



Billing Code 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1112, 1130, and 1236

[CPSC Docket No. 2017-0020]

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 oir_submission@omb.eop.gov.

Other comments, identified by Docket No. CPSC-2017-0020, 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-2017-0020, 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.”

[<https://www.cpsc.gov/s3fs-public/Proposed%20Rule%20-%20Safety%20Standard%20for%20Infant%20Inclined%20Sleep%20Products%20-%20March%2022%2C%202017.pdf>]

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 1236, 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 1236, *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 1236, *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 1236 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.

[[https://www.cpsc.gov/s3fs-public/Proposed%20Rule%20-](https://www.cpsc.gov/s3fs-public/Proposed%20Rule%20-%20Safety%20Standard%20for%20Infant%20Inclined%20Sleep%20Products%20-%20March%202022%2C%202017.pdf)

[%20Safety%20Standard%20for%20Infant%20Inclined%20Sleep%20Products%20-](https://www.cpsc.gov/s3fs-public/Proposed%20Rule%20-%20Safety%20Standard%20for%20Infant%20Inclined%20Sleep%20Products%20-%20March%202022%2C%202017.pdf)

[%20March%202022%2C%202017.pdf](https://www.cpsc.gov/s3fs-public/Proposed%20Rule%20-%20Safety%20Standard%20for%20Infant%20Inclined%20Sleep%20Products%20-%20March%202022%2C%202017.pdf)] 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
1236	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 1236

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)(46) 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) * * *

(46) 16 CFR part 1236, Safety Standard for Infant Inclined Sleep Products.

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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 adding paragraph (a)(19) 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 1236 to read as follows:

PART 1236-SAFETY STANDARD FOR INFANT INCLINED SLEEP PRODUCTS

Sec.

1236.1 Scope.

1236.2 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).

§ 1236.1 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.

§ 1236.2 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: April 3, 2017

Todd A. Stevenson,
Secretary, Consumer Product Safety Commission

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