



**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 Sleep Products**

**AGENCY:** Consumer Product Safety Commission.

**ACTION:** Supplemental notice of proposed rulemaking.

**SUMMARY:** In the *Federal Register* of April 7, 2017, the Consumer Product Safety Commission (CPSC) published a notice of proposed rulemaking (2017 NPR) pursuant to the Danny Keysar Child Product Safety Notification Act, section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), to promulgate a consumer product safety standard for infant inclined sleep products (inclined sleep products). The 2017 NPR allowed an incline between 10 and 30 degrees for the seat back angle of an inclined sleep product. The 2017 NPR proposed to adopt a voluntary standard for inclined sleep products developed by ASTM International, with a modification to the standard's definition of "accessory." Based on subsequent information and events, the Commission is now issuing a supplemental proposed rule (Supplemental NPR), proposing to adopt the current ASTM standard for inclined sleep products, with modifications that would make the mandatory standard more stringent than the voluntary standard. The proposed changes include limiting the seat back angle for sleep to 10 degrees or less. CPSC's proposed standard would cover products intended for infant sleep that are not already addressed by another standard. Additionally, the Commission proposes to include the mandatory standard for infant sleep products in the Commission's list of notices of requirements (NORs). The Commission also proposes to amend the consumer registration rule to identify

explicitly infant 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 infant 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](mailto: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. CPSC does not accept comments submitted by electronic mail (e-mail), except through [www.regulations.gov](http://www.regulations.gov). CPSC encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

*Written Submissions:* Submit written submissions in the following way: Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions) to: Division of the Secretariat, 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 electronically any confidential business

information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If you wish to provide such information, please submit it 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](mailto:ckish@cpsc.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background and Statutory Authority**

*A. Statutory Authority*

Section 104(b) of the CPSIA, 15 U.S.C. 2056a(b), 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. 15 U.S.C. 2056a(b)(1)(B).

Section 104 of the CPSIA 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.<sup>1</sup> The consultation process for the inclined sleep products rulemaking commenced in 2011, and CPSC staff has been actively participating in the development of the new standard since that time.

A “durable infant or toddler product” is a “durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years.” *Id.* 2056a(f)(1). The CPSIA includes a non-exhaustive list of categories of products that are durable infant or toddler products, such as cribs, toddler beds, and bassinets and cradles. *Id.* 2056a(f)(2). As discussed in section I.B of this preamble, in the 2017 NPR CPSC proposed to categorize infant inclined sleep products as a “durable infant or toddler product” under section 104 of the CPSIA, as a subset of the bassinet and cradle category. In this Supplemental NPR, CPSC proposes to identify “infant sleep products” as a category of durable infant or toddler products under section 104(f) of the CPSIA. CPSC proposes to define “infant sleep products” as products that provide sleeping accommodations for infants and are not currently covered by bassinets/cradles, cribs (full-size and non-full size), play yards, and bedside sleepers, as a durable infant or toddler product under section 104(f) of the CPSIA. Section 104(d) of the CPSIA requires durable infant or toddler products to establish product registration programs and comply with CPSC’s implementing rule, 16 CFR part 1130. Under section 14 of the CPSA, children’s products (such as durable infant or toddler products) must comply with testing and certification requirements that are implemented through 16 CFR parts 1107 and 1109.

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<sup>1</sup> ASTM International website: [www.astm.org](http://www.astm.org), About ASTM International.

*B. 2017 NPR*

When staff began work on the bassinet and cradle standard, staff considered infant inclined sleep products to fall within the scope of the bassinet/cradle standard. However, because the bassinet/cradle standard did not address products on the market that had a sleep incline greater than 10 degrees, the Commission directed staff to initiate a separate rulemaking effort for infant inclined sleep products. Accordingly, the infant inclined sleep products safety standard was an outgrowth of the bassinet/cradle safety standard, intended to address products with an incline greater than 10 degrees from horizontal.

In 2011, at the time CPSC separated infant inclined sleep products from the bassinet/cradle standard, ASTM simultaneously began work on developing a voluntary standard for infant inclined sleep products. ASTM published the resulting infant inclined sleep products standard in May 2015, and updated the standard twice in 2016 and twice in 2017. ASTM's latest standard for this product category is designated, ASTM F3118-17a, *Standard Consumer Safety Specification for Infant Inclined Sleep Products* (ASTM F3118-17a).

Pursuant to the procedure described in section 104 of the CPSIA, the 2017 NPR proposed a mandatory standard for infant inclined sleep products, incorporating by reference the then-current voluntary standard, ASTM F3118-17, with a modification to the standard's definition of "accessory." 82 FR 16964 (April 7, 2017). At the time of the 2017 NPR for infant inclined sleep products, which included hammocks, the Commission was aware of 14 fatal incidents related to infant inclined sleep products, which were reported to have occurred between January 1, 2005 and September 30, 2016. Staff determined that 8 of the 14 infant deaths involved freestanding, framed inclined sleep products, and that 3 infant deaths involved an unrestrained infant who was found to have rolled over into a facedown position. Staff found that in two additional deaths, the infant reportedly rolled over into a facedown position, but the reports did

not include any information about use of a restraint. CPSC staff had little information about the cause or manner of the three remaining infant deaths. *Id.* at 16965-66. Staff’s incident data analysis in the 2017 NPR considered that these 14 fatalities and other reported incidents could be addressed by the requirements in the voluntary standard, ASTM F3118-17. *Id.* at 16967-68.

The 2017 NPR indicated that ASTM F3118-17 addressed the primary hazard patterns CPSC identified in the 657 incidents (including 14 deaths), except for the definition of “accessory.” Specifically, the 2017 NPR proposed that CPSC’s standard would not include the term “rigid frame” in the definition of “accessory inclined sleep product” in section 3.1.1 of ASTM F3118-17, broadening the definition to encompass a new product that did not have a rigid frame. *Id.* at 16968-69, and 16975. The Commission concluded that these more stringent requirements were necessary to further reduce the risk of injury associated with infant inclined sleep products relating to the use of an inclined sleep product accessory. *Id.* at 16967.

As the 2017 NPR explained, durable infant or toddler products are children’s products that must be certified as complying with all applicable CPSC-enforced requirements. 15 U.S.C. 2063(a); 82 FR at 16969. Certification must be based on testing conducted by a CPSC-accepted third party conformity assessment body (test laboratory). 15 U.S.C. 20163(a)(2). CPSC must publish a NOR for the accreditation of test laboratories to assess a product’s conformity with a children’s product safety rule, such as the proposed rule on infant inclined sleep products. Accordingly, the 2017 NPR proposed that if issued as a final rule, the new *Standard Consumer Safety Specification for Infant Inclined Sleep Products*, to be codified at 16 CFR part 1236, would be added to the list of NORs for children’s product safety rules in 16 CFR part 1112, so that test laboratories applying for CPSC-acceptance could seek accreditation to test inclined infant sleep products. 82 FR at 16969.

Finally, the 2017 NPR proposed to amend 16 CFR part 1130, the Commission's requirements for consumer registration for durable infant or toddler products. *Id.* at 16969-70. The Commission proposed to amend the definition of "durable infant or toddler product" to clarify that infant inclined sleep products fall within the term, and are subject to the product registration card requirements in part 1130. *Id.*

On June 12, 2019, CPSC staff submitted a briefing package and a draft *Federal Register* notice to the Commission recommending that the Commission terminate the 2017 NPR. Staff recommended terminating the 2017 NPR because, by that time, CPSC had received reports of 42 additional fatalities since issuing the 2017 NPR, which were associated with rocker-like inclined sleep products, and because the Commission had issued additional safety alerts and recalls involving infant inclined sleep products. On October 16, 2019, staff provided the Commission with a briefing package recommending that the Commission instead issue this Supplemental NPR.<sup>2</sup>

### C. 2019 Supplemental NPR - Overview

In this Supplemental NPR, the Commission proposes to issue a standard for infant sleep products, *i.e.*, products that (1) provide sleeping accommodations for infants and (2) are not currently covered by bassinets/cradles, cribs (full-size and non-full size), play yards, and bedside sleepers. The Supplemental NPR proposes to incorporate by reference ASTM F 3118-17a with modifications to require that: (1) the seat back angle intended for sleep must be equal to or less than 10° and (2) the infant sleep product must meet the requirements for a bassinet/cradle in the standard at 16 CFR part 1218. The Commission also proposes to amend the consumer

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<sup>2</sup> The October 16, 2019, Staff Briefing Package: Draft Supplemental Notice of Proposed Rulemaking for Infant Sleep Products under the Danny Keysar Child Product Safety Notification Act (Staff Supplemental Briefing Package) is available at: [https://www.cpsc.gov/s3fs-public/SupplementalNoticeofProposedRulemakingforInfantSleepProducts\\_10\\_16\\_2019.pdf?TPVAJZEQcz9x9sKeEGltm4LskkonxUWv](https://www.cpsc.gov/s3fs-public/SupplementalNoticeofProposedRulemakingforInfantSleepProducts_10_16_2019.pdf?TPVAJZEQcz9x9sKeEGltm4LskkonxUWv).

registration rule to identify “infant sleep products” as a category of durable infant or toddler products under section 104(f) of the CPSIA. Additionally, the Commission proposes to amend its regulation at 16 CFR part 1112 to add infant sleep products to the list of products that require third party testing.

## **II. Product Description**

### *A. Scope of Products Within the Supplemental NPR*

The scope of products covered by the 2017 NPR tracked the scope of ASTM F3118-17, covering “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 Supplemental NPR proposes to incorporate ASTM F3118-17a with substantial modifications, including revisions in the scope of the standard, section 1.3, to remove the term “inclined,” and to include any infant sleep product not currently covered by another mandatory rule for infant sleep products: bassinets/cradles, cribs (full-size and non-full-size), play yards, and bedside sleepers. Accordingly, the scope of the Supplemental NPR includes all of the products in the 2017 NPR, plus additional infant sleep products not covered by any other infant sleep product standard. The following types of infant sleep products fall within the scope of the Supplemental NPR:

- *Frame-Type Inclined Sleep Products* – Frame-type inclined sleep products are elevated, intended to be placed on the floor, and are self-supporting. Typically, this design uses a metal frame covered by a fabric insert that contains the occupant. Some frame-type products have a rigid plastic insert under the sleeping surface, and/or extra padding with head positioning cushions. The base may be stationary or allow side-to-side/head-to-toe rocking. This type of product could have a fixed incline or be

adjustable. Frame-type products can be intended for use by newborns or infants, or both, depending on the size of the product.

- *Hammocks* – Hammocks are typically constructed of fabric and suspended from one or two points, either above or on either side. Hammock 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 semi-rigid sleeping surface that maintains the product’s form.

Hammocks are intended to be suspended and can be supported by a frame or other structure, such as a ceiling.

- *Compact Inclined Sleep Products* – Compact inclined sleep products are freestanding, with the bottom of the seat a maximum of 6 inches (152 mm) above the floor. These products tend to be constructed of foam and are intended to be used on the floor.
- *Accessory Inclined Sleep Products* – An accessory inclined sleep product is intended to provide sleeping accommodations for infants or newborns and are attached to, or supported in some way, by another product. These products can be fixed or adjustable. An inclined sleep accessory is typically 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.

#### B. *Market Description*

The Supplemental NPR proposes to cover any infant product “primarily intended and marketed<sup>3</sup> to provide sleeping accommodations” that is designed for infants five months old or

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<sup>3</sup> This would include marketing information (such as on websites or in ad campaigns), product and retail package labeling, as well as supplier statements about the product.

younger and that is not covered by another standard.<sup>4</sup> In general, the Supplemental NPR does not propose to cover products with adjustable seat back positions that are covered by other mandatory or voluntary standards in inclined position(s), such as bouncers, rockers, hand-held carriers, or infant swings, unless they have a seat back angle that is specifically marketed for sleep for children 5 months or younger. To date, CPSC staff has found one bouncer on the market with an inclined position marketed for sleep for children in this age range.

Inclined infant sleep products sell on the U.S. market for approximately \$65 for a frame-style inclined sleeper, \$110 for a compact sleeper, \$165 for an infant hammock,<sup>5</sup> and \$236 for a play yard with an inclined sleeper accessory.<sup>6</sup> A hammock-style crib accessory that would be covered by the Supplemental NPR (but does not currently fall under the voluntary inclined sleeper standard or another sleep standard) sells for approximately \$50.

Several product categories would not fall under the scope of the Supplemental NPR: (1) sleep positioners; (2) sleep wedges, many of which are marketed as medical devices, putting them under the jurisdiction of the Food and Drug Administration; and (3) miniature infant hammocks marketed exclusively for use as photographic props (*i.e.*, photos of newborn babies).

### **III. Incident Data and Hazard Patterns**

At the time of the 2017 NPR, the Commission was aware of 14 fatal incidents related to infant inclined sleep products, which were reported to have 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

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<sup>4</sup> These include: Safety Standard for Full-Size Baby Cribs (16 CFR 1219); Safety Standard for Non-Full-Size Baby Cribs and Ply Yards (16 CFR 1220 and 1221); Safety Standard for Bedside Sleepers (16 CFR 1222); and Safety Standard for Bassinets and Cradles (16 CFR 1218).

<sup>5</sup> The average price for an infant hammock supplied by a home-based manufacturer is approximately \$200.

<sup>6</sup> Staff averaged prices across all models found for a particular type. Staff ignored as unknown shipping costs for a few hammock models delivered from overseas suppliers, which means that the average cost for an infant hammock may be a low estimate, depending upon how many hammocks are entering the U.S. via these overseas suppliers.

facedown position. Two additional cases also reported a rollover into a facedown position, but the reports did not include any information about use of a restraint. CPSC had little information about the cause or manner of the three remaining deaths. The NPR recognized that reporting was ongoing and the number of reported fatalities could change. This Supplemental NPR updates fatal and nonfatal incident reports associated with the use of an infant inclined sleep product.

CPSC is aware of 451 incidents (59 fatal and 392 nonfatal) related to infant inclined sleep products that occurred from January 1, 2005 through June 30, 2019 and reported between October 1, 2016 and June 30, 2019. This count includes incidents reported after the reporting end date stated in the 2017 NPR. Forty-three percent of the incident reports (196 out of 451) are based solely on information from manufacturers/retailers. 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. Tab A of the Staff Supplemental Briefing Package describes the incident data and the hazard patterns associated infant inclined sleep products.

#### *A. Fatalities*

Since the 2017 NPR, through June 30, 2019, CPSC received reports of 59 deaths. One fatality involved a foam-based infant reclined sleeper; two fatalities occurred in napper attachments of play yards; and the remaining fatalities occurred in freestanding framed inclined sleep products. CPSC staff reviewed and categorized incident reports associated with the fatalities:

- Twenty-eight of the 59 reports contain unclear, conflicting, and/or inconsistent information. For example, in this category medical examiners often conclude the

cause of death to be Sudden Infant Death Syndrome (SIDS) or Sudden Unexpected Infant Death (SUID) along with a co-contributing condition such as unsafe sleep environment (*e.g.*, soft bedding, inclined sleep surface) or other pre-existing medical condition. Considering all factors in each report confounds staff's ability to determine the pre-dominant factor causing a fatality. Occasionally, wording on the documents cite "several possibilities" and the cause of death is coded as Undetermined. Lack of clarity in these reports make it difficult for CPSC staff to consistently classify the 28 deaths.

- Eighteen reports describe infants placed in the product supine but who ended up in a compromised position in the product, resulting in suffocations or positional asphyxiations. In 11 of the 18 cases, no restraints were used; another six infants were placed in a supine position, but the use of restraints is unknown; and in one case, the infant was left restrained and supine, but found supine, slumped in a chin-to-chest position. One additional unrestrained infant fell out of the product and became wedged in a confined space.
- Eight reports provide very little information on the incidents. Lack of any information on the circumstances leading up to the death does not allow staff to classify these deaths.
- Four reports describe infant placement issues; three of the four decedents were reportedly placed prone on soft bedding in the product; and another decedent suffocated when a young sibling climbed into the sleep product on top of her.

CPSC does not know the age for 10 deceased infants. Staff concludes that for the remaining deaths, 39 infants were 5 months or less in age, while six infants were between 6- and 8-months of age. One decedent was 9-months old.

## B. *Nonfatal Incidents*

Reports indicate that 96 of the 451 inclined sleep product-related nonfatal incidents involved an injury to the infant during product use. The severity of the injury types among the 96 reported injuries are as follows:

- Seven infants required hospital admission. Six of the seven infants suffered episodes of respiratory distress due to rolling over in the product; mold in the product; or undetermined reasons. One of the seven infants had to be hospitalized for *scoliosis* (curvature) of the back attributed to product use.
- Sixteen infants were treated and released from emergency departments (EDs). Eleven of these infants were treated for head injuries and contusions/bruises resulting from falls; three infants were treated for unexplained respiratory distress. Mold growth on the product was associated with respiratory distress in one additional infant and seizure symptoms in another.
- Seventy-three infants received some professional medical care, first-aid treatment, or the level of care received was not reported. Among them, 32 infants suffered from plagiocephaly (flat head syndrome), torticollis (twisted neck syndrome), or both conditions, associated with the use of the inclined sleep product; 27 infants suffered mostly respiratory and some skin problems associated with mold on the product; infants sustained the remaining injuries due to a fall from the product or a minor electric shock, or their injuries are unspecified.

The remaining 296 incident reports indicate that no injury occurred to the infant or provided no information about an injury. However, many of the descriptions indicate the potential for a serious injury, or even death, similar to those reported in the incident data.

### *C. Hazard Pattern Identification*

The 2017 NPR identified nine hazard patterns among the 657 reported incidents. These hazard patterns included: design issues, lack of structural integrity, inadequate restraints, electrical issues, non-product-related or unknown issues, difficulty with correct positioning, miscellaneous product-related issues, unspecified falls, and consumer comments. Although the distribution of the data in this Supplemental NPR update varied somewhat, CPSC finds that the broader hazard categories are very similar. Within the broader hazard category of design, the Supplemental NPR identifies one new hazard pattern, as described below.

CPSC staff considered all 451 reported incidents (59 fatal and 392 nonfatal) to identify hazard patterns associated with infant inclined sleep products. The infant inclined sleep products category includes a variety of products. Some products, like hammocks, are suspended in air, while other seat-like products are meant to be placed on a floor level (yet incident reports indicate these products often were not placed on floor level). Other products sit on top of larger nursery products as attachments. CPSC staff identified hazard patterns that are quite different depending on which product is involved and how the product is being used. In order of frequency of incident reports, CPSC staff grouped the hazard patterns into the following categories:

1. ***Design*** of the infant inclined sleep product: One hundred and thirty-eight of the 451 reported incidents (31 percent) are in this category. Staff identified three major issues:
  - a. Fifty-nine reported incidents (43 percent) involved infants who developed respiratory and/or skin ailments due to the growth of mold on the product;
  - b. Forty-six reported incidents (33 percent) involved infants that rolled over—fully or partially—from their original supine position. Reports describe infants as young as 1- or 2-months of age as having rolled over; parents/caregivers, who witnessed and

reported some of the nonfatal incidents, were able to rescue distressed infants quickly. Eighteen infants died due to suffocation or asphyxiation. Although a few of the infants were strapped into the product, a majority of the infants were either not restrained or the use of restraint is unreported.

- c. Thirty-three reported incidents (24 percent) involved infants that developed physical deformations from extended product use, such as *plagiocephaly* (flat head syndrome), *scoliosis* (curvature) of the back, and/or *torticollis* (twisted neck syndrome).

The design category includes 19 deaths, 5 hospitalizations, and 4 emergency department (ED) visits. All but two of the deaths resulted from infants rolling over into a prone or semi-prone position, one decedent was found still supine and restrains, but slumped in a chin-to-chest position. The other infant rolled out of the product and wedged into a confined space. Infants unrestrained in the product caused two ED-treated falls. An additional 62 non-hospitalized, non-ED injuries are reported in this category.

2. **Electrical** issues: One hundred and twenty-seven of the 451 incident reports (28 percent) report battery leakage, electric shock, and/or overheating/melting of components, such as the vibrating unit, battery cover, switch, plug, or motor. Reports include two injuries in this category due to electric shock.

3. **Consumer comments**: Ninety of the 451 reports (20 percent) fall into this category. The reports consist of consumer comments/observations of perceived safety hazards, complaints about unauthorized sale of infant inclined sleep products, or inquiries regarding safety recall on inclined sleep products. One complaint describes misinformation in the instruction material. None of these reports indicate that an incident actually occurred.

4. **Undetermined** due to confounding information: Thirty-four of the 451 reports (8 percent) provide unclear, conflicting, and/or inconsistent information. Among the 28 deaths

reported in this category, for example, medical examiners often concluded the cause of death to be SIDS or SUID, along with a co-contributing condition such as an unsafe sleep environment (e.g., soft bedding, inclined sleep surface) or pre-existing medical condition. Staff is unable to determine the role of the product when documents describe multiple potentially contributing factors. Occasionally, the wording on the documents cite “several possibilities,” and the cause of death is coded as Undetermined. For the 6 nonfatal injuries, including the 2 hospitalized and 2 ED-treated injuries, the report described respiratory distress due to temporary cessation of breathing; however, these reports contain no official diagnosis for these episodes.

5.     **Lack of *structural integrity***: Twenty-eight of the 451 incidents (6 percent) report some sort of breakage of the product or its components. These reports include complaints of buckle/straps breaking, components such as hub, rail, or leg detaching/disengaging, hardware coming loose, and other unspecified components breaking. This category includes two ED-treated injuries, both due to falls.

6.     ***Other product-related*** issues: Thirteen of the 451 incidents (3 percent) report other product-related issues, such as instability (product tipping over), inadequacy of restraint (infants falling out in spite of being restrained), or product assembly/installation difficulties. This category contains seven fall-related injuries, including two injuries that were treated and released from a hospital ED.

7.     ***Infant placement*** issues: Four of the 451 incidents reports (1 percent) indicate that infant placement contributed to the incident. Of the four fatalities, reports describe three infants placed in a prone position on soft bedding; and another infant being crushed by a young sibling who climbed on top of her.

8.     ***Insufficient information***: For 17 of the 451 incidents (4 percent), reports contain insufficient information for staff to categorize them accurately. Staff has no information

available on the circumstances of 8 deaths in this category. Reports for six injuries in this category describe unspecified falls treated in hospital EDs, with no information was on restraint usage.

*D. Product Recalls and Safety Alerts*

From May 10, 2000 to August 20, 2019, CPSC conducted 13 consumer-level recalls involving infant inclined sleep products. The recalls were conducted in response to hazards involving strangulation, suffocation, fall, structural stability, entrapment, exposure to mold, and death. Six recalls involved infant hammocks, six recalls involved infant inclined sleep products, and one recall involved an infant inclined sleep accessory included with a play yard. Tab G in the Staff Supplemental Briefing Package contains a detailed chart outlining recalls involving infant inclined sleep products.

The six infant hammocks were recalled for hazards including: strangulation, suffocation, fall, structural stability, and entrapment. Recalls affected approximately 25,400 units of infant hammocks.

The six infant inclined sleep products and one infant inclined sleep accessory included with a play yard were recalled due to hazards including: entrapment, suffocation, fall, exposure to mold, and death after infants rolled from their back to their stomach or side while unrestrained in the products. Recalls affected approximately 6.4 million units of infant inclined sleep products. One recall for exposure to mold affected 800,000 units, and two recalls for entrapment and suffocation affected 195,000 units.

In 2019, two recalls occurred due to reports of infant deaths while using infant inclined sleep products, after the infants rolled from their back to their stomach or side while unrestrained, or under other circumstances. In response to the reported deaths in those products, CPSC conducted two additional recalls due to safety concerns with infant inclined sleep

products, one with an infant inclined sleep product, and one with an infant inclined sleep accessory included with a play yard. Recalls involving infant inclined sleep products affected approximately 5.4 million units and the recall involving the infant inclined sleep accessory affected approximately 71,000 units.

The Commission also has issued two safety alerts involving infant inclined sleep products. A May 31, 2018 safety alert<sup>7</sup> advised of infant rollover deaths in inclined sleep products, and reminded caregivers to always use restraints and to stop using the product as soon as an infant can roll over. An April 5, 2019 safety alert<sup>8</sup> advised consumers to stop use of the inclined sleep product when an infant reaches three months of age, or as soon as an infant exhibits rollover capabilities.

#### **IV. Mannen Study**

During the development of this Supplemental NPR briefing package, staff received reports of 451 new incidents, 59 of which were deaths that occurred while in infant inclined sleep products. Accordingly, Commission staff contracted with Dr. Erin Mannen, Ph.D., a mechanical engineer with a biomechanics specialization, to conduct infant testing to evaluate the design of inclined sleep products. Tab B of the Staff Supplemental Briefing Package contains Dr. Mannen's study, *Biomechanical Analysis of Inclined Sleep* (Mannen Study).

The Mannen Study examined how 10 infants move and use their muscles on flat, inclined surfaces, and in selected inclined sleep products, and whether such product designs directly impact safety or present a risk factor that could contribute to the suffocation of an infant. Testing compared infants' muscle movement and oxygen saturation on a flat crib mattress at 0°, 10°, and 20° versus seven different inclined sleep products. Researchers

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<sup>7</sup> <https://www.cpsc.gov/content/cpsc-consumer-alert-caregivers-urged-to-use-restraints-with-inclined-sleep-products>

<sup>8</sup> <https://www.cpsc.gov/Newsroom/News-Releases/2019/CPSC-ALERT-CPSC-and-Fisher-Price-Warn-Consumers-About-Fisher-Price-Rock-N-Play-Due-to-Reports-of-Death-When-Infants-Roll-Over-in-the-Product>

recorded infant muscle activity using surface electromyography (EMG), and recorded oxygen saturation using a medical grade pulse oximeter. Researchers placed infants in a random order in each of the 10 testing conditions, in both the supine and prone positions, for at least 60 seconds (unless the oximeter data fell below 95%, in which case they were removed early to ensure safety).

Following are key findings of the Mannen Study:

- Inclined surfaces and incline sleep products resulted in significantly higher muscle activity of the turn core muscle (abdominals), which may lead to quicker fatigue and suffocation if an infant finds themselves prone in an incline sleep product.
- Muscle synergies (*i.e.*, how muscles work together) are significantly different in inclined sleep products. If an infant rolls from supine to prone in an inclined sleep product, it is likely the first time the baby has experienced the position and the demands the position requires of the muscles.
- Some inclined sleep products require greater neck and trunk adjustments during prone positioning, indicating that infants may struggle to adjust their posture to enable breathing and attempt to self-correct if a roll from supine to prone occurs.
- Prone lying in the incline sleep products puts infant at higher risk of suffocation as evidenced by oxygen saturation results.
- Some evidence was found that supports the idea that the inclined sleep products make the babies roll more easily from supine to prone. The flexed trunk and ease of head lifting during supine lying in an inclined sleep product may indicate that supine to prone rolling is achieved more easily.

- If babies roll from supine to prone in an inclined sleep product, then, due to the high musculoskeletal demands necessary to maintain safe posture to prevent suffocation, babies would fatigue faster than they would on a stable, flat surface.
- None of the inclined sleep products that were tested and evaluated as a part of this study are safe for infant sleep.

Additionally, the Mannen Study concludes:

- ***20-Degree Incline Puts Infants at Risk for Muscle Fatigue and Suffocation***

Based on the results of the biomechanical study, the 20-degree incline resulted in significantly different muscle activity for the infants compared to the zero-degree incline surface. The increased demand on the abdominal muscles could lead to increased fatigue and suffocation if an infant is unable to reposition themselves after an accidental roll from supine to prone occurs.

- ***10-Degree Incline Does Not Significantly Impact Infant Motion or Muscle Activity***

Based on the results of the biomechanical study, fewer differences in muscle activity or lying posture were revealed at a 10-degree mattress incline compared to the zero-degree incline surface. Ten degrees is a safe incline for sleep on a crib mattress surface.

- ***Inclines Between 10 and 20 Degrees Should Be More Thoroughly Studied***

The experimental design of this study did not examine the angles between 10 and 20 degrees, so future work should focus on understanding which, if any, angles between 10 and 20 degrees may be safe for infant sleep.

The Mannen Study further states: “It is likely that in incidents where babies were found deceased in the prone position, that an accidental roll occurred, and after some amount of struggling, the

baby was fatigued and could no longer move into a position to prevent suffocation.” Dr. Mannen concludes that an incline of 20 degrees or more puts an infant at risk compared to a 0-10 degree incline. Although her study did not test infants on inclines between 10-20 degrees, and thus did not offer conclusions for these angles, CPSC staff advises that additional testing on inclines between 10-20 degrees is unnecessary, because staff concludes that a flat surface that does not exceed 10 degrees offers the safest sleep environment for infants. This conclusion comports with staff’s recommendations to remove the term “inclined” from the proposed mandatory standard, and to require that all sleep products not otherwise specified as cribs (full-size or non-full-size), play yards, or bedside sleepers meet the requirements in 16 CFR 1218 Safety Standard for Bassinets and Cradles, which, among other requirements, mandates that the seat back surface angle intended for sleep be 10 degrees or less.

## **V. International Standards for Inclined Sleep Products**

The 2017 NPR described international standards that include infant inclined sleep products within their scope, noting that these standards are intended primarily to address hazards associated with products having flat sleeping surfaces, such as bassinets and cradles. These standards 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. CPSC staff determined that the Canadian regulation provides similar performance requirements as ASTM F3118, but contains a more stringent requirement limiting the sleep seat back angle to 7° or less. However, the Canadian regulation allows a

product to be marketed as a “napper,” which the Supplemental NPR proposes not to allow.

- *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. CPSC staff believes the ASTM standard is more inclusive because it includes all hammock styles. Additionally, EN 1130 does not address the hazards identified in the Mannen Study.
- *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. Staff is unclear whether 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, as well as general provisions, such as those for included toys. AS/NZS 4385 has some similar performance requirements as ASTM F3118, but is not as comprehensive. Additionally, the AS/NZS 4385 does not address the hazards identified in the Mannen Study.

## **VI. 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, the Commission directed CPSC staff to work with ASTM to 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 F3118-17a, was approved on September 1, 2017, and published in October of 2017. This is the fourth revision to the standard since it was first published in May 2015. ASTM F3118-17a is intended to address the following hazards: (1) falls, (2) positional asphyxiation, and (3) obstruction of nose and mouth by bedding.

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

The 2017 NPR described the key provisions of ASTM F3118-17, including: scope, terminology, general requirements, performance requirements, test methods, marking and labeling, and instructional literature. 82 FR at 16967. The Supplemental NPR proposes to incorporate by reference the most recent version of the voluntary standard, ASTM F3118-17a, which is substantially the same as ASTM F3118-17, except that the accessory definition was updated to match the modification recommended in the 2017 NPR. Like the previous version, ASTM F3118-17a describes the scope of the voluntary standard, defines terms for various types of inclined sleep products, and sets out requirements for performance (such as for structural

integrity and stability) and for warnings and instructions. As discussed elsewhere in this preamble, CPSC’s proposed standard would make substantial modifications to ASTM F3118-17a.

## **VII. Assessment of the Voluntary Standard ASTM F3118-17a**

In the 2017 NPR, CPSC proposed that incorporating by reference ASTM F3118-17, with a modification to the definition of “accessory,” would address the primary hazard patterns identified in the incident data. 82 FR at 16967-68. However, since the 2017 NPR, CPSC has become aware of additional fatalities and contracted the Mannen Study. The Mannen Study and more recent incident data indicate that ASTM F3118-17a is not adequate to address the risk of injury associated with infant inclined sleep products because the standard allows for products with a seat back angle greater than 10 degrees. The Commission finds that more stringent requirements than those found in ASTM F3118-17a are necessary in a mandatory rule to further reduce the risk of injury associated with infant inclined sleep products.

Following is an explanation of how the Supplemental NPR would address the product-related hazard patterns identified in section III.C of this preamble, discussing the proposed more stringent requirements where appropriate.

### *A Design Problems*

#### 1. Suffocation Hazard

The Mannen Study results reveal that a 20° incline results in significantly different muscle activity for the infants compared to a 0° incline surface. The increased demand on infant abdominal muscles could lead to increased fatigue and suffocation if an infant is unable to reposition themselves after a roll from supine to prone occurs. At a 10° incline, fewer differences in muscle activity or lying posture were revealed compared to the 0° incline surface. According to Dr. Mannen’s report, “ten degrees is likely a safe incline for sleep on a crib

mattress surface.” Accordingly, the Commission proposes modifications to the introduction, scope, definitions, and performance requirements in ASTM F3118-17a, as described in section VIII of this preamble, to address the potential hazards of an infant sleeping on an inclined surface. Although her study did not test infants on inclines between 10°-20°, and thus did not offer conclusions for these angles, CPSC staff advises that additional testing on inclines between 10°-20° is unnecessary, concluding that a flat surface that does not exceed 10° offers the safest sleep environment for infants and would further reduce the risk of injury associated with inclined sleep products.

## 2. Additional Design Issues

CPSC staff identified two additional design issues: (1) 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, no evidence supports this belief. 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. Tab E of the Staff Supplemental Briefing Package provides the Directorate for Health Science's analysis of plagiocephaly and torticollis related to infant sleep products.

*B. Electrical issues*

Staff determined that 127 of the 451 new incidents are related to electrical issues. The electrical-related issues included battery leakage, electric shock, and overheating of components. Some inclined sleep products have accessories that provide music, rocking motion, or vibration, which are either battery- or a/c-powered; however, F3118-17a does not include any performance requirements for electrical components. Other juvenile products that have similar features include performance requirements that could apply for infant sleep products. CPSC staff has raised this issue and is working with the ASTM Ad Hoc task group to develop performance requirements to address electrical hazards across juvenile products. Performance requirements would apply to other children's product standards, such as bouncers, swings, and bassinets. Because these requirements are currently under development, the Commission is not proposing electrical requirements in this Supplemental NPR, and instead expects staff to continue working with applicable ASTM subcommittees to develop electrical requirements for all applicable durable infant or toddler products with electrical components.

*C. Structural Integrity and Other Product Related Issues*

Structural integrity and other product related issues identified in this Supplemental NPR are similar to issues previously found in bassinet/cradle incidents. Accordingly, performance and testing requirements in the bassinet/cradle standard will likely address these incidents for infant sleep products.

*D. Infant Placement Issues*

Infants placed prone on soft bedding in inclined sleep products are at great risk for suffocation because of the incline and the soft bedding. Although requiring infant sleep products to comply with the bassinet/cradle standard will reduce the incline angle, and will provide warnings about not using soft bedding, parents may still place infants prone in the product. Staff will continue to work with ASTM and other organizations with information and education campaigns to prevent infants' deaths due to unsafe sleep practices.

**VIII. Proposed Standard for Infant Sleep Products**

This Supplemental NPR proposes to establish a children's product safety standard for infant sleep products as a type of durable infant or toddler product under section 104 of the CPSIA. The Mannen Study findings and incident reports indicate that neither ASTM F3118-17, nor ASTM F3118-17a, are adequate to address the risk of injury associated with infant inclined sleep products, because these voluntary standards allow for infant inclined sleep products with a seat back angle greater than 10 degrees. More stringent requirements are necessary in the mandatory standard to further reduce the risk of injury associated with infant inclined sleep products. Accordingly, the Supplemental NPR proposes to incorporate by reference ASTM F3118-17a as the mandatory standard for infant sleep products, with the following modifications:

- a. Modify the introduction and scope of the standard to state the purpose of the standard is to address all infant sleep products not already covered by traditional sleep product

standards.

- b. Modify the definitions of accessory, compact, infant inclined sleep products, and newborn inclined sleep products to remove the term “inclined.”
- c. Modify seat back angle so the maximum allowable seat back angle must be equal to or less than 10° in all positions recommended for sleep.
- d. Add new requirement - infant sleep products must meet 16 CFR 1218 Safety Standard for Bassinets and Cradles.
- e. Remove all the performance requirements except for the above new or modified requirements.
- f. Remove all test methods except for maximum seat back angle.

The Supplemental NPR proposes that infant sleep products meet 16 CFR 1218 Safety Standard for Bassinets and Cradles because this standard is an established standard for products that provide sleep accommodations for infants, and the standard addresses the hazard associated with inclined sleep by limiting the seat back angle to 10 degrees or less. Additionally, the name of CPSC’s standard would not include the term “inclined,” and would be codified as 16 CFR part 1236, Safety Standard for Infant Sleep Products. A redline of these proposed changes is included at Tab C of the Staff Supplemental Briefing Package.

The Supplemental NPR proposes that infant sleep products meet the warning requirements in the bassinet and cradle standard, instead of those stated in ASTM F3118-17a. For this proposed modification, the Supplemental NPR relies on focus groups with parents and grandparents of infants less than 1 year of age. Participants provided information on caregivers’ perceptions and reactions to safety messaging, indicating that participants were aware of warning labels on infant sleep products. Additionally, participants reported that the label shown during the focus group looked similar and contained comparable information to

labels that they find on products they own. Some participants reported that they tend to gloss over warning labels, as they believe the language to be the same on every label. Some participants reported that they thought the main message on a warning label was to be careful and keep an eye on their infant. In contrast, a few participants believed that manufacturers use warning labels to protect themselves from liability or litigation. Participants' recommendations to improve warning labels included making the labels more concise and making the labels "stand out." CPSC staff is working with a contractor to develop new safe sleep warnings and messaging, potentially across all sleep products. In the future, staff could recommend changes in warnings based on this work.

#### **IX. Proposed Amendment to 16 CFR part 1112 to Include NOR for Infant 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 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 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](http://www.cpsc.gov/labsearch).

#### **X. 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, including several types of infant sleep products, such as cribs and bassinets and cradles. Section 104(f)(2)(A) & (L). As discussed previously, the infant sleep products safety standard is an outgrowth of the bassinet safety standard. The Supplemental NPR proposes that any infant sleep product that is not already subject to a mandatory consumer product safety rule for infant sleep, be subject to proposed part 1236, which would limit the seat back incline angle to 10 degrees or less. Like bassinets, such sleep products are durable products within the meaning of section 104 of the CPSIA.

Because this infant sleep product standard is an outgrowth of the bassinet standard, infant 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 infant 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 Supplemental NPR, the Commission proposes to amend the definition of “durable infant or toddler product” in the consumer registration rule to clarify that infant sleep products fall within the term “durable infant or toddler product” as a subset of bassinets and cradles, and must comply with the product registration card rule and section 104 of the CPSIA.

## **XI. Incorporation by Reference**

The Commission proposes to incorporate by reference ASTM F3118-17a, with substantial modifications to further reduce the risk of injury. 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 VIII of this preamble summarizes the provisions of ASTM F3118-17a that the Commission proposes to incorporate by reference. ASTM F3118-17a 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.

## **XII. 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 F3118-17a is a relatively 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 F3118-17a, with substantial modifications to further reduce the risk of injury associated with infant inclined sleep products. To allow time for infant sleep product manufacturers to bring their products into compliance after a final rule is issued, the Commission proposes a 12-month effective date after publication of a final rule, for products manufactured or imported on or after that date. Because of the number of proposed modifications to ASTM F3118-17a, compliance with the mandatory standard may require time beyond the typical 6-month effective date for a section 104 rule. The Commission expects that most firms should be able to comply within the 12-month timeframe. Alternatively, given the hazards involved with infant inclined sleep products, the Commission could issue a final rule with a shorter effective date so that safer products would be available sooner. The Commission requests comments on whether either a longer or shorter effective date would be appropriate.

## **XIII. 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. 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

Additionally, 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.

CPSC staff prepared an IRFA for this rulemaking which appears at Tab F of the Staff Supplemental Briefing Package. We provide a summary of the IRFA below.

*B. Reasons for Agency Action and Legal Basis for Supplemental NPR*

As explained elsewhere in this preamble, section 104 of the CPSIA authorizes the Commission to issue standards for durable infant or toddler products and requires that such products comply with product registration requirements. The Commission is issuing this Supplemental NPR in response to reports of deaths involving inclined sleep products.

*C. Supplemental NPR Requirements*

The Supplemental NPR would incorporate by reference the voluntary standard for inclined sleep products (ASTM F3118-17a) with substantial modifications described in section VIII of this preamble. Products subject to the proposed standard would need to have a sleep surface angle no greater than 10° and would need to meet the requirements of the CPSC standard for bassinets and cradles. If the Commission issues a final rule, the proposed rule would become a mandatory standard, and firms with a sleep product that is subject to the rule would need to evaluate their product, determine what changes would be required to meet the standard, and modify the product so that it complies with the standard or cease supplying the product to the U.S. market. The manufacture or importation of noncompliant products would be prohibited after the effective date of the standard. Additionally, manufacturers and importers must certify that their products comply with applicable children's products safety standards, and this certification must be based on testing by a third party. 16 CFR part 1107.

*D. Small Entities Supplying Infant Sleep Products and the Supplemental NPR's Impact on Small Businesses*

Since the Commission issued the 2017 NPR, the U.S. inclined sleep product market has changed substantially. Manufacturers and importers have largely stopped producing for sale most frame-style inclined sleep products from the market, including some that were not subject

to recalls, although one or two types of products remain.<sup>9</sup> Additionally, a significant decline in the infant hammock market has occurred, both among larger-scale suppliers and home-based manufacturers.

As part of the current market evaluation, staff identified 18 firms still supplying sleep products to the U.S. market with sleep surface angles greater than 10 degrees, but less than or equal to 30 degrees. Staff identified an additional firm supplying a sleep product with an incline of 10 degrees or less that is not being tested for compliance with either the bassinet standard or another sleep product standard (and thus, likely would be subject to the Supplemental NPR). Of these 19 total firms, six appear to be very small, home-based manufacturers of infant hammocks (two operating domestically and four overseas).<sup>10</sup> The RFA covers only domestic suppliers. Seven of the 19 firms are not as small as the home-based infant hammock manufacturers, but would meet the definition of “small” domestic entities based on U.S. Small Business Administration (SBA) guidelines for their North American Industry Classification System (NAICS) codes. These seven firms typically have only one inclined sleep model in their product lines.

In summary, CPSC staff is aware of nine small domestic firms currently marketing products that would be impacted by the Supplemental NPR in the United States (two home-based domestic hammock manufacturers, four small domestic manufacturers of inclined sleep products, and three small importers of inclined sleep products). Staff cannot definitively determine the impact of the Supplemental NPR because the impact would depend on several unknown factors including:

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<sup>9</sup> Some units may still be available for sale even for products that are no longer being produced (this does *not* include recalled models).

<sup>10</sup> These suppliers were identified online, and staff believes that there may be additional home-based manufacturers supplying infant hammocks on a very small scale (possibly including some without an on-line presence).

- How firms respond to the rule (*e.g.*, they would redesign, remarket, or drop products subject to the Supplemental NPR);
- The costs associated with redesigning, remarketing, or replacing an inclined sleep product;
- The change, if any, on demand for that product.

Staff estimates that third party testing costs could be \$30 to \$100 per sample for the maximum incline test alone, and testing to the bassinet standard could add costs up to another \$1000. Reliance on third party tests obtained by suppliers as allowed by the component part testing rule (16 CFR part 1109) could reduce testing costs to some extent. Staff found that third party costs are likely to be significant for the two very small home-based manufacturers of infant hammocks *if they choose to redesign*; and costs could be significant for an additional two small manufacturers, if they chose to redesign their products and testing as few as four units per model were required to provide a “high degree of assurance.”

#### *E. Alternatives*

At least two alternatives are available that could minimize the economic impact on small entities while also meeting the statutory objectives:<sup>11</sup> (1) eliminate the requirement that products must meet the bassinet standard if they do not already fall into another sleep product standard; or (2) allow a later effective date. However, under the first alternative, the cost of redesign would still likely be significant. Moreover, the Supplemental NPR is intended to ensure that all products providing sleep accommodations for infants meet a base set of safety requirements.

This alternative would not accomplish this goal.

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<sup>11</sup> Staff considered whether adopting the voluntary inclined sleeper standard with no modifications might also be an alternative, but ruled it out because it would not address the injuries and deaths that led to the recent inclined sleeper recalls.

Second, the Commission could also reduce the Supplemental NPR's impact on small businesses by setting a later effective date than the proposed 12 months. A later effective date would reduce the economic impact on firms redesigning their existing products 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 requests comments on the 12-months effective date, which was set to help reduce the impact on affected firms, as well as feedback on how firms would likely respond to the Supplemental NPR.

*F. 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 CFR part 1112. Consequently, the Commission proposes to amend 16 CFR part 1112 to establish the NOR for those testing laboratories that want to test for compliance with the infant sleep products final rule (in essence, test for maximum seat back angle). 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 rule to include the NOR for the infant sleep product standard will not have a significant adverse impact on small laboratories. Moreover, based upon the number of laboratories in the United States that have applied for CPSC acceptance of the accreditation to test for conformance to other juvenile product standards, we expect that only a few laboratories will seek CPSC acceptance of their accreditation to test for conformance with the infant sleep product 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 infant sleep product 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. Consequently, the Commission certifies that the NOR for the infant sleep product standard will not have a significant impact on a substantial number of small entities.

#### **XIV. 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 Supplemental NPR falls within the categorical exclusion.

## **XV. 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 Sleep Products

*Description:* The Supplemental NPR would incorporate by reference ASTM F3118-17a, *Standard Consumer Safety Specification for Infant Inclined Sleep Products*, but with modifications, including to sections 8 and 9 which contain requirements for marking, labeling, and instructional literature. The Supplemental NPR would exclude from the rule infant sleep products covered by another mandatory standard for sleep products (Section 1.3). However, the Supplemental NPR would modify section 5.2 of ASTM F3118-17a to require that accessory, compact, infant sleep products, and newborn sleep products meet the requirements of the Safety Standard for Bassinets and Cradles (16 CFR 1218), including the marking, labeling, and

instructional requirements. These marking, labeling, and instructional 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 sleep products.

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

Table 1 – Estimated Annual Reporting Burden

Burden Type	Type of Supplier	Number of Respondents	Frequency of Responses	Total Annual Responses	Hours per Response	Total Burden Hours
Labeling	Home-based manufacturers	6	1	6	7	42
	Other Suppliers	13	1	13	1	13
<b>Labeling Total</b>						<b>55</b>
Instructional literature	Home-based manufacturers	6	1	50	300	300
<b>TOTAL BURDEN</b>						<b>355</b>

Our estimate is based on the following:

Two groups of quantifiable entities supply infant sleep products to the U.S. market that will likely need to make some modifications to their existing warning labels to meet the requirements for bassinet and cradle warnings. The first group consists of very small home-based manufacturers, which may not currently have warning labels on their infant sleep products. Similar rulemakings (such as that for sling carriers) assumed that it would take home-based manufacturers approximately 15 hours to develop a new label. Given that some home-based manufacturers supply infant sleep products with warning labels already, we have estimated approximately 7 hours per response for this group of suppliers. Therefore, the total burden hours for very small home-based manufacturers is 7 hours per model x 6 entities x 1 models per entity = 42 hours.

The second group of quantifiable entities supplying infant sleep products to the U.S. market that will need to make some modifications to their existing warning labels are non-home-based manufacturers and importers. These firms do not operate at the low production volume of the home-based firms. All of the firms in this second group have existing warning labels on their products, but not for bassinets and cradles and would therefore, have to make label modifications. Given that these firms are used to working with warning labels, we estimate that the time required to make any modifications now or in the future would be about 1 hour per model. Based on an evaluation of supplier product lines, each entity supplies an average of 1 model of infant sleeper; therefore, the estimated burden associated with labels for this second group is 1 hours per model x 13 entities x 1 models per entity = 13 hours.

The total burden hours attributable to warning labels is the sum of the burden hours for both entity groups: very small home-based manufacturers (42 burden hours) + non-home-based manufacturers and importers (13 burden hours) = 55 burden hours. We estimate the hourly compensation for the time required to create and update labels is \$34.61 (U.S. Bureau of Labor Statistics, “Employer Costs for Employee Compensation,” March 2019, total compensation for all sales and office workers in goods-producing private industries, series id CMU201G000200000D: <http://www.bls.gov/ncs/>). Therefore, the estimated annual cost to industry associated with the labeling requirements is \$1,904 (\$34.61 per hour x 55 hours = \$1,904). No operating, maintenance, or capital costs are associated with the collection.

The Standard for Bassinets and Cradles (section 9) requires instructions to be supplied with the product. As already noted, the proposed Safety Standard for Infant Sleep Products requires accessory, compact, infant sleep products, and newborn sleep products to meet these requirements. 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 infant sleep products that generally require use instructions but lack such instructions. However, it is possible that the six home-based manufacturers of infant hammocks 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. 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 \$10,383 (50 hours per model x 6 entities x 1 models per entity = 300 hours x \$34.61 per hour = \$10,383). Not all firms would incur these costs every year, but new firms that enter the market would incur these costs, and this is a highly fluctuating market. Other firms are estimated to have no burden hours associated with section 9 of the Standard for Bassinets and Cradles because any burden associated with supplying instructions with infant sleep products would be “usual and customary” and not within the definition of “burden” under the OMB’s regulations.

Based on this analysis, CPSC staff estimates that the Supplemental NPR for infant sleep products would impose a burden to industry of 355 hours at a cost of \$12,287 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;
- the estimated burden hours required for home-based manufacturers to modify warning labels;
- the estimated burden hours associated with label modification for non-home-based suppliers, including any alternative estimates;
- the estimated burden hours required for home-based manufacturers to modify (or, in some cases, create) instruction manuals.

## **XVI. 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.

## **XVII. Request for Comments**

This Supplemental NPR proposes a rule under section 104(b) of the CPSIA to issue a consumer product safety standard for infant sleep products, to amend part 1112 to add infant 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 infant sleep products as a durable infant or toddler product subject to CPSC consumer registration requirements. The Commission requests comments on the standard’s scope language; the proposed effective date; the costs of compliance with, and testing to, the proposed Safety Standard for Infant Sleep Products; and any aspect of this proposal. During the comment period, the ASTM F3118-17a Standard Consumer Safety Specification for Infant Inclined Sleep Products, is available as a read-only document at:

<http://www.astm.org/cpsc.htm>.

The Commission requests comments on the following specific issues:

- Products likely to be impacted by the Supplemental NPR, including the product categories discussed in the preamble and any additional types of products that commenters believe may be impacted by the Supplemental NPR.
- How firms with inclined sleep surfaces will likely respond to the Supplemental NPR, including suppliers of products with inclines above 10 degrees and products with inclines less than or equal to 10 degrees that do not already comply with the bassinet standard. We would also appreciate any information on the possible responses of consumers to changes in marketing. Additionally, any information on the approximate percentage of revenue attributable to these types of products

would be valuable. The Commission also requests any information regarding the safety of sleep angles in excess of 10 degrees but less than 20 degrees

- The impact that promulgating the Supplemental NPR would have on the cost of testing and certifying products, particularly on small manufacturers and importers. Any information on the number of samples that must be tested would be especially helpful. The Commission also requests comments on the third party testing costs of the maximum incline test in the Supplemental NPR.
- The cost of redesign, the time required for redesign, the likely response of manufacturers to the Supplemental NPR's requirements (*i.e.*, redesign, remarket, or drop), the possible change in demand due to remarketing or changing the sleep surface's degree of incline, the cost of (and time required for) remarketing, and (for firms supplying comments) the relative significance of inclined sleepers to their total revenue. The Commission also requests comments on testing costs, including the number of inclined sleeper units that typically need to be tested to provide a "high degree of assurance" of compliance.
- The age and developmental milestones referenced in the scope and definitions of the various infant inclined sleep products covered by ASTM F3118-17a. Because this Supplemental NPR proposes to address "infant sleep products" not already covered by traditional sleep products, the Commission is considering removing the upper age limit from the scope of the mandatory standard, to accommodate a broad scope of infant sleep products within the standard. The Commission's consideration is based on the fact that when staff knew the age of an infant, twenty percent of the fatalities and injuries involved infants 6 months and older.

- The 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). Section XII of this preamble proposes a 12-month effective date after publication of a final rule, for products manufactured or imported on or after that date, stating that a longer effective date than the typical 6 months for a section 104 rule may be necessary because of the number of proposed modifications to ASTM F3118-17a. Given the hazards involved with infant inclined sleep products, the Commission could issue a final rule with a shorter effective date so that safer products would be available sooner. The Commission requests comments on whether either a longer or shorter effective date would be appropriate.

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

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 or test method?**

\* \* \* \* \*

(b) \* \* \*

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

\* \* \* \* \*

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

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

**Authority:** 15 U.S.C. 2056a, 2065(b).

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

**§ 1130.2 Definitions.**

\* \* \* \* \*

(a) \* \* \*

(12) Bassinets and cradles, including bedside sleepers and infant sleep products;

\* \* \* \* \*

5. Add part 1236 to read as follows:

## **PART 1236-SAFETY STANDARD FOR INFANT SLEEP PRODUCTS**

Sec.

1236.1 Scope.

1236.2 Requirements for infant sleep products.

**Authority:** Sec. 104, Pub. L. 110-314, 122 Stat. 3016 (15 U.S.C. 2056a); Sec. 3, Pub. L. 112-28, 125 Stat. 273.

### **§ 1236.1 Scope.**

This part establishes a consumer product safety standard for infant sleep products, including: frame-type, hammock, compact, and accessory. This consumer product safety standard covers all infant sleep products that are not covered by another consumer product safety standard, including:

- (a) 16 CFR part 1218 Safety Standard for Bassinets and Cradles;
- (b) 16 CFR part 1219 Safety Standard for Full-Size Baby Cribs;
- (c) 16 CFR part 1220 Safety Standard for Non-Full-Size Baby Cribs;
- (d) 16 CFR part 1221 Safety Standard for Play Yards; and
- (e) 16 CFR part 1222 Safety Standard for Bedside Sleepers.

### **§ 1236.2 Requirements for infant sleep products.**

(a) Except as provided in paragraph (b) of this section, each infant sleep product must comply with all applicable provisions of ASTM F3118-17a, Standard Consumer Safety Specification for Infant Inclined Sleep Products (approved on September 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, email [fedreg.legal@nara.gov](mailto:fedreg.legal@nara.gov), or go to:

[www.archives.gov/federal-register/cfr/ibr-locations](http://www.archives.gov/federal-register/cfr/ibr-locations).

(b) Comply with ASTM F3118-17a with the following additions or exclusions:

(1) Instead of complying with Introduction of ASTM F3118-17a, comply with the following:

(i) *Introduction.* (A) This consumer safety specification addresses incidents associated with infant inclined sleep products identified by the U.S. Consumer Product Safety Commission (CPSC).

(B) In response to incident data compiled by the CPSC, this consumer safety specification attempts to minimize the following: fall hazards, positional asphyxiation, and obstruction of nose and mouth by bedding. The purpose of the standard is to address infant sleep products not already covered by traditional sleep product standards and to prevent deaths due to the use of Infant Sleep Products with a seat back angle greater than 10° from the horizontal.

(C) This consumer safety specification is written within the current state-of-the-art of infant sleep product technology and will be updated whenever substantive information becomes available that necessitates additional requirements or justifies the revision of existing requirements.

(ii) [Reserved].

(2) In section 1.1 of ASTM F3118-17a, replace the term “infant inclined sleep products” with “infant sleep products.”

(3) In section 1.2 of ASTM F3118-17a, replace the term “infant inclined sleep products” with “infant sleep products.”

(4) Instead of complying with section 1.3 of ASTM F3118-17a, comply with the following:

(i) 1.3 This consumer safety performance specification covers products that are not covered by other ASTM standards such as:

(A) ASTM F1169 Standard Consumer Safety Specification for Full-Size Baby Cribs;

(B) ASTM F406 Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards;

(C) ASTM F2194 Standard Consumer Safety Specification for Bassinets and Cradles;  
and

(D) ASTM F2906 Standard Consumer Safety Specification for Bedside Sleepers. This consumer safety performance specification covers free standing products with an infant 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 smaller products intended for newborns up to 3 months old or when a 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 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 infant 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.

(ii) [Reserved].

(5) In section 1.4 of ASTM F3118-17a, replace the term “infant inclined sleep product” with “infant sleep product.”

(6) Instead of complying with section 2 of ASTM F3118-17a, comply with the following:

(i) 2. Referenced Documents.

(ii) 2.1 ASTM Standards.<sup>1</sup> (A) F406 Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards;

(B) F1169 Standard Consumer Safety Specification for Full-Size Baby Cribs;

(C) F2194 Consumer Safety Specification for Bassinets and Cradles;

(D) F2906 Standard Consumer Safety Specification for Bedside Sleepers.

(iii) 2.2 Federal Standards.<sup>2</sup>

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<sup>1</sup> For referenced ASTM standard, visit the ASTM website, [www.astm.org](http://www.astm.org), or contact ASTM Customer Service at [service@astm.org](mailto:service@astm.org). For Annual Book of ASTM Standards volume information, refer to the standard's Document Summary page on the ASTM website.

<sup>2</sup> Available from U.S. Government Printing Office Superintendent of Documents, 732 N. Capitol St., NW, Mail Stop: SDE, Washington, DC 20401, <http://www.access.gpo.gov>.

- (A) 16 CFR part 1218 - Safety Standard for Bassinets and Cradles;
  - (B) 16 CFR part 1219 - Safety Standard for Full-Size Baby Cribs;
  - (C) 16 CFR part 1220 - Safety Standard for Non-Full-Size Baby Cribs;
  - (D) 16 CFR part 1221 - Safety Standard for Play Yards; and
  - (E) 16 CFR part 1222 - Safety Standard for Bedside Sleepers.
- (7) Do not comply with sections 2.3 and 2.4 of ASTM F3118-17a, including Figures 1 and 2.
- (8) In section 3.1.1 of ASTM F3118-17a, replace the following terms:
- (i) Replace the term “accessory inclined sleep product” with “accessory infant sleep product.”
  - (ii) Replace the term “inclined sleep product” with “infant sleep product.”
- (9) In section 3.1.2 of ASTM F3118-17a, replace the following terms:
- (i) Replace the term “compact inclined sleep product” with “compact infant sleep product.”
  - (ii) Replace the term “newborn inclined sleep product” with “newborn infant sleep product.”
- (10) Do not comply with sections 3.1.3 through 3.1.6 of ASTM F3118-17a.
- (11) Instead of complying with section 3.1.7 of ASTM F3118-17a, comply with the following:
- (i) 3.1.7 *infant sleep product, n*—a freestanding product, intended to provide a sleeping accommodation for an infant up to approximately 5 months of age, that is generally supported by a stationary or rocker base and that is not subject to any of the following standards:
    - (A) 16 CFR part 1218 – Safety Standard for Bassinets and Cradles;
    - (B) 16 CFR part 1219 – Safety Standard for Full-Size Baby Cribs;

(C) 16 CFR parts 1220 and 1221 – Safety Standard for Non-Full-Size Baby Cribs and Play Yards; and

(D) 16 CFR part 1222 – Safety Standard for Bedside Sleepers.

(ii) [Reserved].

(12) Do not comply with sections 3.1.7.1 through 3.1.9 of ASTM F3118-17a.

(13) Instead of complying with section 3.1.10 of ASTM F3118-17a, comply with the following:

(i) 3.1.10 *newborn sleep product, n*—a free standing product, intended to provide sleeping accommodations for a newborn up to approximately 3 months of age, that is supported by a stationary or rocker base and whose seat back length, measured from the bight, is not greater than 17 in. (432 mm) and that is not subject to any of the following standards:

(A) 16 CFR part 1218 – Safety Standard for Bassinets and Cradles;

(B) 16 CFR part 1219 – Safety Standard for Full-Size Baby Cribs;

(C) 16 CFR parts 1220 and 1221 – Safety Standard for Non-Full-Size Baby Cribs and Play Yards; and

(D) 16 CFR part 1222 – Safety Standard for Bedside Sleepers.

(ii) [Reserved].

(14) Do not comply with sections 3.1.11 through 3.1.13 of ASTM F3118-17a.

(15) Do not comply with section 5 of ASTM F3118-17a.

(16) Do not comply with sections 6.1 through 6.8 of ASTM F3118-17a.

(17) Instead of complying with section 6.9 of ASTM F3118-17a, comply with the following:

(i) 6.9 *Maximum Seat Back Angle*.

(ii) *6.9.1 Accessory, Compact, and Infant Sleep Product*—The angle of the seat back surface intended for sleep along the occupant’s head to toe axis relative to the horizontal shall not exceed 10° when tested in accordance with 7.11.2.

(iii) *6.9.2 Accessory, Compact, and Newborn Sleep Product*—The angle of the seat back surface intended for sleep along the occupant’s head to toe axis relative to the horizontal shall not exceed 10° when tested in accordance with 7.11.3.

(iv) *6.9.3 Accessory, Compact, Infant Sleep Products, and Newborn Sleep Products*—shall meet requirements of 16 CFR part 1218 Safety Standard for Bassinets and Cradles.

(18) Do not comply with sections 6.10 through 7.10 of ASTM F3118-17a.

(19) In section 7.11.2.1 of ASTM F3118-17a, replace “*Infant Inclined Sleep Product and Infant Inclined Sleep Product Accessory*” with “*Accessory, Compact, Infant Sleep Products, and Newborn Sleep Products.*”

(20) In section 7.11.2.1 of ASTM F3118-17a, replace “If applicable, place the product in the manufacturer’s recommended highest incline angle position.” with “If applicable, place the product in the manufacturer’s recommended highest seat back angle position intended for sleep.”

(21) In section 7.11.3 of ASTM F3118-17a, replace “*Newborn Inclined Sleep Product and Newborn Inclined Sleep Product Accessory*” with “*Accessory, Compact, Infant Sleep Products, and Newborn Sleep Products.*”

(22) Do not comply with sections 7.12 through 9, or the Appendix, of ASTM F3118-17a.

**Alberta E. Mills,**

*Secretary, Consumer Product Safety Commission.*

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