TAB B: Staff's Review and Evaluation of ASTM F3118-17, *Standard Consumer Safety Specification for Infant Inclined Sleep Products*, for Incorporation by Reference into Staff's Draft Proposed Rule

TAB B

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

Memorandum

Date: March 8, 2017

To: Celestine T. Kish
Infant Inclined Sleep Products Project Manager
Directorate for Engineering Sciences

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

Patricia Adair
Supervisory Program Analyst
Office of Hazard Identification and Reduction

From: Richard McCallion
Mechanical Engineer
Office of Hazard Identification and Reduction

Subject: Staff's Review and Evaluation of ASTM F3118-17, *Standard Consumer Safety Specification for Infant Inclined Sleep Products*, for Incorporation by Reference into Staff's Draft Proposed Rule

I. INTRODUCTION

In accordance with the Danny Keysar Child Product Safety Notification Act (section 104) of the Consumer Product Safety Improvement Act (CPSIA), this memorandum assesses the effectiveness of ASTM F3118, *Standard Consumer Safety Specification for Infant Inclined Sleep Products* (ASTM F3118), and outlines staff's recommendation to incorporate by reference this standard (ASTM F3118-17[1]) into the proposed mandatory rule for infant inclined sleep products.

[1] Current edition approved on January 1, 2017. Published March 2017. This is the second revision to the newly published standard originally published May 2015.

II. PRODUCT DESCRIPTION

An "infant inclined sleep product" is defined in ASTM F3118-17, Section 1.3 as a freestanding product with an inclined sleep surface primarily intended and marketed to provide sleeping accommodations for an infant up to 5 months old or when the infant begins to roll over or pull up on sides, whichever comes first. Additionally, the standard is applicable to: smaller products intended for newborns up to 3 months old, approximately when a newborn begins to wiggle out of position or turn over in the product or weighs more than 15 lb (6.8 kg); and infant and newborn inclined sleep product accessories, which are attached to, or supported by, another product with the same age or abilities, or both, as the freestanding products.

There are many different styles of infant inclined sleep products available for infants and newborns. These can be categorized as hammocks, frame-type (newborn or infant), compact, and inclined sleep product accessory (newborn or infant). Newborn and infant products are generally similar in design, but products intended for use with newborns are required to have a seat back length of 17 inches (432 mm) or less. The types of products within the scope of this standard are described, as follows:

Hammocks

Hammocks are typically constructed of fabric and suspended from one or two points, either above or on either side (Figure 1).

Support from Above

Side Support

Figure 1: Hammock Support

These styles of products are constructed of various materials and generally conform to the shape of the child when placed in the product. However, some hammock designs use a mat, mattress, or other type of pad to provide a semirigid sleeping surface that maintains the product's form (Figure 2). Hammocks are intended to be suspended and can be supported by a frame or other structure, such as a ceiling.

Figure 2: Semi-Rigid Sleep Surface

Frame-Type Inclined Sleep Products

Frame-type inclined sleep products (Figure 3) are elevated, intended to be placed on the floor, and are self-supporting. Typically, these types of design use a metal frame with a rigid or semirigid sleeping surface. The base may be stationary or allow side-to-side rocking. This type of product could have a fixed incline or be adjustable, but it must have at least one position between 10° and 30° angle. Frame-type products can be intended for use by newborns or infants, or both, depending on the size of the product.

Figure 3: Frame-Type Inclined Sleep Product

Compact

Compact-type inclined sleep products (Figure 4) are freestanding, with the bottom of the seat a maximum of 6 inches (152.4 mm) above the floor. These products tend to be constructed of foam, with a fixed seat back angle between 10° and 30°. These products are intended to be used on the floor.

Figure 4: Compact Inclined Sleep Product

Inclined Sleep Product Accessories

Inclined sleep product accessories are intended to provide sleeping accommodations and are attached to, or supported in some way, by another product (Figure 5). These products can be fixed or adjustable, but they must have at least one seat back position with an angle between 10° and 30°. An inclined sleep accessory intended for a newborn or infant is a rigid-frame product that has a stationary or fixed base, and in some cases, inclined sleep product accessories may be removed and used independently. Products intended for newborn use have a seat back less than 17 inches (432 mm) long.

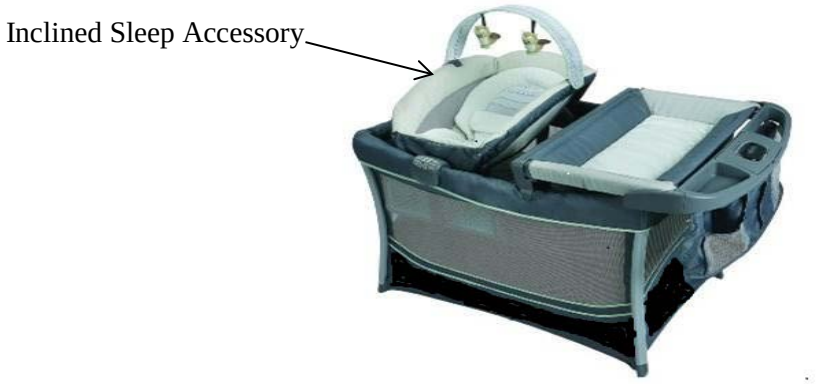


Figure 5: Play Yard with Inclined Sleep Accessory

III. ADEQUACY OF ASTM F3118-17 TO ADDRESS IDENTIFIED HAZARD PATTERNS

CPSC staff identified the hazard patterns and worked with ASTM to develop the performance requirements in ASTM F3118. In the process of working with ASTM on standard development, staff tested multiple samples of infant inclined sleep products of each of the types described in the product description section of this memorandum. This included testing products that are no longer available for sale or not available for sale in the United States. This was done for comparison with currently available product designs to create an effective standard. Each of the samples tested was subjected to all of the applicable performance requirements of ASTM F3118-17.[2]

CPSC staff identified 657 incidents, including 14 deaths, related to the use of inclined sleep products. Incident data from the CPSC databases were the basis for the development of ASTM F3118, with CPSC staff's support throughout the process. The new standard contains performance requirements to address many of the hazard patterns identified. These include: performance requirements for stability, folding, restraints, side height, containment, mesh/fabric, side to side containment, incline, seat back length, stability, and structural integrity. These are in addition to the general requirements that are typically

[2] At the time testing was performed, ASTM F3118-15 was the current version. However, the performance requirements are the same in the ASTM F3118-17 version.

included with most juvenile product standards. Each of the hazard patterns identified, and staff's assessment of the adequacy of ASTM F3118-17 as it relates to each hazard pattern, is discussed below.

A. Design

There were 492 incidents involving the two issues associated with this hazard category. Those issues are mold on the product and development of plagiocephaly (flat head syndrome) and/or torticollis (twisted neck syndrome). There are no performance requirements included in ASTM F3118-17 to address these incidents. Staff has reviewed the reports and does not recommend the inclusion of any performance-related requirements because they are not addressable with performance standards. The health effects related to these issues are addressed in the Directorate for Health Sciences staff's memorandum.

B. Inadequate Restraints

Thirty-five incidents involving restraints that failed to adequately restrain the child in the product were reported. This included two deaths resulting from the child repositioning in the product while restrained. Nine injuries were reported, with three resulting from falls from the product. This standard does not require the inclusion of any type of restraint system. However, for products that do include restraints, performance requirements are included to address their operation and function.

Section 6.3 of ASTM F3118-17 requires inclined sleep products that include restraints to meet the following requirements: (1) that the anchor points be subjected to a 35 lb (156 N) load test and not break or separate, and (2) the inclined sleep product must include both a waist and crotch restraint, such that the crotch component use is mandatory when the restraint is used. Shoulder straps are not to be included. Although no provisions in the performance requirements address the actual use of the restraint, ASTM F3118 contains labeling requirements regarding proper use. See the Division of Human Factors memorandum for more information regarding labeling requirements.

C. Structural Integrity

Structural failure of the product was reported in 36 incidents. There were no deaths or injuries associated with structural failures. The majority of failures were the result of loose hardware, frame component failures, or other unspecified components breaking. ASTM F3118-17 includes requirements for evaluating structural integrity. Both static and dynamic load tests are to be performed sequentially. Dynamic load testing consists of dropping an 18 lb (8.2 kg) shot bag onto a 6 x 6 x ¾ in (150 x 150 x 19 mm) wood block. The block is positioned at the seat bight of the product, and the shot bag is dropped from a height of 1 in (25.4 mm) a total of 50 times onto the block. The static test requires the use of a 50 lb (22.7 kg) weight or a weight equivalent to three times the maximum manufacturer's recommended user weight, whichever is greater. The weight is then placed on the wood block. Any breakage of seams, materials, or changes in adjustments that could affect the product's ability to support the child is considered a failure. These tests address structural integrity in a similar manner to other ASTM juvenile product standards, and after

evaluation by staff, they have been determined to address satisfactorily the types of incidents that have been identified for inclined sleep products.

D. Positioning

Almost all positioning incidents are related to hammocks suspended from above or from the sides, whose sleeping surfaces shift with the movement or placement of the child. CPSC has reports of 13 incidents, including two deaths. Incidents resulted from children being placed into an unsafe chin-to-chest position or from product shift that led to an unsafe non-level lateral sleep surface incline.

Traditional hammock designs that are constructed of fabric and have a sleep surface that conforms to the child's body are typically associated with the chin-to-chest positioning incidents. In these types of products, initial placement of the child determines the incline angle. Initially placing the child in the product off center can result in a child being at a large incline angle in the head-to-foot or foot-to-head orientation. In either case, it is possible that a child's head could be forced downward toward the chest. In traditional, fabric hammocks, placement of the child is the cause of the incidents, and that is considered a human factors issue that cannot be addressed by testing and performance requirements.

A non-level rest position typically occurs in hammocks with semirigid or rigid bases, such as hammocks with a pad or mattress. In these cases, the child shifts position, and the sleep surface shifts, sometimes creating a "V-shaped" angle between the sleep surface and the side material that entraps the child between the side and the soft sleep surface. Both deaths involving this inclined sleep product resulted in a similar scenario in a product that has been recalled. Multiple factors can contribute to these types of incidents, such as the design of the support structure, which can lead to the instability of the sleep surface. This includes the fabric or material used on the side, and the inclusion of a pad or mattress. Because the factors involved in these incidents are complex and not easily addressable, ASTM F3118-17, at this time, does not include specific performance requirements to directly address this scenario. However, instability is evaluated in section 6.1 with a performance test, although its intent is to address incidents such as siblings pulling on the side and tipping the inclined sleep product. A 23-lb (10.4 kg) vertical load is placed at the most onerous position along the upper side surface, with an additional 5 lb (22 N) horizontal load. This testing is done while a newborn CAMI dummy is located in the center of the product. The product fails if it tips over during the test. This test could be used as a basis to develop a performance requirement to evaluate the sleep surface angle in these types of products. However, at this time, staff believes that this hazard was limited to the product that was recalled. Staff will work with ASTM, as necessary, to develop additional performance requirements, and staff seeks comments on potential performance requirements to address this scenario.

E. Miscellaneous Product-Related

Incidents in this category included rough finishes, sharp edges, stray objects in packaging, incomplete packaging, noxious odors, and instability. There were nine incidents in this category. Stray objects,

incomplete packaging, missing parts, and unpleasant odors are considered manufacturing quality-control issues, not safety standards issues, which are outside the scope of the rulemaking, and therefore, not addressed here.

Rough finish and sharp edges and points are included in the general requirements of ASTM F3118-17. These include:

- Requirements that inclined sleep products shall meet 16 C.F.R. part 1303 for lead in paint;
- Requirements for small parts and edges in 16 C.F.R. § 1500.48-49 and 16 C.F.R. part 1501;
- Requirement that all wood parts shall be smooth and free of splinters;
- Requirement that products are designed to prevent injury from scissoring, shearing, and pinching;
- Requirements setting minimum and maximum openings dimensions to prevent finger entrapments; Requirement to cover any accessible coil springs;
- Requirements protecting against inadvertent removal of graspable items; and
- Requirements for toys or mobile requirements in ASTM F963.

ASTM F3118-17 includes performance requirements for the stability of infant, newborn, and compact inclined sleep products. Compact products are tested on a 20° surface; with an infant-size CAMI dummy placed in the product; the product must not tip. Infant and newborn inclined sleep products are tested on a flat surface. A 23-lb (10.4 kg) vertical load is placed at the most onerous position along the upper side surface with an additional 5-lb (22 N) horizontal load. This is done with a newborn CAMI dummy placed in the center of the product. The product fails if it tips over during the test. Staff evaluated these requirements and determined that the requirements adequately address instability incidents.

F. Non-Product-Related

This category includes incidents in which the product was placed in hazardous locations (for example, a crib), or incidents lacking sufficient information to categorize. There were a total of 18 incidents, including 10 deaths. Of these incidents, one was related to a fall due to misassembly, and a second had no information available. The remaining incidents, including three deaths, were related to children rolling out of position and partially exiting the inclined sleep product. Placement of the product in a hazardous location, such as a crib, during use, was a contributing factor in some of the deaths. Incidents of this type are not completely addressable by product design; however, the standard's performance requirements, discussed below, are intended to reduce the risk of injury in the types of incidents included in this category.

Sections 6.3-6.7 of F3118-17 address the containment of the child in the product with the use of restraints, if provided, and with the requirements for side-to-side containment, side height, and head, foot, and side containment. The side-to-side surface containment requirement was developed to address incidents involving a child in an inclined sleep product with a semirigid sleep surface. The intent of this test is to limit the side-to-side movement of the child and eliminate the possibility of the child rotating into an unsafe position in the seat. For example, one of the fatalities occurred after a child was left unrestrained and was

found with their face buried into the side of the inclined sleep product. The side-to-side provision tests the geometry of the seating area of the product. In this test, the hinged weight gage (infant or newborn depending on the product) may not be rotated more than 30° from the centerline of the long axis of the inclined sleep product with the application of a 60 in-lb (6.8 Nm) of torque. This was specially developed to address these particular types of incidents. Staff is not aware of a similar test in other juvenile product performance standards. There is no research or detailed information available to determine the optimum width or dimensions of the sleep surface to prevent the child from maneuvering into a potentially unsafe position. Consequently, this requirement was developed using product design information, incident information, and the experience and technical expertise of the ASTM subcommittee. ASTM, with CPSC staff's support, will evaluate the effectiveness over time. However, staff believes that this requirement will reduce the risk of injuries to children in inclined sleep products.

A minimum side height requirement is included to reduce the possibility of a child getting over the side of the product and becoming entrapped between the product and another object. The side- and end-containment tests use a 5 lb (2.3 kg) sphere to check the containment of the respective sides of the inclined sleep product. The sphere must not fall from the product when placed inside.

G. Electrical

Since CPSC staff has been monitoring incident data, electrical incidents have gone from 1% to 3% of the total incidents. There were 22 reports of electrical-related issues, such as overheating or melting components, and one thermal burn injury reported. Some inclined sleep products have accessories that provide music, rocking motion, or vibration, which are either battery or a/c powered, however, the current F3118-17 does not include any performance requirements for electrical components. Other juvenile products that have similar features include performance requirements that would apply for inclined sleep products. CPSC staff has raised this issue with and will work with ASTM to develop performance requirements to address any electrical hazards, and we seek comments on effective requirements to consider, but are not recommending adding reuirements in this proposed NPR.

H. Unspecified Falls

There were 9 reports of falls from the product, with little detail on what led to the injury. Without details, it is unclear how the incident occurred, or if it would be addressable by any performance standard. However, the new ASTM standard includes stability and containment requirements (described in earlier sections) that address known hazard patterns that could result in falls. The standard also contains an unintentional folding requirement for products that do not have latching mechanisms to keep the product from inadvertently folding. There are also provisions to test inclined sleep products with single- or double-action release mechanisms. A 20 lb (89 N) force is applied in the direction of folding, with the CAMI dummy in the center of the product, for designs without a latching or locking device. One product designed with a single-action locking or latching device is subject to a 10-lb. (45 N) force in a similar manner. Products with a

double-action latching or locking device are tested by performing the first release action with a hinged weight gage inside.

I. Consumer Comments

The last category contained 23 reports from consumers about perceived product hazards that were not the result of incidents. Staff reviewed the reports and determined that the information did not describe a hazardous situation or a situation that is not already addressed in the ASTM standard. Based on this evaluation, staff believes no action is required to address these reports at this time.

J. *Miscellaneous Changes to ASTM F3118-17*

ASTM developed F3118 as a new standard, with CPSC staff's involvement, as a result of the emerging popularity and availability of inclined sleep products and the lack of a specific standard to address the product-specific hazards associated with these types of products. ASTM F3118-17 is the third revision. Section 3.1.1 added a new definition for "accessory inclined sleep product," for rigid-frame sleep products that attach to another product. Additionally, the seat back measurement section was changed from seat back to usable seat back, and more descriptive information is provided regarding how to measure. Figure 13 was updated to reflect the seat back measurement better. Other typographical and editorial edits were made to the standard that do not affect the performance of the product.

IV. OTHER STANDARDS

There are other standards that include infant inclined sleep products within their scope but are primarily intended to address hazards associated with products with flat sleeping surfaces, such as bassinets and cradles. These international standards include: the Cribs, Cradles, and Bassinets regulation in the Canada Consumer Product Safety Act; the European standard, SS-EN 1130 Furniture, Cribs, and Cradles Safety Requirements; and the Australian standards, AS/NZS 4385 Infants' rocking cradles --Safety requirements.

The Canadian regulation has similar requirements to ASTM F3118, such as warnings, labels, and general performance requirements (lead content, small parts, openings). This regulation has additional requirements that are not all applicable to inclined sleep products, including slat strength, mesh material, structural integrity, and mattress supports. Staff determined that this regulation provides similar performance requirements, but does not provide the comprehensive product assessment of the hazards specific to inclined sleep products identified in CPSC incident data.

EN 1130 includes bassinets and cradles and only includes inclined sleep products with a body and frame. They would not include hammocks or similar products that are suspended from ceilings or other structures. This standard includes requirements for construction and materials similar to the general ASTM F3118 requirements. Additional requirements include labeling, use instructions, packaging, and stability. This standard is primarily intended to address hazards associated with bassinets and cradles and not the unique

hazards associated with inclined sleep products. Staff believes that the ASTM standard is more inclusive, covering all hammock styles, and staff finds that the standard provides a more comprehensive assessment of the potential hazards associated with inclined sleep products.

AS/NZS 4385 is intended for rocking cradles that swing, rock, or tilt, but the standard specifically excludes hammocks that do not have this feature. It is unclear if tilt means incline, thereby including inclined sleep products, as defined in ASTM F3118. This standard contains requirements for construction, toxicology, and flammability. There are also other general provisions, including provisions for toys. This standard has some similar performance requirements, but this standard is not considered to be as comprehensive as ASTM F3118 in assessing the potential hazards associated with infant inclined sleep products.

V. RECOMMENDATIONS

Staff recommends that the Commission publish a draft notice of proposed rulemaking (NPR) that incorporates by reference the requirements contained in ASTM F3118-17 as the mandatory safety standard for infant inclined sleep products, with the new definition for accessories, as discussed in the briefing memorandum. ASTM F3118-17 is a standard that was developed with CPSC staff participation and includes performance requirements that provide sufficient methods of assessing the addressable hazards that have been identified in CPSC incident data. Staff believes this draft NPR would address incidents and reduce the number of injuries and deaths from infant inclined sleep products.

TAB C: Human Health Effects of Exposure to Mold

TAB C

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

Memorandum

Date: December 19, 2016

TO : Celestine T. Kish, MA, Infant Inclined Sleep Products Project Manager, Division of Human Factors, Directorate for Engineering Sciences

THROUGH: Alice M. Thaler, DVM, Associate Executive Director for Health Sciences
Michael A. Babich, Ph.D., Director, Division of Toxicology & Risk Assessment

FROM : Eric Hooker, MS, DABT, Toxicologist, Division of Toxicology & Risk Assessment

SUBJECT : Human Health Effects of Exposure to Mold

Purpose

Section 104 of the Consumer Product Safety Improvement Act (CPSIA) directs CPSC to study and develop safety standards for durable infant and children's products. In support of standards regarding a subset of these products, inclined sleep products, and in response to reports of mold in a particular model of inclined sleep products, the Directorate for Health Sciences provides a summary of the health effects of mold in infants and young children.

Background

The concern about mold in inclined sleep products arose from reports of mold in a particular model of inclined sleep product, which consists of an elevated rocking seat intended for newborn infants up to 6 months of age. The seat is inclined and has a plastic insert within its fabric and mesh seat sling to provide support to the infant. A separate, removable, machine-washable soft pad is provided for the seat. Between January 1, 2005 and September 30, 2016, the CPSC received 17 reports of hospitalizations of infants for respiratory problems suffered due to mold on the sleep product; an additional 90 infants were treated for mostly respiratory and some skin problems associated with mold on the product (CPSC, 2016). The manufacturer received at least 600 reports of mold on the product. Mold developed between the removable seat cushion and the hard plastic frame of the sleeper when it remained wet/moist or was cleaned infrequently. Although mold was not present at the time of purchase, mold growth occurred after use of the product. Reports of infants being treated for respiratory issues, coughs, and hives after sleeping in the product led to a recall of the inclined sleep product on January 8, 2013 (CPSC, 2013).

This memorandum provides a brief summary of the human health effects of inhalation and dermal exposure to molds. Information resources on the health effects of mold reviewed to draft this memorandum include published and unpublished studies identified in online searches of literature databases (*e.g.*, PubMed,

TOXNET, Google Scholar). In addition, the CPSC recently contracted with Toxicology Excellence for Risk Assessment (TERA) to draft a review report that would help staff gain a better understanding of the human hazards of mold exposure, as well as the basic biology and characteristics of common mold species. The report titled, "Review of the Health Risks of Mold, Basic Mold Characteristics," was submitted to the CPSC in June 2015.[1]

Overview of Mold

Molds are organisms of the kingdom Fungi that grow in the form of multicellular filaments called hyphae. No one knows how many species of fungi exist, but estimates range from tens of thousands to perhaps three-hundred thousand or more [Centers for Disease Control and Prevention (CDC), 2014]. Molds can be found in both indoor and outdoor environments. Many molds are ubiquitous in the environment, but location of growth generally depends on the qualities of their immediate environment. Fungi are heterotrophic, meaning they require organic carbon from an external source for nutrition. Molds meet this requirement by embedding into their food source and are capable of metabolizing complex carbohydrates (*e.g.*, lignin – a component of wood). Although molds are commonly associated with damp conditions, many species can grow on substrates with very low moisture content (TERA, 2015).

Identification of molds can be challenging [Institute of Medicine (IOM), 2004; World Health Organization (WHO), 2009]. Molds can sometimes be identified based on the differences in the macroscopic physical characteristics, such as colonial form, surface color, pigmentation, and growth rate (Brandt and Warnock, 2011). The specific types of mold found in the mold incident inclined sleep products have not been identified. However, commonly occurring molds include species of the following genera (TERA, 2015; Integrated Taxonomic Information System):[2] *Alternaria* (461 species), *Aspergillus* (362 species), *Chaetomium* (239 species), *Cladosporium* (258 species), *Dicyma* (9 species), *Epicoccum* (41 species), *Malassezia* (17 species), *Penicillium* (352 species), *Phoma* (980 species), *Stachybotrys* (69 species), and *Rhizopus* (73 species).

Health Effects Associated with Human Exposure to Mold

Authoritative reviews of the health effects of molds are most commonly in the context of indoor air quality in buildings, such as homes or office buildings [United States Environmental Protection Agency (US EPA), 2016; WHO, 2009; IOM, 2004; CDC, 2014]. Other reviews describe mold as a contaminant in dietary sources (Reddy et al., 2010). Very little information is available in the literature describing the health hazards of molds in consumer products.

Exposure to molds or mold components occurs by inhalation, dermal contact, and ingestion. Mold exposure has been associated with a variety of health effects, including irritant and allergic reactions. The four types of mechanisms by which molds can produce human illness are immunologic reactions (sensitization and asthma), toxicity (from mycotoxins), infection, and irritation (Seltzer and Fedoruk, 2007; Moore et al., 2011). Table 1 summarizes the health effects of several genera of commonly occurring molds (TERA, 2015).

[1] The TERA (2015) report is available online at: http://www.cpsc.gov/Global/Research-and-Statistics/Technical-Reports/Chemical/CPSCStatementBasiMoldCharaceristicsJune2015.pdf.
[2] Integrated Taxonomic Information System (http://www.itis.gov/).

Sensitization and Asthma

Sensitization

Exposure to proteins or other antigens in mold spores can produce an immune response in susceptible individuals. Approximately 10 percent of the population are believed to have immunoglobulin E (IgE) antibodies to common inhalant molds (Homer et al., 2005); and about 5 percent of the population are predicted to have had allergic symptoms as a consequence of exposure to fungus-related allergens (ACOEM, 2002; Bush et al., 2006). Exposure to molds by sensitized people can cause symptoms such as nasal stuffiness, eye irritation, wheezing, or skin irritation. Those with serious allergies to molds may have more severe reactions, including fever and shortness of breath (CDC, 2014). Cross-reactivity across mold species and genera is known to occur (Horner et al., 1995)

Hypersensitivity pneumonitis (HP), or allergic alveolitis, is an inflammation of the alveoli within the lungs, caused by exposure to an allergen to which the individual is sensitized. It is characterized by flu-like symptoms, coughing, and temporary chest tightness. Breathing may become difficult because the alveoli become inflamed and may fill with fluid. HP has been associated with inhalation of *Aspergillus*, *Epicoccum, Penicillium,* and *Phoma* in adults and children (Binder and Lass-Florl, 2013; Government Accountability Office, 2008; Klich, 2009; Mazur and Kim, 2006; Seltzer and Fedoruk, 2007; do Pico, 1976; Metzger et al., 2010; Moran et al., 2002).

Asthma

Asthma is a major noncommunicable disease characterized by recurrent attacks of breathlessness and wheezing, which can vary in severity and frequency (WHO, 2013). During an asthma attack, the lining of the bronchial tubes becomes inflamed and narrows the airways, reducing the flow of air into and out of the lungs. Asthma is a common disease among children. The causes of asthma are not well understood but are thought to include a combination of genetic predisposition and environmental exposure to allergens, such as molds (WHO, 2013).

Epidemiology studies have identified an increase in mold-related allergy and asthma in adults and children exposed to airborne fungi in home or school environments (TERA, 2015; Meng et al., 2012; Portnoy et al., 2005). Molds of several genera have been associated with asthma attacks in sensitive adults and children (TERA, 2015). Eighty percent of individuals in the United States with confirmed asthma have a positive allergic reaction to *Alternaria* (Nasser and Pulimood, 2009). Perzanowski et al. (1998) reported that sensitization to *Alternaria* correlated with asthma in school-aged children. Sensitization to *Cladosporium* was an important determinant in increased risks of mild, moderate, or severe persistent asthma in a study of 10,000 human subjects (Cazzoletti et al., 2009). *Cladosporium* sensitization was found to develop in children by the age of 4 and was correlated with a diagnosis of asthma (Tariq et al., 1996). *Cladosporium, Penicillium, and Aspergillus* were found in homes with asthmatic children, more often than homes without an asthmatic child (Meng et al., 2012). Allergic reactions to *Malassezia* are associated with increased asthma symptoms and severity, increased asthma risk, and even death (TERA, 2015). *Penicillium* and other mold exposures were associated with increased risk for developing both allergic symptoms and asthma among infants (1 to 12 months of age) and children (Gent et al., 2002). Epidemiology studies have identified an increase in allergic rhinitis, asthma, and asthma-like symptoms (*e.g.*, wheezing and long-term cough) among children exposed to home or school environments with moisture problems; at least some of these asthma cases were suspected to be caused by *Phoma* species of molds (Tarlo et al., 1988; Taskinen et al., 1997).

Reponen et al. (2011), reported that children with a high exposure to mixed mold species at 1 year of age had more than twice the risk of having asthma at 7 years of age than children with low exposures at their

first year. Three-year-old children exposed to high amounts of visible mold in the home during infancy were seven times more likely to have a positive Asthma Predictive Index[3] than those with no visible household mold (Iossifova et al., 2009).

Infection

Mycosis is an infection caused by a fungus such as mold. Many fungal infections occur secondary to another illness or injury, especially one that compromises the immune system; these are called "opportunistic infections" (TERA, 2015). It is uncommon for a fungal infection to progress in a healthy immunocompetent person, but it is possible (López-Martinez et al., 1999; Lyratzopoulos et al., 2002). The most common infections by molds are cutaneous and subcutaneous skin infections, which are characterized by erythema, desquamation of the skin, red papules and ulceration (TERA, 2015). Oculomycosis (fungal infections of the eye), onychomycosis (fungal infections of the nails), otomycosis (fungal infection of the ear canals) and invasive and non-invasive rhinosinusitis are other examples of infection of human tissues by mold species (Pastor and Guarro, 2008; TERA, 2015). Invasive fungal infections of mold species in internal organs, such as the lung, brain, and myocardium have been reported in organ transplant patients and drug abusers (TERA, 2015; Barron et al., 2003; Anandi et al., 1989; Abbott et al., 1995).

A large body of literature is available on infections of *Aspergillus* species in human tissues. *Aspergillus* spores can colonize the airways, nose, sinuses (sinusitis), skin, ear canals, and nails (onychomycosis) and persist as superficial infections without progressing to invasive infection (TERA, 2015; Aznar et al., 1989; Binder and Lass-Florl, 2013; De Lucca, 2007; Versalovic et al., 2011). *Aspergillus* species can also cause corneal infections following ocular injury with subsequent contamination to the mold (De Lucca, 2007). Aspergilloma (chronic mycetoma) is a generally benign ball of *Aspergillus* (Binder and Lass-Florl, 2013; Kilch, 2009) and is found in the lungs of people with pre-existing damage to the lung (*e.g.*, tuberculosis infection or fungal sinusitis). Invasive asperillosis (IA) is an opportunistic mold infection that occurs primarily in the respiratory tract, particularly amongst immunocompromised persons and those with chronic granulomatous disease, an inherited immunodeficiency (TERA, 2015; Ascioglu et al., 2002; Ben-Ami et al., 2010; Binder and Lass-Florl, 2013; Brakhage, 2005; De Lucca, 2007; De Pauw et al., 2008; GAO, 2008; Hope et al., 2005; Klich, 2009; Versalovic et al., 2011).

Mycotoxins

Mycotoxins are toxic compounds that can be produced by certain mold species and can affect many of the body's biological systems. Many mycotoxins are secondary metabolites of fungi, meaning they are not required for the organism's survival (Gallup, 2006; Fox and Howlett, 2014). They are produced under suboptimal conditions for the fungus, such as when nutrients are limited. Some mycotoxins are only produced under very specific environmental conditions, such as temperature, humidity, and maturity of the fungus. Therefore, the mere presence of a particular type of mold does not guarantee the production of mycotoxins associated with that genus or species (Gallup, 2006). Additionally, some mycotoxins can persist in an area after the producing fungi are no longer present (McGinnis, 2004). Many mycotoxins, such as aflatoxin B1, cyclosporine, and ochratoxin A, are known or suspected to be human carcinogens [International Agency for Research on Cancer (IARC), 2012, National Toxicology Program (NTP), 2014]. Mycotoxins are also known to affect target tissues such as the liver, kidneys, and nervous and immune systems, and adverse effects can be acute or chronic. Some mycotoxins may affect human reproduction and development (TERA, 2015). The current memorandum is not intended to provide an extensive review of

[3] The Asthma Predictive Index is a guide to determining which small children will likely have asthma in later years (Castro-Rodriguez, 2010).

individual mycotoxins and their health effects; reviews are available if this information is required (IARC, 2012; TERA, 2015; Robbins et al., 2000; Wild and Gong, 2010).

Human data suggest that children are more vulnerable than adults are to acute hepatotoxicity resulting from ingestion of aflatoxin (IARC 2002). There is some evidence for adverse health effects to humans in occupational environments, where the exposure to mycotoxins is high. However, the available evidence and research regarding adverse health effects due to inhalation of mycotoxins support the hypothesis that the risk is low in normal residential and office environments because the concentrations in inhalable air are too low (Gallup 2006).

There is little information on dermal absorption of mycotoxins by direct contact with human skin, but the available data indicate that some mycotoxins can penetrate human skin. A recent study found that aflatoxin B1, ochratoxin A, citrinin, zearalenone and T-2 toxin were able to penetrate human skin in an *in vitro* system, but fumonisin B1 did not (Boonen et al., 2012). For those mycotoxins that penetrated human skin, the permeability rates were relatively low, and except for aflatoxin B1, no significant health risk was calculated in agricultural or residential exposure scenarios (Boonen et al., 2012). *In vitro* and *in vivo* dermal penetration studies of T-2 toxin showed that the vehicle in which the mycotoxin is delivered can affect the permeability rates (Kemppainen et al., 1987a; Kemppainen et al., 1987b).

Irritation

Irritation differs from sensitization, or an allergic response, in that irritation does not require an immune response. Irritation occurs when contact with a substance has a direct adverse effect on the tissue(s) with which it makes contact. Tissues typically affected by irritants include the skin, conjunctiva, and respiratory tract (Jackson, 1996).

Irritation associated with molds has been studied less than the health effects described above. Microbial volatile organic compounds (MVOCs) have been identified as possible causes of some of the adverse health effects attributed to mold exposure (Seltzer and Fedoruk, 2007). MVOCs include low-molecular-weight alcohols, aldehydes, and ketones produced as products of metabolism by molds. Irritant effects attributed to these compounds include discomfort, paresthesias, itching, burning, and skin sensitivity (McGinnis, 2004). The musty, disagreeable odor associated with mold growth is due to the MVOCs geosmin and 2-methyl-isoborneol (McGinnis, 2004).

Summary

Molds are ubiquitous in the environment and can grow in many places where they have access to moisture and nutrients. The CPSC received at least 107 reports of infants treated for respiratory and skin problems associated with mold after using inclined sleep products in which mold developed between the removable seat cushion and the hard plastic frame. The four types of mechanisms by which molds can produce human illness are: (1) immunologic reactions, which can produce allergic responses and/or asthma attacks in susceptible individuals; (2) local or systemic toxicity from mycotoxins; (3) mycoses of certain tissues, usually as an opportunistic infection in a person with another health complication; and (4) irritation, possibly from MVOCs released by molds. Many studies show that very young children can be especially susceptible to health complications by various mold types. Full maturation of the lungs does not occur until 6 to 8 years of age; and maturation of the immune system is not complete until puberty. Therefore, infants who use an inclined sleep product that is known to develop visible mold are at risk of developing health effects, such as allergies, asthma, mycosis, and effects of mycotoxins.

Table 1. Summary of Key Health Effects by Selected Organisms, Based on Animal and Human Data[a]

Genus	Growth Locations	Allergy or Asthma	Opportunistic Infection	Mycotoxin Target Tissues	Cancer Concern
Alternaria	Ubiquitous	Yes	Yes	Inadequate data	Inadequate data
Aspergillus	Ubiquitous	Yes	Yes	Liver, kidney, immune, neuro, repro	Yes
Chaetomium	Affinity to cellulose	No	Yes	Inadequate data; Possible liver, immune, developmental effects	Inadequate data
Cladosporium	Affinity to cellulose; *Not* on plastics	Yes	Yes	No mycotoxins	No
Dicyma	Organic materials	No data	Yes	No mycotoxins	No data
Epicoccum	Fruit and Vegetables; Clay materials; Quartz	Suggested	Yes	No mycotoxins	No
Malassezia	Skin (healthy and diseased)	Yes	Yes	No mycotoxins	No
Penicillium	Food; Affinity to cellulose; *Not* on plastics	Yes	Yes	Kidney, liver, immune, neuro, repro, developmental	Yes
Phoma	Cruciferous vegetables; Asbestos, cement, oil-paint, plaster, crockery	Yes	Yes	Inadequate data	Inadequate data
Stachybotrys	Affinity to cellulose; may be present on plastics.	No clear evidence	No	Immune, kidney, liver, respiratory	Yes
Rhizopus	Ubiquitous on organic surfaces	No	Yes	No mycotoxins	No

a. Table compiled from data presented in TERA, 2015.

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TAB D: Directorate for Health Sciences response to consumer complaints that the sleep product caused plagiocephaly (flat head syndrome), and torticollis (twisted neck syndrome) or both conditions.

TAB D

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

Date: January 30, 2017

TO : Celestine T. Kish, MA, Infant Inclined Sleep Products Project Manager,
Division of Human Factors, Directorate for Engineering Sciences

THROUGH: Alice Thaler, D.V.M., MS Bioethics, Associate Executive Director
Directorate for Health Sciences
Jacqueline Ferrante, Ph.D., Division Director
Division of Pharmacology and Physiology
Directorate for Health Sciences

FROM : Suad Wanna-Nakamura Ph.D., Physiologist
Division of Pharmacology and Physiology
Directorate for Health Sciences

SUBJECT : Directorate for Health Sciences response to consumer complaints that the sleep product caused plagiocephaly (flat head syndrome), and torticollis (twisted neck syndrome) or both conditions.

I. BACKGROUND

CPSC incident data indicate that some parents believe use of an inclined sleep product caused plagiocephaly (flat head syndrome) and torticollis (a term used to describe the tilting/rotation of an infant's head to one side). Parents also expressed concerns that these morphological changes can have lasting effects on the child's appearance and might have lasting effects on normal development. In this memorandum, Health Sciences (HS) staff describes the various underlying causes of "flattened heads" in infants, and explains that the recent increased incidence of post-natal flattening of infant's head is not unique to inclined sleep products, and also explains that the post-natal head flattening associated with infant sleep position is unlikely to have any lasting negative impact on mental function and developmental capability.

II. DISCUSION:

A. Etiology of Plagiocephaly:

Plagiocephaly[1] is a term used to describe cranial asymmetry, where one surface of the skull appears flattened. It is commonly applied to describe infants who have a flattened area of their occipital bone,

[1] Plagiocephaly means "oblique head" (Greek origin,'plagios', meaning oblique and 'kephalê' meaning head).

which is the bone located in the lower part of the posterior region of the skull (*i.e.,* at the back of the head). To allow passage through the birth canal during delivery, and allow for brain growth in early childhood, an infant's skull is soft and pliable at birth, and it gradually hardens over the first 4 years of life. Plagiocephaly in infants can result from different causes, and the appropriate treatment may differ significantly according to cause.

***1. Positional Plagiocephaly*:**

Positional plagiocephaly, otherwise known as "*flat head syndrome,*" is a visible flattening of one side of the skull of an infant due to maintained external pressure exerted on the head. It is the also the most common type of cranial asymmetry in infancy. This deformity may be present at birth due to mechanical constraint of fetal movement in the womb during pregnancy, mainly due to intrauterine crowding as in the case of multiple births.[1] For example in twins, the 55.6 percent prevalence of plagiocephaly is more than four times greater than with singletons.[2,3] It may also be the result from the use of vacuum or forceps during assisted deliveries due to the extraneous pressures such measures can have on the infant skull. Plagiocephaly is common in premature infants.

Plagiocephaly may also develop during the first few months following birth,[4, 5] when an infant's skull remains relatively soft and pliable. The cause of post-natal skull deformity or head molding is due primarily to sustained pressure on the back of the head that can occur while the baby is placed in a supine sleeping position. Similar pressure can be exerted on the skull when an infant is placed in a reclined infant carrier/seat. Premature infants are particularly vulnerable because their skull development lags behind a full term infant and therefore have softer skulls for a longer period following birth.

While the incidence of post-natal plagiocephaly is not uncommon, there has been a six-fold increase in the number of reported incidents since the early 1990s.[6-12] Studies have suggested that this may be a consequence of American Association of Pediatrics' (AAP) recommendation in 1992 that infants be put to sleep in the supine (back) rather than prone position. While that recommendation has been credited with a dramatic decline in incidence of Sudden Infant Death Syndrome (SIDS), an unintended consequence is that the positioning of an infant in the supine position overnight places added pressure to the back of the pliable skull, which increases the risk of plagiocephaly.[4,5]

Although the flattened appearance of an infant's head can be alarming to parents, there is no scientific evidence to suggest that positional plagiocephaly interferes with brain development or function. The condition appears to be preventable and reversible when appropriately treated. The only lasting effect is on the physical shape/deformity of the head.[13-27, 34] There are strategies to reduce the development of plagiocephaly that largely involve methods for minimizing the pressures on the skull leading to the deformity. Pediatrician should inform parents of the following possible interventions:

- Varying the position of the sleeping infant's head by turning it to the left or right side[11, 13,26] so that the non-flattened side rests on the sleeping surface (ideally a firm crib mattress).
- Increasing the amount of supervised "tummy time" during the infant's waking hours,[11] which helps strengthen muscles of the upper body, arms, and neck.
- Increasing the time the baby is held by parents/caregivers, which also helps strengthen the baby's neck muscle.
- Physiotherapy and repositioning to help align and attain shoulder girdle strength[27,28] and alleviate discomfort.

- In some cases that do not respond adequately to these interventions, pediatricians may recommend a customized orthotic helmet[15, 19, 31] to help reshape the infant's head.

2. Plagiocephaly due to Craniosynostosis:

Craniosynostosis is a more serious condition where an infant's misshapen head results from premature hardening and fusion of the skull bones'sutures [ossification of fibrous junctions (sutures) separating skull bones].[20, 30-35] This can result in insufficient space to accommodate an infant's growing brain, which has very serious consequences. This type of birth defect is a much less common cause of plagiocephaly, but cannot be self-corrected in response to the behavioral interventions listed above. It requires surgical intervention during the first year of life to avoid devastating consequences. The infant's misshapen skull may be present at birth or could develop during the first few months of life. Therefore, it is extremely important for pediatricians to carefully evaluate infants with plagiocephaly in order to differentiate between the underlying causes as early as possible.[10, 11] Accurate diagnosis is critical for reducing morbidity and optimizing management strategies.

***B. Torticollis*:**

Torticollis[2] (twisted neck) can be present either at birth or it may develop in the first 6 to 8 weeks of life. Muscular torticollis is a musculoskeletal condition characterized by shortening of the *sternocleidomastoid*, [the muscle that extends from the jawbone (mastoid) to the clavicle (collarbone) and sternum (breastbone), on the side of the neck.][34-38] Clinical signs include a head tilt and a strong preference to look to one side.

Torticollis can be congenital or acquired with the former condition being more prevalent. Congenital torticollis is often associated with positional plagiocephaly because both are caused by constraint of head and neck movement. Facial asymmetry is a characteristic feature of congenital torticollis and often used to distinguish it from acquired torticollis. For most babies, stretch exercises and simple changes in how the infant is held or positioned that are aimed at gradually lengthening the muscle should help correct the problem.

Acquired torticollis on the other hand is not a diagnosis but rather a presentation of other underlying illnesses usually either muscular or neurological in nature.[36-38] They can include skeletal abnormalities (abnormal shape of body parts), damage to the spinal cord induced by trauma and malignancies (exerted pressure by tumors in the neck and the base of the skull). Other causes of acquired torticollis include infection ocular and psychiatric disorders. These conditions require specialized treatments.

III. SUMMARY

The development of positional plagiocephaly and torticollis are not exclusively attributable to the use of infant inclined sleep products, and the conditions are not addressable with performance standards. Staff is not recommending any modifications to the voluntary standard to address these issues.

[2] The word torticollis (twisted neck) is derived from the Latin words "torus" means "twisted" and "collum" means "neck."

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TAB E: Human Factors Assessment of ASTM 3118-17 Requirements for Infant Inclined Sleep Products (CPSIA Section 104)

TAB E

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

Memorandum

DATE: March 8, 2017

TO: Celestine T. Kish, Project Manager, Infant Inclined Sleep Products Rulemaking, Division of Human Factors, Directorate for Engineering Sciences

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

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

FROM: Sarah B. Newens, Human Factors Engineer,
Division of Human Factors, Directorate for Engineering Sciences

SUBJECT: Human Factors Assessment of ASTM F3118-17 Requirements for Infant Inclined Sleep Products (CPSIA Section 104)

BACKGROUND

The ASTM International (ASTM) voluntary standard ASTM F3118, *Standard Consumer Safety Specification Infant Inclined Sleep Products*, establishes requirements for infant inclined sleep products (referred to here as inclined products) in the United States, and is intended to minimize the hazards associated with the reasonably foreseeable use and misuse, or abuse, of these products. ASTM developed this voluntary standard in response to incident data supplied by staff of the U.S. Consumer Product Safety Commission (CPSC or Commission). The current published version of the voluntary standard is ASTM F3118-17.

Section 8 of the voluntary standard specifies marking and labeling requirements, which include warning statements that must appear on each inclined product. Section 9 specifies the instructional literature that must be provided with each inclined product. This memorandum, prepared by staff of CPSC's Directorate for Engineering Sciences, Division of Human Factors (ESHF), assesses the adequacy of these sections of the voluntary standard in addressing the risk of injuries and deaths associated with the use of inclined sleep products.

DISCUSSION

PRODUCT

Infant inclined sleep products encompass a wide range of products and several product categories. The voluntary standard was initially created to address infant hammocks, and the scope was expanded to include various infant products meant to provide sleeping accommodations for an infant, such as nappers and inclined sleep products that can be free-standing or supported by another product. The standard addresses infant (0- to approximately 5-months old) and newborn (0- to approximately 3 months old) inclined products, compact inclined products (for newborn and infant), and accessory inclined sleep products (for newborn and infant). A compact inclined product is meant to be used low to the ground; an accessory inclined product is meant to be used within and possibly outside another product (typically, a play yard). (See Tab B of briefing package for more detailed descriptions of inclined sleep products.)

ESHF STAFF REVIEW OF INCIDENT DATA

The hazard patterns outlined by CPSC's Directorate for Epidemiology (EPI) are related to the following categories: design, structural integrity, inadequate restraints, electrical, non-product-related or unknown, positioning, miscellaneous product-related, unspecified falls, and consumer comments. A majority of the incidents were categorized as being related to the design, although no deaths were reported as being related to the design. The reported fatalities were related to inadequate restraints, positioning, and non-product-related/unknown. The fatality victims ranged in age from 2 months old to 8 months old.

The voluntary standard was created to mitigate the risk of injury and fatalities by addressing the hazard patterns. Throughout the standard development and revision process, ESHF staff provided feedback based on the developmental milestones of children intended to use the product. Additionally, the warnings were carefully devised to help inform caretakers of the appropriate age-range of use.

CURRENT ASTM WARNING AND INSTRUCTIONAL REQUIREMENTS

As CPSC implemented CPSIA section 104, promulgating mandatory standards for durable infant or toddler products, several of the subcommittee members associated with the ASTM F15 juvenile product/durable nursery products raised concerns about inconsistency among various durable nursery product rules. For this reason, an ASTM Ad Hoc Wording Task Group (ad hoc task group) was formed to harmonize the wording and language used across nursery product standards. The ad hoc task group consists of members of the various voluntary standards subcommittees affected by the durable nursery products rules. This ad hoc task group also took on the task of developing recommendations for harmonizing warning formats across standards. CPSC staff worked closely with the ad hoc task group to develop recommendations that are based largely on the requirements of the ANSI Z535.4, American National Standard for Product Safety Signs and Labels.

In October 2016, the ad hoc task group published a working document titled, "Ad Hoc Wording

– October 16, 2016." Since then, the juvenile product subcommittees have been balloting incorporation of the formatting recommendations into their standards. In September 2016, new warning format requirements were balloted and accepted by the F15.18 subcommittee for Infant Inclined Sleep Products; the recommendations are reflected in F3118-17.

Section 8, Marking and Labeling of ASTM F3118-17 specifies labeling and warning requirements for inclined sleep products. In short, all inclined sleep products must include warnings on the product about the risk of fall and suffocation hazards. Due to the wide variety of inclined sleep products, the voluntary standard provides eight warning labels for manufacturers to use based on their product(s) design.

The work of the ad hoc task group resulted in permanent, conspicuous, and consistently formatted on-product warning labels across juvenile products. On-product warning labels that meet the requirements in the F3118-17 (see Figure 1) will address numerous warning format issues related to capturing consumer attention, improving readability, and increasing hazard perception and avoidance behavior. Additionally, HF staff believes that the warning adequately informs consumers of the fall and suffocations hazards, consequences of the hazards, and instructions on how to reduce the risks of injury and death due to falls and suffocation.

Figure 1: Sample inclined product warning

Figure 2 illustrates the types of warning labels that currently appear on inclined sleep products. New placement and formatting requirements in F3118-17 will reduce the inconsistencies seen on labeling in the past.

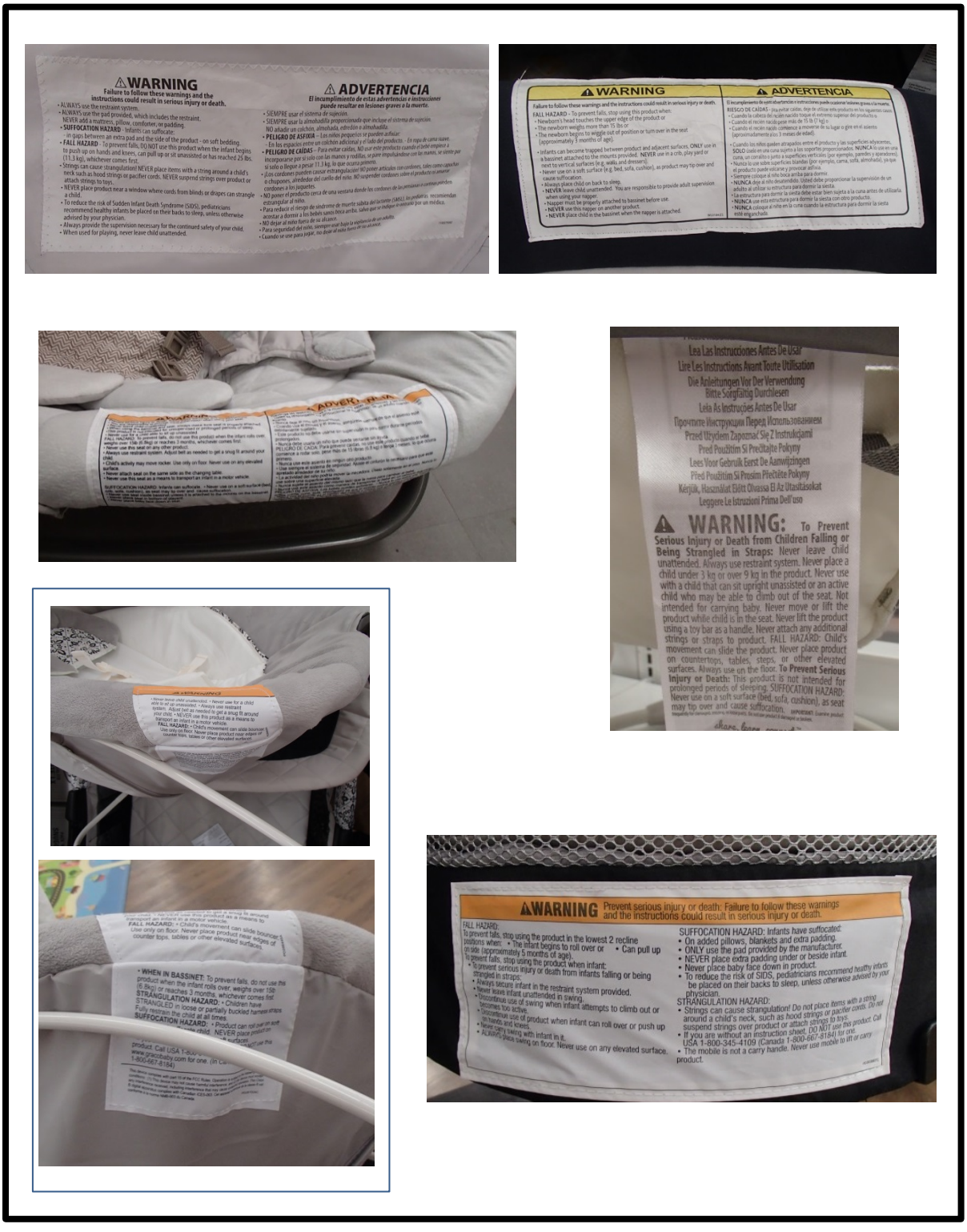

Figure 2. Example of current warning labels on inclined products

Section 9. Instructional Literature specifies that instructions that are easy to read and understand must be provided with the product. The on-product warnings are also required in the instructions.

CONCLUSIONS

With the inclusion of the ad hoc warning requirements that are in the current ASTM inclined sleep product standard, ESHF staff believes that the formatting and context for warning and instructional requirements specified in Sections 8 and 9 of ASTM F3118-17 adequately address the risk of injuries and deaths associated with the use of infant inclined sleep products.

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TAB F: Initial Regulatory Flexibility Analysis of the Staff-Recommended Proposed Standard for Infant Inclined Sleep Products, the Accreditation Requirements for Conformity Assessment Bodies for Testing Conformance to the Infant Inclined Sleep Products Standard, and the Impact of the Product Registration Rule

TAB F

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

Memorandum

Date: March 8, 2017

TO : Celestine T. Kish
Project Manager, Infant Inclined Sleep Products
Division of Human Factors
Directorate for Engineering Sciences

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

Robert L. Franklin
Senior Staff Coordinator
Directorate for Economic Analysis

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

SUBJECT : Initial Regulatory Flexibility Analysis of the Staff-Recommended Proposed Standard for Infant Inclined Sleep Products, the Accreditation Requirements for Conformity Assessment Bodies for Testing Conformance to the Infant Inclined Sleep Products Standard, and the Impact of the Product Registration Rule[1]

I. Introduction

ASTM F3118-17, *Standard Consumer Safety Specification for Infant Inclined Sleep Products*, is the current ASTM International (ASTM) standard for infant inclined sleep products (inclined sleep products or inclined sleepers). Staff recommends that the U.S. Consumer Product Safety Commission (CPSC, or Commission) amend 16 C.F.R. part 1130

[1] Industrial Economics, Incorporated (IEc) served as a consultant on this project, performing research and analysis to support Directorate for Economic Analysis (EC) staff.

to identify infant inclined sleep products as a durable infant or toddler product and issue a proposed rule under the requirements of the Danny Keysar Child Product Safety Notification Act (section 104) of the Consumer Product Safety Improvement Act (CPSIA) that incorporates by reference the most recent ASTM standard for inclined sleep products, with a modification to the definition of an "accessory inclined sleep product."

This memorandum evaluates the potential economic impact of the staff-recommended inclined sleep product standard on small entities, including small businesses, as required by the Regulatory Flexibility Act (RFA).[2] Section 603 of the RFA requires that agencies prepare an initial regulatory flexibility analysis (IRFA) and make it available to the public for comment when the general notice of proposed rulemaking (NPR) is published, unless the head of the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. As explained below, staff cannot rule out a significant economic impact for 10 of the 14 (71 percent) known small suppliers of inclined sleep products to the U.S. market. Accordingly, we have prepared an IRFA and pose several questions for public comment to help us with our assessment.

The IRFA must describe the impact of the proposed rule on small entities and identify significant alternatives that accomplish the statutory objective and minimize any significant economic impact. Specifically, the IRFA must contain:

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

II. The Product

An "infant inclined sleep product," as defined in ASTM F3118-17 has three key components. One, the product is intended for infants up to 5 months old (3 months for smaller products intended for newborns). The product may be intended for older children as well, possibly in a different configuration, but it must also be intended for children up to 5 months old. Two, the product must have at least one inclined sleep surface position that is greater than 10 degrees, but less than or equal to 30 degrees. Three, the product must be intended or marketed to provide sleeping accommodations.

In general, products with adjustable seat back positions that are covered by other mandatory or voluntary standards in the inclined position(s), such as bouncers, rockers,

[2] 5 U.S.C. §§ 601-612.

hand-held carriers, or infant swings, are excluded from the scope of the inclined sleeper standard. The exception is multiuse products that can be put into an inclined sleep product configuration that is specifically marketed for sleep. So, a bouncer that has an inclined position greater than 10° and less than or equal to 30° that is marketed for "sleep" would be covered under both the bouncer standard and the inclined sleeper standard. On the other hand, a bouncer with one or more inclined positions greater than 10° and less than or equal to 30°, none of which are marketed for "sleep," would fall solely under the bouncer standard.

Compact inclined sleep products and inclined sleep product accessories are also included under the ASTM standard. "Inclined sleep product accessories" are inclined sleep products that attach to or are supported by another product. The ASTM standard currently limits inclined sleep product accessories to rigidly framed products, but staff recommends that "rigid framed" be removed from the definition to encompass recently identified soft-sided products that attach to cribs and play yards. "Compact inclined sleep products" are low-to-the-ground free-standing products with "a distance of 6.0 in. (152 mm) or less between the underside of the lowest point on the seat bottom and the support surface (floor)."

The inclined sleep product category includes soft-sided infant hammocks designed to conform to a child's shape and sway naturally with their movement, even if they are *not* marketed to provide sleeping accommodations. Both staff and ASTM consider such products as intended for sleep regardless of how they are marketed. Infant hammocks may be attached to various types of stands or to the ceiling. In some cases, they may also be considered compact inclined sleep products when they are within 6 inches off the ground. Conversely, there are three product categories that would not fall under the inclined sleep product scope even if they had a relevant incline position: mats for children's activity centers/gyms; nursing pillows and positioners; and sleep wedges. Finally, both staff and ASTM consider miniature infant hammocks that are marketed exclusively for use as photographic props (*i.e.*, in photographing newborn babies) to be outside the scope of the standard.

The prices for these products range from $50 for some of the simplest standalone inclined sleep products to $600 for some of the high-end infant-hammock-type inclined sleep products.

The scope of ASTM F3118-17 includes the products described above. However, the ASTM subcommittee recognizes a lack of clarity and is currently working to tighten the language. Staff is working closely with members of the subcommittee on the revised language, but at this time does not recommend any changes to the scope for the NPR. Instead, staff requests comments on the scope of the proposed mandatory standard (*i.e.*, products covered by the standard and those excluded).

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

Section 104 of the CPSIA requires the CPSC to examine and assess the effectiveness of any voluntary consumer product safety standards for durable infant or toddler products and promulgate 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 requirements would further reduce the risk of injury associated with the products. While a number of sleep products are specifically mentioned as a durable infant or toddler product in section 104(f)(2), including cribs and bassinets, inclined sleep products are not.

Until relatively recently, inclined sleep products were not recognized as a distinct product category. In January 2010, a series of fatalities in infant hammocks came to the attention of CPSC staff and staff considered including these products in the bassinets and cradles rulemaking that was being developed at the time. However, bassinets have flat sleep surfaces and it was impossible to make infant hammocks, which are inherently inclined, conform to that standard without fundamentally changing them (i.e., making them flat rather than inclined). Additionally, other inclined sleeping products for infants and toddlers entered the market, making it more effective to address the inclined products together, as a new product type. Therefore, CPSC staff began working with ASTM to develop a voluntary standard that would cover the wide array of products on the market that provide infants and toddlers with inclined sleeping environments. ASTM first published the resulting standard in May 2015. Three revisions have since been published.

CPSC staff recommends adopting the current voluntary ASTM standard for inclined sleep products (F3118-17) with a change to the definition of an "accessory inclined sleep product." Since the original development of the infant inclined sleep products standard, at least two new products have entered the U.S. marketplace that are clearly inclined sleep product accessories (i.e., inclined sleep products that attach to, or are supported by, other products such as cribs or play yards), except that they do not have rigid frames. Removing the words "rigid framed" from the definition of an "accessory inclined sleep product" will ensure that these products are not excluded from the standard's scope. This issue has been raised in the ASTM meetings and staff expects that a change will be forthcoming, although the timing is uncertain.

As inclined sleep products were not specifically mentioned as a durable infant or toddler product in section 104(f)(2) of the CPSIA, staff recommends that the Commission amend 16 CFR part 1130 to identify infant inclined sleep products as a durable infant or toddler product. The regulation at 16 C.F.R. part 1130 is the Requirements for Consumer Registration of Durable Infant or Toddler Products (product registration rule). Amending the rule to include inclined sleep products will make these products newly subject to the product registration rule, the impact of which is discussed in Section IX. Staff requests comments on the appropriateness of identifying inclined sleep products as durable infant or toddler products.

IV. Requirements of the Proposed Rule

The draft proposed rule would incorporate by reference the voluntary standard for inclined sleep products (ASTM F3118-17) with a modification to the "accessory inclined sleep product" definition, making it a mandatory product safety rule under the Consumer Product Safety Act (CPSA), if finalized. Firms whose inclined sleep products do not comply will need to evaluate their products, determine what changes would be required to meet the standard, and decide how to proceed. Noncompliant products would need to be removed from the U.S. market or modified to meet the staff-recommended proposed standard if the standard became mandatory.

To assist in the evaluation of the economic impact of the draft proposed rule, EC staff contacted nine firms (four of which responded). However, it was later determined that the products of one of the responding firms did not actually fall within the scope of the inclined sleep standard. [3]

The performance requirements from ASTM F3118-17 that firms would be expected to meet are presented below.

- Stability—intended to prevent inclined sleep products from tipping over while in use.
- Unintentional folding—intended to prevent unintentional folding while the product is in use, regardless of type of lock/latch the product uses, if any.
- Restraint systems—intended to ensure the integrity and effectiveness of restraint systems, which (when present) must include both a waist and crotch restraint, but not shoulder straps. Additionally, the inclined sleeper's restraint system must be designed such that the crotch restraint has to be used whenever the restraint system is used. The restraint system must be attached to the product in one of the manufacturer's recommended use positions at the time of shipment.
- Side height—intended to prevent falls, in conjunction with head, foot, and side containment requirements.
- Head, foot, and side containment—intended to prevent falls, in conjunction with side height requirements.
- Side to side surface containment—intended to ensure a seat back shape that prevents children from rotating into a sideways position.
- Seat back length—intended to prevent older children from being placed in inclined sleep products intended for younger users by restricting the head containment area available on the seat back.

[3] Additional information on the ASTM standard and how it addresses various hazard patterns can be found in the memorandum from Richard McCallion, Mechanical Engineer, Office of Hazard Identification and Reduction, dated, March 8, 2017, Subject: Staff's Review and Evaluation of ASTM F3118-17, Standard Consumer Safety Specification for Infant Inclined Sleep Products, for Incorporation by Reference into Staff's Draft Proposed Rule.

- Structural integrity—intended to ensure that the inclined sleeper remains cohesive after both dynamic and static load testing. Also intended to ensure that the product can support the intended user's weight when a safety margin is factored in.

The voluntary standard also includes various general requirements common to most voluntary children's product standards: (1) torque and tension tests to ensure that components cannot be removed; (2) requirements to prevent entrapment and cuts (minimum and maximum opening size,[4] coverage of exposed coil springs, small parts, hazardous sharp edges or points, smoothness of wood parts, and edges that can scissor, shear, or pinch); (3) marking and labeling requirements, including permanency requirements; (4) tests to ensure that the product has sleep position(s) at the appropriate incline; (5) requirements for warning labels; (6) requirements for instructional literature; and (7) toy accessory requirements. ASTM F3118-17 includes no reporting or recordkeeping requirements.

In addition, staff recommends modifying the definition of an "accessory inclined sleep product" to remove the "rigid framed" condition. This would enable the inclusion of a newly identified type of inclined sleep product accessory that has soft sides, yet still attaches to, or is supported by, another product, as outlined in the definition. Staff has identified two products that would be included in the proposed rule if the staff-recommended change is adopted. Both are supplied by small manufacturers and the impact on those firms is discussed in Section VI.

V. Other Federal or State Rules

CPSC staff has not identified any federal or state rule that either overlaps or conflicts with the staff-recommended proposed rule.

VI. Impact on Small Businesses

We identified 25 firms supplying inclined sleep products to the U.S. market. More than half of these firms (16 firms) produce infant hammocks. The majority of the 25 known firms are domestic (including 12 manufacturers and 5 importers). The remaining eight firms are foreign (including seven manufacturers and one retailer).[5] Staff expects that the inclined sleep products of six of the 25 firms are already compliant with ASTM F3118 because the firms either: (1) have their inclined sleep products certified by the Juvenile Products Manufacturers Association (JPMA) (one firm); or (2) claim compliance with the voluntary standard (five firms).[6] Further details are provided subsequently.

[4] Starting with ASTM F3118-16a, opening tests for mesh and fabric-sided products were included as well.
[5] Determinations were made using information from Dun & Bradstreet and ReferenceUSAGov, as well as firm websites.
[6] This count includes all firms, foreign and domestic, small and large.

Additional firms not identified by CPSC staff may manufacture or sell inclined sleep products via online marketplaces for hand-crafted products, such as Etsy. Market research identified no more than half a dozen firms selling infant hammocks that would be subject to the staff-recommended proposed rule (*i.e.*, not intended solely for photographic purposes) on Etsy at any one point in time. These firms or individuals likely produce homemade infant hammocks on a very small scale.

Under U.S. Small Business Administration (SBA) guidelines, a manufacturer of inclined sleep products is considered small if it has 500 or fewer employees; and importers and wholesalers are considered small if they have 100 or fewer employees. Staff limited our analysis to domestic firms because SBA guidelines and definitions pertain to U.S.-based entities. Based on these guidelines, about 14 of the 17 domestic firms are small—ten manufacturers and four importers. Additional unknown small domestic inclined sleeper suppliers may be operating in the U.S. market. Table 1 describes the firms in the inclined sleep product market.

Table 1. Firms in the U.S. Inclined Sleep Product Market

CATEGORY	NUMBER OF FIRMS
Total Firms	**25**
Domestic	17
Small	**14**
Manufacturers	**10**
Compliant with ASTM Voluntary Standard	3
Not Compliant with ASTM Voluntary Standard	7
Importers or Wholesalers	**4**
Compliant with ASTM Voluntary Standard	0
Not Compliant with ASTM Voluntary Standard	4
Large	**3**
Foreign	8

Highlighted categories are the focus of this analysis.

A. Small Manufacturers

1. Small Manufacturers with Compliant Inclined Sleep products

Of the ten small manufacturers, three produce inclined sleep products that are likely to comply with the voluntary standard (ASTM F3118-16) currently in effect for testing purposes under the Juvenile Product Manufactures Association (JPMA) certification program. Although only one large firm is currently listed on the JPMA website as having certified inclined sleep products, we expect the products of three small manufacturers to comply, because the firms were involved in the standard's development. In general, we expect that small manufacturers whose inclined sleep products comply with the current voluntary standard will remain compliant with the voluntary standard as it evolves, because they follow and, in this case, actively participate in the standard development process. Therefore, compliance with the voluntary standard is part of an established business practice. ASTM F3118-17, the version of the voluntary standard upon which the staff-recommended mandatory standard is based, has already been published and will be in effect by the time the mandatory standard becomes final[7] and these firms are likely to be in compliance based on their history.

Given that all of these firms are expected to comply with ASTM F3118-17 by the time it becomes effective and that none would be impacted by the staff-recommended change to the definition of an "accessory inclined sleep product," the economic impact of the staff-recommended proposed rule should be small for the three small domestic manufacturers supplying compliant inclined sleep products to the U.S. market.

2. Small Manufacturers with Noncompliant Inclined Sleep products

Seven small manufacturers produce inclined sleep products that do not comply with the voluntary standard. Two of these small manufacturers would only be included under the mandatory rule if the staff-recommended change to the definition of an "accessory inclined sleep product" is adopted. Staff tested the inclined sleep accessory of one of these two firms and found that it met all of the requirements except those associated with warning labels and instruction manuals; staff has not had an opportunity to examine the other firm's product. Generally, a straightforward modification to an existing label would not generate costs that would be considered significant relative to any of the inclined sleeper firm's revenues. This is consistent with the input from the inclined sleeper suppliers contacted. For this reason, staff does not believe that the staff-recommended proposed rule would have a significant impact on the accessory inclined sleeper that staff tested.

Staff cannot rule out a significant economic impact for any of the remaining six small manufacturers, including the second firm impacted by the staff-recommended definition change. These firms may not be aware of the ASTM voluntary standard or may believe that their product falls outside the scope of the standard. Products from all six firms are likely to

[7] There is typically a six month period between ASTM standard publication and its adoption for JPMA certification.

require modifications, some of which may be significant. Four of these firms may not currently have warning labels or instruction manuals for their products and will have to develop the required labels and instruction manuals. The costs of developing warning labels and instruction manuals are expected to be greater for firms that do not have experience in developing or designing warning labels and instruction manuals, and they may require additional time to comply. Additionally, these four firms appear to be very small, supplying very few products in very low quantities.[8] The cost of developing warning labels and instruction manuals is, therefore, more likely to have a significant economic impact on these firms, as their resources may be more limited.

Additionally, staff believes that as many as five of the seven firms with noncompliant inclined sleep products may not be aware of the inclined sleep products voluntary standard or even that they may be subject to existing federal regulations on other rules that may apply to their products. This could increase the time period required for firms to come into compliance. Therefore, staff is recommending a longer than usual effective date of 12 months to give firms time to familiarize themselves with the scope of the new standard and develop new/modified products if needed.

Staff requests comments on the change to the definition of an "accessory inclined sleep product" that would result in the inclusion of non-rigid inclined sleeper accessories under the staff-recommended proposed rule. Staff also requests information on the changes that may be required to meet the voluntary standard ASTM F3118-17, in particular whether redesign or retrofitting would be necessary, as well as the associated costs and time frame. Staff also requests information on the cost and time period required to modify warning labels and instruction manuals, particularly the additional costs that may be involved in creating warning labels and instruction manuals for firms unfamiliar with such requirements. Staff would also appreciate input on the recommended effective date.

3. Third Party Testing Costs for Small Manufacturers

Under section 14 of the CPSA, once the inclined sleep requirements become effective as a CPSC children's product safety rule, all manufacturers will be subject to the third party testing and certification requirements under the CPSA and the Testing and Labeling Pertaining to Product Certification rule (16 CFR part 1107) (1107 rule). Third party testing will include any physical and mechanical test requirements specified in the final inclined sleep products rule. Manufacturers and importers should already be conducting required lead testing for inclined sleep products. Third party testing costs are in addition to the direct costs of meeting the inclined sleep products standard.

Three of the ten small inclined sleeper manufacturers are already testing their products to verify compliance with the ASTM standard, though not necessarily by a third party. For these manufacturers, the impact to testing costs will be limited to the difference between

[8] Little information is available on most of these companies given their small size. However, based on the information available, it appears that these firms typically have 5 or fewer employees and most sell one inclined sleep product model (in one case, handmade through Etsy).

the cost of third party tests and the cost of current testing regimes. Contacted suppliers estimate that third party testing inclined sleep products to the ASTM voluntary standard would cost about $300 to $1,000 per model sample. For the three small manufacturers that are already testing, the incremental costs are unlikely to be economically significant. This is consistent with information provided in informal discussions with several firms actively participating in the ASTM voluntary standard development process.

For the seven small manufacturers that are not currently testing their products to verify compliance with the ASTM standard, the impact of third party testing, by itself, could result in significant costs for one firm. This determination was made based on an examination of firm revenues from recent Dun & Bradstreet or ReferenceUSAGov reports. While it is unknown how many samples will be needed to meet the "high degree of assurance" criterion required in the 1107 rule, testing costs could exceed one percent of gross revenue with as few as four samples tested for this firm (assuming high-end testing costs of $1,000 per model sample). However, revenue information was not available for four small manufacturers and, therefore, no impact evaluation could be made. All four firms are very small, however, so a significant impact cannot be ruled out. Most only sell inclined sleep products in what are likely to be very low volumes. One is a small scale Etsy supplier.

We welcome comments regarding overall testing costs and incremental costs due to third party testing (*i.e.,* how much does moving from a voluntary to a mandatory third party testing regime add to testing costs, in total and on a per test basis). In addition, staff would like comments regarding the number of inclined sleeper units that typically need to be tested to provide a "high degree of assurance."

B. Small Importers

There are four small importers supplying inclined sleep products to the U.S. market; none of their products are compliant with the ASTM voluntary standard. There is insufficient information to rule out a significant impact for these firms, particularly given the lack of revenue data. Whether there is a significant economic impact will depend upon the extent of the changes required to come into compliance and the response of their supplying firms. Any increase in production costs experienced by their suppliers as a result of changes made to meet the mandatory standard may be passed on to the importers.

Two of the four known importers are directly tied to their foreign suppliers. Therefore, finding an alternative supply source would not be a viable alternative. However, the foreign suppliers to these firms may have an incentive to work with their U.S. distributors to maintain an American market presence. Discontinuing the sale of inclined sleep products would likely have a significant impact on one of these firms because their entire product line consists of inclined sleep products and accessory products. The remaining two small importers do not supply many other products either. Therefore, discontinuing the sale of inclined sleep products could have a significant impact on those firms as well.

As with manufacturers, importers will be subject to third-party testing and certification requirements, and consequently, will be subject to costs similar to those for manufacturers if their supplying foreign firm(s) does not perform third party testing. The four known small importers do not currently test their products to verify compliance with the ASTM standard, therefore the full extent of third party testing costs would be due to the staff-recommended proposed rule. Based on the revenue data available, it does not appear that third party testing will have a significant impact on one of the four small importers. However, there was no revenue data available for the remaining three small importers of inclined sleep products not believed to comply with the voluntary ASTM standard. Therefore, we had no basis for evaluating the size of the impact on those firms.

C. Summary of Impacts

CPSC staff is aware of 14 small firms, ten domestic manufacturers and four domestic importers, currently marketing inclined sleep products in the United States. Of the ten small manufacturers, it appears that four are unlikely to experience significant economic impacts. However, we could not rule out a significant economic impact for the remaining six. Based on a review of firm revenues for the four small importers, as well as the options available, staff cannot rule out a significant economic impact. In summary, based upon current information, we cannot rule out a significant economic impact for 10 of the 14 firms (71 percent) operating in the U.S. market for inclined sleep products. The 12 month staff-recommended effective date will help to spread costs over a longer time-frame.

VII. Alternatives

At least three alternatives are available to minimize the economic impact on small entities supplying inclined sleep products while also meeting the statutory objectives: (1) adopt ASTM F3118-17 with no modifications; (2) allow a later effective date; and (3) time the effective date for warning labels and instruction manuals to coincide with the timing of model changes in the durable nursery product market.

First, section 104 of the CPSIA requires that the Commission promulgate a standard that is either substantially the same as the voluntary standard or more stringent if the Commission determines that more stringent standards would further reduce the risk of injury. Therefore, adopting ASTM F3118-17 with no modifications is the least stringent rule that could be promulgated. While this alternative would not reduce the testing costs triggered by the rule, it would eliminate the impact on the two firms that would be included in the rulemaking as a result of the staff-recommended change to the definition of an "accessory inclined sleep product." However adopting ASTM F3118-17 with no modifications would not address the risk of injuries and death in what are clearly inclined sleep product accessories except that they do not have rigid frames. Additionally, the impact on one of these firms is limited to the warning label and instructional literature changes associated with meeting the ASTM voluntary standard portion of the staff-recommended proposed rule.

Second, the Commission could also reduce the staff-recommended proposed rule's impact on small businesses by setting a later effective date. A later effective date would reduce the economic impact on firms in two ways. Firms would be less likely to experience a lapse in production/importation, which could result if they are unable to bring their products into compliance and certify compliance based on third party tests within the required timeframe. Also, firms could spread the costs of developing compliant products over a longer time period, thereby reducing their annual costs, as well as the present value of their total costs (*i.e.*, they could time their spending to better accommodate their individual circumstances). Staff believes that the current 12-month effective date will allow firms that may not be aware of the ASTM voluntary standard or may believe that their product falls outside the scope of the standard time to make this determination and bring their products into compliance. However, an even later effective date would further reduce these costs. Staff specifically requests comments on the 12 month effective date, as well as feedback on how firms would likely comply with the proposed rule.

Third, the Commission could time the effective date for the proposed rule to coincide with the timing of model changes in the durable nursery product market. One of the firms contacted during the market research phase of the IRFA noted that the timing of changes to the warning label and instructional manual requirements can affect those costs and also impact retailers. This is because warning labels and instruction manuals are keyed to model and SKU numbers, which means that changing them can cause inventory problems, particularly when they take place during a busy time of the year for retailers. The firm noted that enacting the changes to coincide with periods where models are typically changed (for example, January) would reduce these costs. Therefore, this alternative may reduce the impact on all of the known small businesses supplying inclined sleep products to the U.S. market. Staff requests comments on the extent of cost savings that may result from timing the effective date of the mandatory rule to coincide with the timing of model changes within the industry, as well as the best time(s) of the year for such changes to be implemented and to the extent to which this may already addressed by the 12 month effective date.

VIII. Small Business Impacts of the Accreditation Requirements for Testing Laboratories

In accordance with section 14 of the CPSA, all children's products that are subject to a children's product safety rule must be tested by a CPSC-accepted third party conformity assessment body (i.e., testing laboratory) for compliance with applicable children's product safety rules. Testing laboratories that want to conduct this testing must meet the NOR pertaining to third party conformity testing. NORs have been codified for existing rules at 16 C.F.R. part 1112. Consequently, staff recommends that the Commission propose an amendment to 16 C.F.R. part 1112 (the 1112 rule) that would establish the NOR for those testing laboratories that want to test for compliance with the inclined sleep products final rule. This section assesses the impact of the amendment on small laboratories.

A Final Regulatory Flexibility Analysis (FRFA) was conducted as part of the promulgation of the original 1112 rule (78 FR 15836, 15855-58) as required by the RFA. Briefly, the FRFA concluded that the accreditation requirements would not have a significant adverse impact on a substantial number of small laboratories because no requirements were imposed on laboratories that did not intend to provide third party testing services. The only laboratories that were expected to provide such services were those that anticipated receiving sufficient revenue from the mandated testing to justify accepting the requirements as a business decision.

Based on similar reasoning, amending the 1112 rule to include the NOR for the inclined sleep products standard will not have a significant adverse impact on small laboratories. Moreover, based upon the number of laboratories in the U.S. 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 inclined sleep products 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 inclined sleeper standard to their scope of accreditation, a cost that test laboratories have indicated is extremely low when they are already accredited for other section 104 rules. As a consequence, the Commission could certify that the NOR for the inclined sleeper standard will not have a significant impact on a substantial number of small entities.

IX. Impact of the Product Registration Rule

As already discussed, inclined sleep products were not listed in section 104(f)(2) of the CPSIA as durable infant or toddler products. Inclined sleep products were also not one of the six products added to the list with the final product registration rule (16 CFR part 1130). As part of the mandatory standard development process, staff recommends that the Commission) amend 16 CFR part 1130 to identify infant inclined sleep products as a durable infant or toddler product. Once effective, this would make inclined sleepers subject to the requirements of the product registration rule. The product registration rule requires that firms provide consumers with a postage-paid consumer registration form with each product, although firms may maintain on-line registration pages as well. The information supplied on the forms (but not necessarily the forms themselves) must be maintained for a minimum of six years. This section assesses the impact on small domestic firms.

Of the 14 small domestic firms identified by staff as supplying inclined sleep products to the U.S. market, it is likely that six will not be significantly impacted by the requirements of the product registration rule. Four of the six firms supply combination products, such as play yards with accessory inclined sleep products, that are already covered under the product registration rule. All six firms have other products that are already subject to the product registration rule, as well as on-line product registration sites. Therefore, these firms should already have the infrastructure to maintain the records and would, at most, require forms to be printed for, and shipped with, their inclined sleep products.

The remaining eight firms (the majority of which produce only infant hammocks on a very small scale) would be required to develop a postage-paid product registration form for their inclined sleep products, include the card with their other packaged materials, and develop/maintain a system to store the information collected. Each model would require a registration form that clearly identifies the product (for example, model name, model number, product identification number, or other identifier typically used by the firm). The form required to be provided to consumers must be "at least the size of two standard post cards connected together with a perforated line so that the portions can be separated."[9]

The design of the product registration forms would likely be simple, even for very small firms. Basic word processing software should be sufficient (firms likely already have access to such a program) and exemplar product registration forms are expected to be easy to find. Staff expects that the time necessary to develop the template could range from 30 minutes to two hours at a cost of about $17 to $67.[10] The cost per inclined sleeper would depend upon the number sold annually. For the smallest suppliers, it could be as low as 20 products ($0.85 to $3.35 per product); for the somewhat larger suppliers, it might be as high as 1,000 ($0.02 to $0.07 per product).[11]

The paper necessary to produce the required two postcard form with perforation separating them can be readily purchased at office supply stores and on-line. As an example, one such store sells this type of paper for $10 for 100 sheets, each sheet with four postcards. So a package of 100 sheets would supply product registration forms for 200 products (2 per product) at a cost of 5 cents per product. The National Highway Traffic Safety Administration (NHTSA), in their evaluation of car seat product registration forms, estimated the "cost of cutting and printing the cards themselves" to be about $0.02 (in 1990 dollars), "regardless of the size of the manufacturer."[12] This is equivalent to $0.04 in 2016 dollars.[13]

Firms that sell fewer than 1,000 units annually might opt to include the postage on each form (currently $0.34 for a postal card). Firms that sell a somewhat larger volume may opt to use the U.S. Postal Service's (USPS) Basic Business Reply Mail (BRM) to pay for the postage on the product registration forms.[14] Under this service, each firm would pay a $215 annual fee and $0.34 for each form returned.[15] NHTSA found that about 27% of the prepaid registration forms for car seats were returned over the years 1996 through 2000.

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[9] 74 *Federal Register* 68674; 16 CFR § 1130.6(a).
[10] The wage data is total compensation for sales and office for all workers in private industry for June 2016 (published September 2016) for goods-producing industries ($33.29). The data is from Table 9 of the Employer Costs for Employee Compensation (ECEC), which can be found at: http://www.bls.gov/ncs.
[11] These estimates are based on information supplied for the infant sling rulemaking. As with infant hammocks, they tend to be produced and sold on a small scale, some even hand-made.
[12] U.S. Department of Transportation, National Highway Traffic Safety Administration (NHTSA), Evaluation of Child Safety Seat Registration, October 2002.
[13] Calculated using http://data.bls.gov/cgi-bin/cpicalc.pl?cost1=.02&year1=1990&year2=2016.
[14] See http://pe.usps.com/qsg_archive/html/qsg_archive_20100104/qsg300/q507a.htm for information on the different types of BRM provided by the U.S. Postal Service.
[15] This assumes that they select first class rather than priority mail. The latter would cost $0.82 for each card returned. See http://pe.usps.com/text/dmm300/Notice123.htm.

Given that these are durable nursery products generally comparable to inclined sleep products in terms of likely lifecycle, this seems to be a reasonable return estimate. Therefore, firms selling only 20 inclined sleep products annually might expect to receive about 5 registration forms back annually, while a firm selling 1,000 inclined sleep products annually might expect to have 270 registration forms returned.

The registration form must "be attached to the surface of each durable infant or toddler product so that, as a practical matter, the consumer must notice and handle the form after purchasing the product."[16] The manner of attachment is left to the supplier. This was also the case with the NHTSA evaluation of car seat product registration forms. NHTSA estimated that it would cost about $0.05 per product (in 1990 dollars) for the materials required to attach the product registration form to the surface of the product. This is equivalent to $0.09 in 2016 dollars.[17]

For very small firms, the number of product registration forms likely to be returned annually would be small enough that merely physically storing the forms for six years would be the simplest and most cost-effective data storage and maintenance system. A firm selling an average of 20 inclined sleep products annually, perhaps making them by hand to order, might expect to receive only 30 forms back over a 6 year period (5 forms returned annually * 6 years = 30). Therefore, on the low end the cost of data storage and maintenance is expected to be negligible. Larger small firms selling up to 1,000 inclined sleep products annually might receive up to 1,620 completed product registration forms over a six year period (270 forms returned annually * 6 years = 1,620). These firms could still opt for a physical storage system, but it might be more convenient for them to use a simple spreadsheet system where the data is manually entered and maintained. If we assume that the total compensation rate for the person entering the data is $33.29 (see footnote 9)[18]and if we also assume that the data can be entered at a rate of 50-100 forms per hour,[19] the data entry cost per unit would be $0.67 to $0.33. Maintenance costs are expected to be negligible for such small storage systems.

Table 2 below, presents a breakout of all of these costs for a low selling and a higher selling firm. The costs are provided on a per unit basis, with the upper part showing the costs for all units sold and the lower part showing the additional costs that would stem from product registration forms that are returned. The prices for the inclined sleep products supplied by the eight firms likely to be impacted by the product registration rule range from $30 to $250. Firms selling inclined sleep products on the high end of that range may be able to easily absorb these costs if they sell a larger volume (for example, a $1.10 per product cost increase represents about 0.004% of a $250 inclined sleeper). On the other hand, it

[16] 74 *Federal Register* 68677; 16 CFR § 1130.5(c).
[17] Calculated using http://data.bls.gov/cgi-bin/cpicalc.pl?cost1=0.05&year1=1990&year2=2016.
[18] Small inclined sleeper suppliers may not necessarily provide benefits beyond wages, so the true compensation rate may actually be lower.
[19] This assumption is consistent with earlier analysis performed by staff for the 2001 advance notice of proposed rulemaking (ANPR) for the purchaser identification card program (https://www.cpsc.gov/PageFiles/92325/purchase.pdf). No comments relative to this assumption were received.

may be more difficult for companies selling their inclined sleep products for $30 to absorb or pass on their cost increase even if they are a relatively high volume firm (a $1.10 per product cost increase represents about 0.037% of a $30 inclined sleeper). The inclined sleep products supplied by the firm most likely to be on the low end of the table below (*i.e.*, as few as 20 sold annually)[20] are priced around $140. A cost increase of $3.87 would represent nearly 2.8% of their price and it is unclear how easily they might be able to absorb the cost or pass it on to their customers.

Staff requests comments on all of the assumptions in this section, including: the possible sales volumes for very small sellers of inclined sleep products; the time required to design, print, and package product registration forms; the return rate on product registration forms for durable nursery products, particularly inclined sleep products; the method that firms, particularly very small firms may use to store and maintain the data collected and the associated costs; the cost of data entry and any maintenance costs for the data systems.

Table 2. Estimated Costs Associated with Product Registration Forms (per product sold)

CATEGORY	LOW (20 INCLINED SLEEP PRODUCTS SOLD ANNUALLY)	HIGH (1,000 INCLINED SLEEP PRODUCTS SOLD ANNUALLY)
Costs Applicable to All Forms	**20 sets of two forms**	**1,000 sets of two forms**
Form Design	$0.85 to $3.35	$0.02 to $0.07
Paper Supplies	$0.05	$0.05
Cutting and Printing	$0.04	$0.04
Annual Fee (or Postage for low volume)	$0.34	$0.22
Form Attachment to Product	$0.09	$0.09
Subtotal	**$1.37 to $3.87**	**$0.42 to $0.47**
Costs Applicable Only to Returned Forms	**5 forms returned**	**270 forms returned**
Fee per Form Returned	$0	$0.34
Data Entry, Storage, and Maintenance	$0.00	$0.33 to $0.67
Subtotal	**$0.00**	**$0.67 to $1.01**
Grand Total	**$1.37 to $3.87**	**$1.10 to $1.48**

[20] Their infant hammocks are handmade and sold on Etsy.