



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

The contents of this document will be discussed at the Commission meeting scheduled for Wednesday, May 19, 2021.

This document has been electronically approved and signed.

THIS MATTER IS NOT SCHEDULED FOR A BALLOT VOTE.

A DECISIONAL MEETING FOR THIS MATTER IS SCHEDULED ON: Wednesday, June 2, 2021

DATE: May 12, 2021

TO: The Commission
 Alberta E. Mills, Secretary

THROUGH: Jennifer Sultan, Acting General Counsel
 Mary T. Boyle, Executive Director

FROM: Daniel Vice, Acting Assistant General Counsel, Regulatory Affairs
 Mary A. House, Attorney, Regulatory Affairs

SUBJECT: Final Rule: Safety Standard for Infant Sleep Products

Staff is forwarding a briefing package to the Commission, recommending that the Commission publish in the *Federal Register* the attached draft final rule establishing a consumer product safety standard for infant sleep products. Pursuant to section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), the draft final rule would incorporate by reference the voluntary standard, ASTM F3118-17a, *Standard Consumer Safety Specification for Infant Inclined Sleep Products*, as the mandatory standard, with modifications to make the standard more stringent, to further reduce the risk of injury associated with flat and inclined infant sleep products.

Additionally, the draft final rule amends the Commission’s regulation regarding third party conformity assessment bodies, to include the mandatory standard for infant sleep products in the list of notices of requirements issued by the Commission; and the consumer registration rule, to identify infant sleep products as a durable infant or toddler product subject to consumer registration requirements, as a subcategory of bassinets and cradles.

Please indicate your vote on the following options:

- I. Approve publication of the attached notice in the *Federal Register*, as drafted.

 (Signature)

 (Date)

II. Approve publication of the attached notice in the *Federal Register*, with the specified changes.

(Signature)

(Date)

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

(Signature)

(Date)

IV. Take other action specified below.

(Signature)

(Date)

Attachment: Draft *Federal Register* notice – Final Rule: Safety Standard for Infant Sleep Products

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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: Final rule.

SUMMARY: Pursuant to the Consumer Product Safety Improvement Act of 2008 (CPSIA), the U.S. Consumer Product Safety Commission (CPSC) is issuing this final rule establishing a safety standard for infant sleep products, which are products marketed or intended to provide a sleeping accommodation for an infant up to 5 months of age, and that are not subject to any of CPSC's mandatory standards for infant sleep. CPSC is also finalizing an amendment to its regulations regarding third party conformity assessment bodies, to include the safety standard for infant sleep products in the list of notices of requirements (NORs) and an amendment to the consumer registration rule, to identify infant sleep products as a durable infant or toddler product subject to consumer registration requirements, as a subcategory of bassinets and cradles.

DATES: This rule will become effective [INSERT DATE 12 MONTHS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The incorporation by reference of the publication listed in this rule is approved by the Director of the Federal Register as of [INSERT DATE 12 MONTHS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Keysha Walker, Compliance Officer, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone: 301-504-6820; e-mail: *kwalker@cpsc.gov*.

SUPPLEMENTARY INFORMATION:

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I. Statutory Authority and Background

A. Statutory Authority

Section 104(b) of the CPSIA, 15 U.S.C. 2056a(b), requires the Commission to: (1) consult with 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 (15 U.S.C. 2056a(b)(1)(A)); and (2) promulgate, in accordance with 5 U.S.C. 553, consumer product safety standards that are substantially the same as such voluntary standards, or are more stringent than such voluntary standards if the Commission determines that more stringent standards would further reduce the risk of injury associated with such products. 15 U.S.C. 2056a(b)(1)(B). Additionally, section 104(b)(2) of the CPSIA directs the Commission to periodically review and revise the standards set forth under this subsection, to ensure that such standards provide the highest level of safety for such products that is feasible.

Section 104(d) of the CPSIA requires manufacturers of durable infant or toddler products to establish consumer registration card programs that comply with CPSC's implementing rule, 16 CFR part 1130. Additionally, under section 14 of the CPSA, children's products (such as durable infant or toddler products) must comply with testing and certification requirements that CPSC implemented through 16 CFR parts 1107, 1109, and 1110. Section 104(f)(1) of the CPSIA states that 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). Section 104(f)(2) of the CPSIA provides 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). The Commission's consumer registration rule at 16 CFR § 1130.2(a) defines a "durable infant or toddler product" as:

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DEFINITION OF DURABLE INFANT OR TODDLER PRODUCT means the following products intended for use, or that may be reasonably expected to be used, by children under the age of 5 years. The listed product categories are further defined in the applicable standards that the Commission issues under section 104(b) of the Consumer Product Safety Improvement Act of 2008, and include products that are combinations of [17 listed] product categories . . .

B. Infant Sleep Products Are Durable Infant or Toddler Products

This rule establishes a category of products called “infant sleep products,” which are all products marketed or intended to provide a sleeping accommodation for an infant up to 5 months of age, and that are not already subject to a mandatory CPSC sleep standard. The product category “infant sleep products” is not included in the statutory list of products in section 104(f)(2) of the CPSIA. However, similar sleep products, such as bassinets and cradles, and cribs, are listed in the statute; and the Commission has the authority to add product categories to the statutory list. The Commission adds product categories to the list of “durable infant or toddler products” through a rulemaking to amend 16 CFR § 1130.2, the Commission’s rule requiring durable infant or toddler products to meet consumer registration rule requirements. All durable infant or toddler products identified in § 1130.2 must meet the product registration card requirement; and because rules issued under section 104 of the CPSIA are children’s product safety rules, these products must also meet the third-party testing and certification requirements in section 14 of the CPSA, and implemented by the Commission in 16 CFR parts 1107, 1109, and 1110.

CPSC issued a notice of proposed rulemaking in 2017 (the 2017 NPR), proposing 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. 82 FR 16963, 16969-70 (Apr.

DRAFT

7, 2017). In 2019, CPSC issued a supplemental notice of proposed rulemaking (the 2019 SNPR), proposing to identify an “infant sleep product,” a broader category of infant sleep, as a durable infant or toddler product under section 104(f) of the CPSIA, also as a subcategory of bassinets and cradles. 84 FR 60949, 60957 (Nov. 12, 2019). The 2019 SNPR proposed to remove the term “inclined” from the proposed mandatory standard, which included removing the term “inclined” from the title, scope, introduction, and definitions of ASTM F3118-17a, and to include within the rule, instead: “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.” 84 FR at 60951. Accordingly, the 2019 SNPR proposed that the scope of the rule include two types of sleep products that are currently unregulated by CPSC under any mandatory standard, including inclined sleep products, meaning infant sleep products with a sleep surface angle greater than 10 degrees from horizontal, and flat (non-inclined) sleep products, meaning infant sleep products with a sleep surface angle equal to or less than 10 degrees.

For this final rule, CPSC will finalize the definition of an “infant sleep product” as a durable infant or toddler product, a category of products that is a subset of the bassinet and cradle standard, consistent with the 2019 SNPR. The final rule defines an “infant sleep product” as “a product marketed or intended to provide a sleeping accommodation for an infant up to 5 months of age,” and that is not already subject to one of CPSC’s mandatory standards for infant sleep:

- 16 CFR part 1218 - Safety Standard for Bassinets and Cradles
- 16 CFR part 1219 - Safety Standard for Full-Size Baby Cribs
- 16 CFR part 1220 - Safety Standard for Non-Full-Size Baby Cribs
- 16 CFR part 1221 - Safety Standard for Play Yards, or
- 16 CFR part 1222 - Safety Standard for Bedside Sleepers.

As defined in the final rule, an “infant sleep product” meets the definition of a “durable infant or toddler product” because the products are intended for infants up to 5 months old, and

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the products are “intended for use,” and “reasonably expected to be used,” by children under 5 years old. Moreover, products marketed or intended as a sleeping accommodation for an infant are similar to the products for infant sleep that are already included in the statutory list of durable infant or toddler products, such as cribs and bassinets and cradles. We also note that “infant sleep products” are further defined in the final rule, as provided in part 1130. Accordingly, adding “infant sleep products” as a durable infant or toddler product is consistent with the Commission’s approach of adding a durable infant or toddler product category that has a mandatory standard to the list of products in part 1130, to clarify that these products must meet the consumer registration rule, and the third-party testing and certification requirements for children’s product safety rules.

C. Consultation Regarding the Effectiveness of the Voluntary Standard

To meet the first requirement in section 104(b) of the CPSIA that the Commission 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). Staff’s participation in ASTM’s voluntary standards process includes providing anonymized incident data, participating in meetings to assess the ability of a voluntary standard to address the incident data, and working through the ASTM process to develop performance and labeling requirements to address identified hazards. Staff also comments or votes on certain ASTM ballots to revise voluntary standards. ASTM subcommittees consist of members who represent producers, users, consumers, government, and academia.¹

¹ ASTM International website: www.astm.org, “About ASTM International.”

DRAFT

In 2011, ASTM began work on a new standard for infant inclined sleep products. Development of this new ASTM standard for infant inclined sleep products, F3118, arose from efforts to update the voluntary standard for bassinets and cradles. Accordingly, staff's consultation process for the inclined sleep product rulemaking commenced in approximately 2011, when ASTM, with CPSC's concurrence, decided to separate hammocks and other inclined sleep products from the development of the bassinet standard, ASTM F2194, to develop a new voluntary standard that would specifically address the characteristics of inclined sleep products. For example, the bassinet standard requires a sleep surface angle of 10 degrees or less, and inclined products have a sleep angle greater than 10 degrees. Since then, staff has been actively participating in developing the voluntary standard for infant inclined sleep products.

In addition to working on ASTM's inclined sleep standard, staff also has been working with the ASTM subcommittee developing the bassinet standard since before 2011, and to this day, continues to provide incident data and participate in task group and subcommittee meetings, including meetings and ASTM ballots involving the currently unregulated flat sleep products within the scope of this final rule.

Sections V.A.3 and V.B.2 of this preamble contain additional information about CPSC staff's work on the products within the scope of the final rule, both inclined and flat sleep products, through the ASTM standards development process for the bassinet and cradle standard, the infant inclined sleep standard, and a new, unpublished standard for in-bed sleepers.

D. 2017 NPR and 2019 Termination Notice

When staff began working on the mandatory standard for bassinets and cradles, and participating with the ASTM standards development subcommittee, staff considered whether infant hammocks and other inclined sleep products should fall within the scope of the bassinet and cradle standard. Because the bassinets and cradles voluntary standard did not address

DRAFT

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 hammocks and other inclined sleep products, to address the characteristics of inclined products. Accordingly, the infant inclined sleep products safety standard was an outgrowth of the bassinet and cradle standard, intended to address products with an incline greater than 10 degrees from horizontal.

In approximately 2011, at the time CPSC separated infant inclined sleep products from the bassinets and cradles 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).

CPSC's 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). The 2017 NPR for infant inclined sleep products, which included hammocks, discussed 14 fatal incidents related to infant inclined sleep products, which were reported to have occurred between January 1, 2005 and September 30, 2016. 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," which was defined too narrowly to address potential hazards. 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 for the mandatory standard, more stringent requirements were necessary to further reduce the risk of injury associated with

DRAFT

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. 2063(a)(2). CPSC must publish an NOR for the accreditation of test laboratories to assess a product’s conformity with a children’s product safety rule. The 2017 NPR proposed that if issued as a final rule, the new *Safety Standard 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 sleep products. 82 FR at 16969. The 2017 NPR also proposed to amend 16 CFR part 1130, the Commission’s requirements for consumer registration for durable infant or toddler products, 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 consumer registration card requirements. *Id.* at 16969-70.

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, since issuing the 2017 NPR, CPSC had received reports of 42 additional fatalities associated with rocker-like inclined sleep products, and because the Commission had issued additional safety alerts and recalls involving infant inclined sleep products. To date, the Commission has not voted on the notice to terminate the 2017 NPR.

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E. 2019 SNPR

On October 16, 2019, staff provided the Commission with a briefing package recommending that instead of terminating the 2017 NPR, the Commission issue an SNPR. During the development of Staff's 2019 SNPR Briefing Package, staff received reports of 451 new incidents; 59 were deaths that occurred in infant inclined sleep products. 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's 2019 SNPR Briefing Package contains Dr. Mannen's study, *Biomechanical Analysis of Inclined Sleep* (Mannen Study).²

The Commission published an SNPR on November 12, 2019. 84 FR 60949. The 2019 SNPR proposed to issue a standard for "infant sleep products," meaning products that (1) provide sleeping accommodations for infants and (2) are not currently subject to a CPSC mandatory standard for infant sleep: bassinets/cradles, cribs (full-size and non-full size), play yards, and bedside sleepers (collectively, CPSC sleep standards). The 2019 SNPR proposed to incorporate by reference ASTM F 3118-17a, with modifications to require that for each infant sleep product: (1) the seat back angle intended for sleep must be equal to or less than 10 degrees from horizontal, and (2) must meet the requirements for a bassinet and cradle in the standard at 16 CFR part 1218. 84 FR at 60956. The Commission also proposed to amend the consumer registration rule to identify "infant sleep products" as a category of durable infant or toddler products under section 104(f) of the CPSIA, and proposed to amend the regulation at 16 CFR

² 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's SNPR Briefing Package) is available at: https://www.cpsc.gov/s3fs-public/SupplementalNoticeofProposedRulemakingforInfantSleepProducts_10_16_2019.pdf?TPVAJZEOcz9x9sKcEGltm4LskkonxUWv.

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part 1112, to add infant sleep products to the list of products that require third-party testing. *Id.* at 60957.

F. Overview of the Final Rule

For the final rule, the Commission is finalizing the requirements largely as proposed in the 2019 SNPR. The final rule incorporates by reference the voluntary standard, ASTM F3118-17a, *Standard Consumer Safety Specification for Infant Inclined Sleep Products*, with modifications to the introduction, scope, performance, and testing requirements, to further reduce the risk of injury associated with infant sleep products, both flat and inclined. The final rule requires that “infant sleep products,” defined as products marketed or intended to provide a sleeping accommodation for an infant up to 5 months of age, and that are not covered by a CPSC sleep standard, be tested to confirm the seat back/sleep surface angle is 10 degrees or less from horizontal, and meet the requirements of 16 CFR part 1218, *Safety Standard for Bassinets and Cradles*, including conforming to the definition of a “bassinet/cradle.” The scope of the final rule is also consistent with this definition of an “infant sleep product.” The final rule specifies CPSC’s sleep standards as:

- 16 CFR part 1218 - Safety Standard for Bassinets and Cradles
- 16 CFR part 1219 - Safety Standard for Full-Size Baby Cribs
- 16 CFR part 1220 - Safety Standard for Non-Full-Size Baby Cribs
- 16 CFR part 1221 - Safety Standard for Play Yards, or
- 16 CFR part 1222 - Safety Standard for Bedside Sleepers.

Products intended for sleep that already conform to a CPSC sleep standard in this list are not within the scope of the final rule.

The scope of the final rule, and the definition of “infant sleep product,” are purposely broader than the scope of the bassinet and cradle standard, and the definition of a “bassinet/cradle,” to capture within the scope of the final rule all products marketed for infant sleep for infants up to 5 months old that are not covered by a CPSC sleep standard; those that are

DRAFT

currently on the market, and any future products developed for this age group. CPSC’s intent is to set a baseline of safety for infant sleep products so that all of these products must, at a minimum, meet the performance and labeling requirements in 16 CFR part 1218, including conforming to the definition of a “bassinet/cradle,” and being tested and certified as meeting these requirements.

Based on the Commission’s review of inclined and flat sleep product incident data, and consideration of the comments on the 2017 NPR and the 2019 SNPR, the Commission is finalizing the requirements as proposed in the 2019 SNPR, with the following clarifications in the:

1. scope of the final rule, 16 CFR § 1236.1, by removing the examples of infant inclined sleep products, and aligning the scope of the rule to be consistent with the definition of “infant sleep product,” to avoid confusion about the scope of the rule, which includes inclined and flat products;
2. introduction of ASTM F3118-17a, by explaining more clearly that both inclined and flat sleep products fall within the definition of an “infant sleep product,” and that the purpose of the rule is to reduce deaths associated with known infant sleep hazards, including, but not limited to, seat back or sleep surface angles that are greater than 10 degrees from horizontal;
3. scope of ASTM F3118-17a, by revising section 1.3 to explain more clearly that inclined and flat products fall within the scope of the rule, and that products subject to the rule are infant sleep products that do not already meet a mandatory standard for a product intended for infant sleep. Consistent with the 2019 SNPR, revised section 1.3 lists existing infant sleep standards, but the final rule lists the five CPSC sleep

DRAFT

standards with a reference to the ASTM standard incorporated by reference in each mandatory standard;

4. scope of ASTM F3118-17a, by adding a new section 1.3.2 stating that crib mattresses that meet the voluntary standard for crib mattresses, ASTM F2933, are not included within the scope of the rule. The final rule does not cover a crib mattress because a crib mattress is not used by itself, and instead, is used as the sleep surface in a crib, a product that already must conform to a CPSC sleep standard;
5. referenced documents in ASTM F3118-17a, by revising section 2.1 to add the voluntary standard for crib mattresses, ASTM F2933;
6. definition of “infant sleep product” in ASTM F3118-17a, by revising section 3.1.7 to remove the phrases “freestanding” and “generally supported by a stationary or rocker base” from the definition, to not inadvertently exclude certain infant sleep products from the scope of the rule, such as those that may not initially have a base, or may be sold as an attachment to another product. Additionally, we revised the age limit in this definition from “approximately 5 months of age” by removing the term “approximately.” This revision is intended to reduce confusion about which products fall within the scope of the rule, and to clarify that any infant sleep product marketed or intended for an infant up to 5 months of age, and that is not already covered by a CPSC sleep standard, falls within the scope of the final rule;
7. definitions in ASTM F3118-17a, by revising section 3.1 to remove the definitions for “accessory inclined sleep product,” “compact inclined sleep product,” and “newborn inclined sleep product,” to simplify the regulation text, because these definitions are unnecessary based on the other modifications made to ASTM F3118-17a in the final rule, and because these products are subsumed within the definition of an “infant

DRAFT

sleep product,” and the final rule does not contain any unique requirements for these products;³

8. requirements in ASTM F3118-17a, by revising section 6.9 to remove separate “Maximum Seat Back Angle” tests for three product types (accessory, compact, and newborn), and leaving only the test for “infant sleep products,” because all products fall within the definition of an “infant sleep product” in the final rule, and because this test is the same for all products;
9. requirements in ASTM F3118-17a, by revising section 6.9 and 6.9.1 to more accurately describe the name of the test by clarifying that the seat back angle also refers to a “sleep surface angle.” This revision is intended to reduce confusion, because flat sleep surfaces do not have a seat back; and
10. requirements in ASTM F3118-17a, by revising section 6.9.3 to remove the references to accessory, compact, and newborn sleep products, and to state that infant sleep products must meet the requirements of 16 CFR part 1218, Safety Standard for Bassinets and Cradles, including conforming to the definition of a bassinet/cradle. This revision is intended to streamline the regulation text to reduce confusion, and to add a specific requirement to meet the definition of a bassinet, which clarifies that infant sleep products must have a stand to meet the performance and labeling requirements in part 1218.

The Commission is also finalizing the amendment to part 1112, to include “infant sleep products” in the list of children’s product safety rules for which CPSC has issued NORs, as well as the amendment to part 1130, to identify “infant sleep products” specifically as a subcategory of bassinets and cradles.

³ Note that in the 2019 SNPR the Commission proposed to revise these terms by removing the word “inclined.”

DRAFT

This final rule is based on information and analysis provided in Staff's Final Rule Briefing Package, submitted to the Commission on May 12, 2021, which can be found on the Commission's website at: [\[insert link\]](#).

II. Product Description

A. *Scope of Products Within the Final Rule*

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 scope of products covered by the 2019 SNPR broadened from the 2017 NPR, proposing to incorporate by reference 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 CPSC mandatory rule for a product intended for infant sleep: bassinets/cradles, cribs (full-size and non-full-size), play yards, and bedside sleepers. 84 FR at 60951.

For the final rule, the scope of products that fall within the rule is consistent with the 2019 SNPR, and includes all of the inclined sleep products in the 2017 NPR, plus additional products marketed or intended to provide a sleeping accommodation for an infant up to 5 months of age, and that are not currently covered by any of the five CPSC sleep standards. Accordingly, as proposed in the 2019 SNPR, the final rule includes the currently unregulated inclined sleep products, such as frame-type inclined sleep products, hammocks, compact inclined sleep products, and accessory inclined sleep products (collectively, inclined sleep products). The final rule also includes the currently unregulated non-inclined, flat, infant sleep products, which means products with a seat back or sleep surface angle that is already 10 degrees or less from horizontal (*i.e.*, baby boxes, in-bed sleepers, baby nests and pods, rigid-sided and rigid-framed

DRAFT

compact bassinets without a stand or legs, various designs of “travel bassinets” with soft padded or mesh sides, and baby tents (collectively, flat sleep products)). 84 FR at 60951. Tabs C and E of Staff’s Final Rule Briefing Package contain additional information and characteristics, as well as pictures of the infant sleep products subject to the final rule.

B. Products Excluded from the Scope of the Final Rule

Consistent with the 2019 SNPR, for the final rule, products with inclined or adjustable seat back positions that are covered by other CPSC standards, such as infant bouncer seats, strollers, hand-held carriers, frame carriers, and infant swings, are excluded from the scope of the ASTM infant inclined sleeper standard, and they are also excluded from the scope of the final rule, unless the product is specifically marketed for infant sleep for an infant up to 5 months of age. *Id.* at 60951-52. If a product’s packaging, marketing materials, inserts, or instructions indicate that the product is for sleep, or includes pictures of sleeping infants, then CPSC will consider the product to be marketed for sleep.

Products that are already compliant with another CPSC sleep standard, such as the bassinet standard (16 CFR part 1218), or the crib standard (16 CFR part 1219), are excluded from the scope of the final rule. Sleep wedge pillows and sleep positioners are out of scope for the final rule, and may be covered by Food and Drug Administration (FDA) regulations as medical devices, if they are marketed to treat a medical condition, such as acid reflux. Infant pillows are also out of scope for the final rule, and these products are subject to 16 CFR § 1500.18, “Banned toys and other banned articles intended for use by children.” Hammocks intended as photo props are out of scope for the final rule. Hammock accessories intended for shopping carts are also not in scope, as those products are not intended for infant sleep. Bath chairs with inclined backs are out of scope, as they are covered by another standard and are not intended for infant sleep. Pet beds, toy hammocks, and play tents labeled for children over 5

DRAFT

months are out of scope of the final rule. Loungers, floor chairs, and rockers are out of scope of the final rule, unless they are marketed for infant sleep on the product itself or its packaging, marketing materials, inserts, or instructions, or the product is advertised with pictures of sleeping infants.

Finally, in response to a comment on the 2019 SNPR, the Commission specifically is excluding from the scope of the final rule crib mattresses that fall within the scope of the voluntary standard for crib mattresses, ASTM F2933. A crib mattress, alone, does not meet the definition of an “infant sleep product,” and is always used in conjunction with a sleep product, such as a crib or play yard, that falls within one of CPSC’s sleep standards. The Commission issued a notice of proposed rulemaking for crib mattresses in 2020, and intends to finalize a separate rule later this fiscal year, providing performance and labeling requirements for crib mattresses, based on ASTM F2933.

C. Market Description⁴

Infant sleep products covered by this rule may be purchased at general retailers, online retailers, mattress and bedding stores, and baby specialty stores. At least 60 small U.S.-based manufacturers and importers are in this market, as well as five large domestic companies, and dozens of foreign companies, some that ship these items directly to customers in the United States via online marketplaces. More than a thousand home-based manufacturers, hundreds based in the United States, sell soft-sided baby nests and pods, in-bed sleepers, and infant hammocks directly to consumers via online marketplaces and as third-party sellers via major retailers’ websites. We estimate total sales in this market at more than \$125 million per year, to at least a third of U.S. households with newborns.

⁴ Tab E of Staff’s Final Rule Briefing Package contains CPSC staff’s analysis of the market for infant sleep products.

DRAFT

Products within the scope of the final rule compete with products for infant sleep that are compliant with one of CPSC's sleep standards and with other small, portable products that are not marketed for sleep. One goal of the final rule is to make it clearer to consumers which products are certified as compliant with a CPSC sleep standard, regardless of the product name or advertising.

The proliferation of physically different products with similar names (particularly "bassinets"), the many suppliers in the market, and new product types each season, reflect a competitive market for innovative sleep products. New sleep products are marketed as filling a need for a small, portable sleeping or napping space. Many items are also marketed specifically to facilitate bed-sharing.⁵ In addition to the marketing as secondary sleeping options, some of these compact and relatively inexpensive sleep products are also marketed as primary sleep spaces for families with limited living space and budget. Baby boxes, in-bed sleepers, and hammocks, in particular, are marketed as primary sleep spaces for babies.

CPSC did not find any evidence that consumer demand for compact, inexpensive, and portable sleep spaces cannot be met by products compliant with an existing CPSC sleep standard. Many small bassinets that are compliant with CPSC's bassinet standard sell for \$50 to \$75 and have a footprint similar to the flat sleep products covered by this rule. As for bed-sharing, bedside sleepers retail for as little as \$100. Cradles compliant with the bassinet and cradle standard have a swinging function similar to a hammock with a frame, often at a lower retail price. Innovative products compliant with the existing CPSC sleep standards have been introduced in recent years, including small, foldable play yards, oval cribs and bassinets,

⁵ Tab D of Staff's Final Rule Briefing Package contains CPSC staff's analysis of the hazards associated with bed-sharing.

DRAFT

bassinets that are attached to an adult chair, bassinets with rocking functions, and bedside sleepers with a rocking base.

1. Inclined Sleep Products

The 2019 SNPR described four types of inclined sleep products within the scope of the rule: frame-type inclined sleep products, hammocks, compact inclined sleep products, and accessory inclined sleep products. 84 FR at 60951. We update the market for these products below, grouping frame-type, compact, and accessory inclined products into one category, and hammocks into another category.

(a) Hard-Frame Inclined Sleepers, Compact Foam Inclined Sleepers, and Play Yard Accessories

Freestanding, inclined hard-frame sleepers retail for \$40 to \$120, depending on brand and features, such as attached toys, fabric coverings, battery-operated sounds, and adjustable positions. Compact foam inclined sleepers retail for about \$100. Hard-frame inclined play yard accessories are not sold separately; they are included in the price of the play yard.

In recent years, sales of inclined sleepers have totaled at least 722,000 units per year.⁶ The sales of these products alone total nearly a quarter of all households with newborn infants, given that just under 3.8 million live births occurred in the United States in 2018.⁷ Additionally, more than 4,000 adoptions from foreign countries occurred, but most of those infants were at least 1-year-olds by the time the adoption was finalized.⁸ We assume that some of the market for inclined sleepers has shifted to other flat sleep product categories covered by this rule, or shifted to small portable sleep products compliant with existing CPSC sleep standards. Since the CPSC published the NPR in 2017, some inclined sleep products have been recalled or otherwise

⁶ The recalled inclined products alone had sales of nearly 6.5 million from May 2010 to August 2019. Assuming that the recalled products represented most of the market, 6.5 million divided by 9 years is 722,000.

⁷ <https://www.cdc.gov/nchs/nvss/births.htm>.

⁸ https://travel.state.gov/content/travel/en/Intercountry-Adoption/adopt_ref/adoption-statistics-esri.html.

DRAFT

removed from the market. However, although reselling recalled products is prohibited, discontinued items sold on the secondary market that have not been recalled, as well as non-recalled physically similar products sold by small companies, are still available.

(b) Baby Hammocks

Hammocks range in price from about \$50 for a simple fabric hammock without a frame, to more than \$300 for a hammock with a wooden or metal stand. Crib hammocks, which are intended to attach to cribs or play yards of any brand, retail for about \$50 to \$100.

Baby hammocks are widely available from small domestic companies, importers, and home-based sellers. The websites of several major general retailers sell these items from third-party sellers. Hammocks are made of a variety of fabrics and may include padded sides or bottoms. They may come without a frame, or with a wooden or metal stand. Some items are solid fabric, while others are mesh or crochet. The market is fragmented, and all of the sellers in the United States are small companies, although some sellers are importers of items made by large foreign companies. The large number of sellers, including at least one company that sells only baby hammocks, and dozens of home-based sellers, suggests that thousands of baby hammocks are sold each year.

2. Flat Sleep Products

(a) Flat Sleep Surface, Soft-Sided Products

The flat sleep surface, soft-sided products that are not covered by a CPSC sleep standard include baby pods or baby nests, which are marketed for use on a hard surface or as in-bed sleepers, and soft-sided “bassinets.” Some soft-sided products are marketed for use inside a crib or bassinet. Some sleep products are marketed as portable or travel infant beds. The flat infant sleep products currently not covered by any voluntary or mandatory sleep standard, but would be regulated under the final rule, include:

DRAFT

- Baby pods and baby nests – These products have a soft floor, usually padded in some way, with low soft fabric or mesh sides, resembling a small pet bed. They can be rectangular, oval, or figure 8-shaped. Some come with a wedge pillow. They are sometimes marketed as suitable for use inside a crib or play yard.
- Soft-sided “travel bassinets” or “travel beds” – These products can have either a soft or semi-rigid floor. Some products come with straps and zippers so that they can be rolled up and carried like a backpack when not in use. Some are marketed as “3-in-1” products that can also be used as a changing mat and include pockets for diapers. Some products have a “cocoon” design, with a soft padded top, intended to cover the body of the occupant.
- Hand-held carriers marketed for sleep – These products are marketed as both a hand-held carrier and a (soft) bassinet, suitable for napping or sleeping.
- In-bed sleepers – These products have low, soft sides and a soft floor, specifically intended and marketed for bed-sharing.

Play yard accessories have mesh or fabric sides that attach to the rails of the play yard and are marketed for infant sleep, including “napping”; and they would not fall within the scope of the rule if they are already compliant with the bassinet standard. Items marketed as changing pads are not considered to be infant sleep products.

The prices for baby nests, baby pods, and in-bed sleepers range from about \$40 to \$200, with the lower-priced items tending to come from home-based manufacturers and foreign direct shippers, and the more expensive items coming from larger U.S. companies. Smaller products intended only for infants up to 5 months of age also tend to be cheaper than larger products intended for children up to 2 years old. The various soft-sided travel bassinets and “travel beds,” some that fold up into a backpack, have a similar price range. At least 30 small businesses,

DRAFT

mostly importers, sell the soft-sided flat sleep surface products.⁹ Dozens of foreign companies ship these sleep products directly to U.S. customers via U.S. Internet retailers, and there are more than 1,000 home-based sellers of baby pods and baby nests.

The estimated annual sales of in-bed sleepers alone are 1 million units,¹⁰ based on public comment and staff analysis. The Durable Nursery Products Exposure survey (DNPES) indicated that 38 percent of parents slept with their child under 1 year of age at least once a week, with 18 percent indicating they sleep with their child under 1 year of age every night. The CDC similarly found¹¹ that 24.4 percent of parents bed-shared with their infant “often or always” and 37 percent indicated they bed-shared “rarely or sometimes.” If parents who regularly sleep with their infants commonly purchase or make a soft-sided baby nest or other type of in-bed sleeper, then these products could be owned by 25 percent of households with newborns, representing about 1 million units sold per year, which is consistent with the estimate from a public comment on the 2019 SNPR.

(b) Flat Sleep Surface, Rigid-Sided and Rigid-Framed Compact Bassinets, Travel Bassinets, and Similar Products

This infant sleep product category includes flat sleep surface, free-standing products that resemble a bassinet without a stand or legs. Baby boxes and other rigid-sided products without a stand are marketed for infant sleep, sometimes as “compact” or “travel” bassinets. Some compact bassinets have mesh sides with a rigid metal or plastic frame. Larger rigid-sided items that comply with the play yard standard, and play yard accessories that are compliant with the bassinet standard, are out of scope for the final rule. Most flat sleep surface, rigid-sided products

⁹ This number is approximate, as the proliferation of Internet retailing allows importers to enter and exit the market quickly, and to switch their product line based on demand.

¹⁰ A public comment on the SNPR estimated the annual sales of “in-bed sleep products” at 500,000 to 1.5 million units, which is consistent with the estimates in the DNPES and from CDC on prevalence of bed-sharing.

¹¹ Bombard JM, Kortsmit K, Warner L, et al., Vital Signs: Trends and Disparities in Infant Safe Sleep Practices — United States, 2009–2015. *MMWR Morb Mortal Wkly Rep* 2018;67:39-46. DOI: <http://dx.doi.org/10.15585/mmwr.mm6701e1>.

DRAFT

are rectangular, but oval and round ones are also available. As noted, some flat, soft-sided items are also marketed as “travel” bassinets. The term “bassinet” is used in product names for rigid-sided items with a stand that meet CPSC’s bassinet standard, but the term is also used in product names of flat and inclined items without a stand, some with low and soft padded sides, which do not meet the bassinet standard. The final rule addresses this issue, and, in part, is intended to make it clearer to consumers which products are safe for infant sleep, regardless of the product name.

Rigid-sided and rigid-framed compact bassinets and travel bassinets typically sell for about \$50 to \$150, which is comparable to the lower end of the price range of bassinets that comply with the bassinet standard. Retail prices for baby boxes start at about \$50 to \$75, depending on the brand and decorative design, although some are sold only as part of a \$300, or more, bundle with clothes, diapers, and other baby items. Baby boxes were given away for free by some state governments and hospitals, so the cost to the consumer was \$0, although those organizations purchased them from a small domestic company that is no longer offering them. Play yard accessories are not priced or sold separately; rather, they are included in the price of the play yard.

Products in this category have a variety of names. Several small domestic manufacturers and small importers, as well as large domestic and foreign companies, sell small, rigid-sided or rigid-framed products that resemble a bassinet without a stand as “compact,” “portable,” or “travel” bassinets, or as infant “travel beds.” About a dozen sellers ship these products from the United States, and a few foreign companies sell through Internet marketplaces. The presence of several large domestic and foreign companies in this market, as well as introductions of innovative products each year, indicate that a strong consumer demand for these products. CPSC believes it likely that some of the demand for inclined rigid-sided products has shifted to this

DRAFT

market sector. Unlike the soft-sided products, this sector does not have many home-based businesses or foreign direct shippers.

Baby boxes are a sub-type of compact bassinet that are made of cardboard. They are sold in the United States by two small domestic companies and one foreign company and can also be purchased directly from several foreign companies. The sales are relatively small; estimated at under 20,000 per year.¹² This means that less than 1 percent of households with newborns purchase these items. Baby boxes are sometimes marketed as “Finnish” baby boxes, because the government of Finland provides new parents with a baby box or cash equivalent. As noted, in the past, some state and local hospitals gave away baby boxes to new parents or made them widely available through social service agencies.¹³ Like other compact bassinets, baby boxes are marketed as a primary sleep environment for newborns.

(c) Baby Tents

Baby tents, which are a small mesh or solid fabric products with a fabric floor are marketed for sun protection, play, and baby sleep. They are sometimes marketed as a combination of tent and “travel bed” or “travel bassinet.” Some baby tents come with flaps, covers, or shades so that the baby can sleep in darkness. Some products come with poles or stakes to fasten the tent to the ground or in the sand at the beach. Some tents have a shallow fillable pool/sandbox in the bottom, which indicates they are not intended primarily for sleep, but rather, for play.

Baby tents retail for about \$20 to \$75; larger and more expensive tents are available, but they are marketed for older children. Baby tents are offered for sale on major Internet general retailer websites and in general retail stores by about a dozen small importers and a few large

¹² A public comment estimated 2018 sales from two of the three U.S. baby box companies at more than 10,000.

¹³ Similar programs now offer free cribs or play yards.

DRAFT

companies. Dozens of foreign companies ship these baby tents directly to U.S. customers via U.S. Internet retailers; the majority of suppliers in this category are foreign direct shippers. Baby tents are marketed as a specialty item for outdoor use, particularly beach trips or camping, to shade the baby from sun and provide a place for playing and sleeping. Indoor “play” tents are also marketed for sleep, but those products are mostly marketed for children over 3 years of age. Indoor play yards with tent-like covers are in the scope of the play yard standard. Although baby tents are a relatively niche product, compared to some of the other types of sleepers, there appears to be sufficient demand for baby tents to support the market presence of dozens of companies, including a few large companies selling a variety of other baby products.

III. Incident Data and Hazard Patterns

A. *Inclined Sleep Products*

1. Incident Data

The 2017 NPR discussed 14 fatal incidents related to 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 facedown position. Two additional cases also reported a rollover into a facedown position, but the reports did not include any information about the use of a restraint. CPSC had little information about the cause or manner of the three remaining deaths. The 2017 NPR recognized that reporting was ongoing and that the number of reported fatalities could change. 82 FR at 16965-66.

The 2019 SNPR updated fatal and nonfatal incident reports associated with the use of an inclined sleep product. At the time of the 2019 SNPR, CPSC was aware of 451 incidents (59 fatal and 392 nonfatal) related to inclined sleep products that occurred from January 1, 2005 through June 30, 2019, and reported between October 1, 2016 and June 30, 2019. This

DRAFT

count included incidents reported after the reporting end date stated in the 2017 NPR. Forty-three percent of the incident reports (196 out of 451) were 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. 84 FR at 60952-53. Tab A of the October 16, 2019 Staff SNPR Briefing Package describes the incident data and the hazard patterns associated with infant inclined sleep products at the time of the SNPR.

For the final rule, the Directorate for Epidemiology staff, Tab B of Staff's Final Rule Briefing Package, describes 71 new incident reports associated with inclined sleep products since the 2019 SNPR. Of the 71 new reported incidents, 10 are fatalities; among the remaining 61 nonfatal incidents, 17 reported an injury. Reporting is ongoing, and therefore, the number of reported fatalities, nonfatal injuries, and non-injury incidents may change in the future.

(a) Fatalities

Since the 2019 SNPR, the Commission is aware of 10 fatalities associated with the use of an inclined sleep product that reportedly occurred during the period from January 1, 2019 through December 31, 2020.

- Three of the 10 fatal reports describe infants placed supine (on their back) in a rocker-like sleeper product, but who ended up rolling over, fully or partially, resulting in suffocations or positional asphyxiations. Staff does not know whether a restraint was used in any of these cases. All three decedents were 3- or 4-month-old infants.
- One report describes a fatality involving a foam-type reclined infant seat. The seat was placed on an adult bed, where the parents were also asleep. The seat was found tipped over on the floor, with the 4-month-old decedent found underneath the seat.

DRAFT

- One incident reports a fatality of a 3-month-old infant, found supine in an infant rocker-like product (in the same position as originally placed) with a blanket covering the infant's face.
- Five remaining fatality reports provide very little information on the incidents. Lack of any information on the circumstances leading up to the death does not allow CPSC staff to classify these deaths. Of the known ages, the decedents ranged in age from 1 to 6 months old.

(b) Nonfatal Incidents

Since the 2019 SNPR, the Commission has received reports of 61 nonfatal incidents associated with the use of an inclined sleep product that occurred between January 1, 2019 and December 31, 2020. Among these 61 reports, 17 reports involved an injury. We describe the severity of the 17 injuries below:

- Four infants required hospital admission. Three of the hospitalizations were for respiratory problems due to mold on the sleep product, and one was for treatment of injuries from a fall when an accessory-type product collapsed.
- Three infants were treated and released from emergency departments. Those infants were treated for respiratory problems from exposure to mold or for fall injuries.
- Ten infants required other medical care, mostly for *plagiocephaly* (flat head syndrome), *torticollis* (twisted neck syndrome), or both conditions, which were associated with prolonged use of inclined sleep products; two of the 10 infants suffered minor bumps/bruises due to falls or near falls.

The remaining 44 incidents reported no injuries, or provided no information about any injury.

However, many of the descriptions indicated the potential for a serious injury, or even death.

Thirty-four percent of the incidents involved infants 0 to 5 months of age, and 9 percent involved

DRAFT

infants 6 months to 12 months of age. CPSC does not know the infant's age in 58 percent of the incidents.

2. Hazard Patterns

The 2017 NPR identified nine hazard patterns among the 657 reported incidents associated with inclined sleep products. 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. 82 FR at 16965-66.

For the 2019 SNPR, CPSC staff considered all 451 reported incidents (59 fatal and 392 nonfatal) to identify hazard patterns associated with inclined sleep products; and staff described the variety of sleep products considered, such as: hammocks, which are suspended in air, seat-like products meant to be placed on a floor level (yet incident reports indicate these products often were not placed on floor level), and products that sit on top of larger nursery products as attachments. CPSC staff identified eight hazard patterns among 451 reported incidents in the 2019 SNPR, which differed, depending on which product was involved, and how the product was being used: design issues, electrical issues, consumer comments, undetermined issues (due to confounding information), structural integrity issues, other product-related issues, infant placement issues, and insufficient information. Staff's identified hazard pattern categories were very similar between the 2017 NPR and the 2019 SNPR. 84 FR at 60952-53.

For the final rule, staff again reports that the staff-identified hazard categories for inclined sleep products are very similar to those identified in the 2019 SNPR. Following a CPSC-issued safety recall on inclined sleep products in April 2019, staff observed a surge of reports related to the recall; these reports are combined with other consumer comments in the hazard categories. Staff identified the following hazard patterns among the 71 reported incidents (10 fatal and 61

DRAFT

nonfatal) associated with the use of infant inclined sleep products. The categories are presented in descending order of frequency:

(a) **Consumer comments:** Thirty-one of the 71 reported incidents (44 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 the April 2019 safety recall on inclined sleep products. Although one complaint describes a minor injury incident, none of the remaining reports indicate that an incident actually occurred.

(b) **Design** of the inclined sleep product: Twenty-four of the 71 reported incidents (34 percent) fall into this category.

(i) Ten incidents report that infants rolled over—fully or partially—from their original supine (on their back) position. Although a few of the infants were strapped into the product, for others, whether a restraint was used is unreported. Reports describe infants as young as 1 month of age rolling over. Some parents/caregivers, who witnessed and reported some of the nonfatal incidents, were able to rescue distressed infants quickly; some of the other infants died due to suffocation or asphyxiation.

(ii) One infant stopped breathing temporarily, due to difficulty positioning his head correctly.

(iii) Eight incidents report that infants developed physical deformations, such as *plagiocephaly* (flat head syndrome) and/or *torticollis* (twisted neck syndrome), from extended product use.

(iv) According to five reported incidents, infants developed respiratory ailments due to the growth of mold on the product.

DRAFT

The design category includes three deaths, three hospitalizations, one ED visit, and eight non-hospitalized, non-ED injuries.

(c) ***Other product-related*** issues: Four of the 71 incidents (6 percent) report other product-related issues, such as instability (posed by products that have completely or nearly flipped over) or lock/latch problem (*i.e.*, the sleep surface failed to remain in position during use). One of the three instability incidents was a fatality that occurred when a foam-type reclined seat tipped over and fell from the adult bed to the floor, trapping the decedent underneath. No injury is reported in this category.

(d) Lack of ***structural integrity***: Three of the 71 incidents (4 percent) report components breaking, such as the rail, hardware, or other unspecified part. This category includes one hospitalization and one non-ED-treated injury due to a fall.

(e) ***Electrical*** issue: One of the 71 incidents (1 percent) describes an odor emanating from the product after a short period of use indicative of overheating; further investigation revealed molten plastic inside. No injury is reported.

(f) ***Non-product-related*** issues: One of the 71 incidents (1 percent) reports a fatality in an unsafe sleep environment. A 3-month-old was placed supine (on their back) in an infant rocker-like product with a blanket covering the face; the decedent was found in the same position, with the blanket still covering the face.

(g) ***Insufficient information***: Seven of the 71 incident reports (10 percent) contain insufficient information for staff to categorize them accurately. For five deaths, staff has no information on the circumstances of the deaths. Reports for two injuries in this category describe unspecified falls treated in hospital EDs, with no information on restraint usage.

Table 1 presents the distribution of the 71 reported incidents by hazard patterns and severity of incidents.

DRAFT

**Table 1: Hazard Patterns and Incident Severity Associated with Infant Inclined Products
2019–2020 Incidents (Reported Since 2019 SNPR)**

<i>Issues</i>	<i>Total Incidents</i>		<i>Deaths</i>		<i>Injuries</i>	
	<i>Count</i>	<i>Percentage</i>	<i>Count</i>	<i>Percentage</i>	<i>Count</i>	<i>Percentage</i>
Product-Related	63	89	4	40	15	88
<i>Comments/Concerns</i>	<i>31</i>	<i>44</i>	<i>--</i>	<i>--</i>	<i>1</i>	<i>6</i>
<i>Design</i>	<i>24</i>	<i>34</i>	<i>3</i>	<i>30</i>	<i>12</i>	<i>71</i>
<i>Other Product-Related</i>	<i>4</i>	<i>6</i>	<i>1</i>	<i>10</i>		
<i>Structural Integrity</i>	<i>3</i>	<i>4</i>	<i>--</i>	<i>--</i>	<i>2</i>	<i>12</i>
<i>Electrical</i>	<i>1</i>	<i>1</i>	<i>--</i>	<i>--</i>	<i>--</i>	<i>--</i>
Non-Product-Related	1	1	1	10	--	--
<i>Unsafe Sleep Environment</i>	<i>1</i>	<i>1</i>	<i>1</i>	<i>10</i>	<i>--</i>	<i>--</i>
Insufficient Information	7	10	5	50	2	12
Total	71	100	10	100	17	100

Source: CPSC epidemiological databases CPSRMS and NEISS. Percentages may not add to sub-totals and totals due to rounding.

B. Flat Sleep Products

In response to the 2019 SNPR, the Commission received public comments regarding the safety of non-inclined sleep products, or flat sleep products, that do not fall within an existing CPSC sleep standard or a voluntary standard that are available in the marketplace. Staff completed a review of CPSC’s epidemiological databases, CPSRMS and NEISS, to respond to these comments and concerns.

Flat sleep products include: in-bed sleepers, baskets (that can function as hand-held carriers as well), baby boxes, compact bassinets (most of which are portable for travel), and baby tents. Based on the descriptions in the incident reports received, some have soft, puffy sides along the sleep area perimeter; others have semi-rigid sides, with mesh or soft-padded sidewalls held in place by tubular structures along the perimeter. Baby boxes have cardboard walls, while baby tents have flexible wires which provide structural support for fabric/mesh tent walls. All of these non-inclined sleep products are flat and come with mattress pads. Some products have

DRAFT

short legs; many can sit on the floor or can be used on a bed or a couch. The data show that some products were placed inside a standard-sized crib, play yard, or bassinet.

For the final rule, we characterize the number of deaths and injuries and the types of hazards related to flat sleep products. CPSC’s characterizations are based on anecdotal incident reports received by the Commission. The number of emergency department (ED)-treated injuries associated with flat sleep products, for the covered time frame, is insufficient to derive any reportable national estimates.¹⁴ Accordingly, we do not present injury estimates here, but include ED-treated injuries in the total count of reported incidents. Moreover, reporting is ongoing and staff considers 2019 – 2020 data incomplete, so the number of reported fatalities, nonfatal injuries, and non-injury incidents reported here may change in the future.¹⁵

1. Incident Data

CPSC staff received a total of 183 incident reports related to flat sleep products available in the marketplace. These incidents reported a date of occurrence between January 1, 2019 and December 31, 2020. Manufacturer and retailer reports submitted through CPSC’s “Retailer Reporting Program” serve as the *only* source of information for 73 percent (133 out of 183) of the incidents. Of the 183 reported incidents, 11 are fatalities. Among the remaining 172 nonfatal incidents, 16 reported an injury. Additionally, staff’s flat sleep product data search was limited to children age 12 months or under, because that is typically the manufacturer-recommended use age for these products. One hundred and fifteen incident reports provided the victim’s age;

¹⁴According to the NEISS publication criteria, an estimate must be 1,200 or greater, the sample size must be 20 or greater, and the coefficient of variation must be 33 percent or smaller.

¹⁵ In the reports received by CPSC, consumers referred to flat sleep products as “cribs,” “bassinets,” “cosleepers,” “cribettes,” “nests,” “pads,” or “positioners.” Because of the variety of terms used by consumers to describe these products—often unfamiliar to CPSC staff— staff’s data search for this analysis was challenging, and staff believes it is possible that some relevant reports may have been missed.

DRAFT

among them, 24 involved a fatality or injury. Table 2 provides the age breakdown among the 183 incident reports.

Table 2: Age Distribution in Flat Sleep Products-Related Incidents in 2019-2020

<i>Age of Child</i>	<i>All Incidents</i>		<i>Injuries and Fatalities</i>	
	<i>Frequency</i>	<i>Percentage</i>	<i>Frequency</i>	<i>Percentage</i>
Unreported*	68	37	3	11
One – Five Months	89	49	19	70
Six – Eight Months	18	10	4	15
Nine – Twelve Months	8	4	1	4
Total	183	100	27	100

Source: CPSC epidemiological databases CPRMS and NEISS.

* Age may be “unreported” under two circumstances: age was unknown, or age was not reported, because the incident involved no injury.

(a) Fatalities

The Commission is aware of 11 fatalities associated with the use of a flat sleep product, meaning flat sleep surface products marketed for infant sleep that are not currently within the scope of an existing CPSC sleep standard or a voluntary standard, reported to have occurred during the period of January 1, 2019 through December 31, 2020. Seven of the 11 fatality reports describe a suffocation death, as follows:

- A 1-month-old was found partially rolled over onto their side in a soft-sided compact bassinet/travel bed.
- A 2-month-old infant was found completely rolled over the edge of an in-bed sleeper.
- A 2-month-old was placed in an in-bed sleeper, in a prone position, stomach down, with his face turned to one side; he was discovered with part of his body outside the sleeper, face down into a blanket.
- A 2-month-old infant was put into a compact bassinet/travel bed placed on top of an adult bed, with one side of the compact bassinet/travel bed leaning against the wall. According to the official report, the combination of the travel bed’s non-reinforced flexible bottom,

DRAFT

along with the soft surface of the adult bed, allowed the infant to sink; he was found trapped between the bed and the wall.

- A 3-month-old, in a handheld basket that was placed on an adult bed, was found completely rolled over from her original supine position.
- A 4-month-old was placed on his back in an in-bed sleeper that was placed inside a standard bassinet; the infant was discovered in a prone position deceased.
- A 7-month-old was wrapped in a blanket and placed supine in an in-bed sleeper. The infant was found deceased, having rolled over into a prone position.

The remaining four fatalities are as follows:

- A 1-month-old was placed in an in-bed sleeper inside a play yard. The official reports describe the decedent as having suffocated on the puffy sides of the sleeper or becoming entrapped somehow, suffering positional asphyxia.
- A 7-month-old was placed in an in-bed sleeper for a nap. According to official reports, at some point, the infant got to the edge of the adult bed and became entrapped between the footboard and the mattress of the adult bed and died of positional asphyxia.
- Official reports deemed the cause and manner of death for two additional fatalities as undetermined. Both decedents were 1-month-olds, one placed in a basket, while the other was in an in-bed sleeper.

(b) Nonfatalities

From among the 172 nonfatal reports, CPSC identified 16 injury reports associated with the use of flat sleep products that occurred between January 1, 2019 and December 31, 2020.

We describe the severity of the injury type among the 16 injuries below:

- Two infants required hospital admission. An 8-day-old infant suffered unspecified breathing difficulties; another 2-month-old infant fell out of an in-bed sleeper and

DRAFT

suffered head injuries when a sibling jumped onto the couch where the in-bed sleeper was situated.

- Ten infants, ranging in age from 1 month to 9 months, required emergency department (ED) visits after falling out of the sleeper product. For most cases, the sequence of events leading to each fall was unreported. In two cases, the infant fell while being transported in the sleeper; and in another case, the sleeper slipped off of the adult bed on which it was placed. The injuries included head injuries, such as a skull fracture, closed-head injury, and head contusion, or other injuries, such as face abrasion and knee contusion.
- Four other injury incidents reported an allergic reaction; a mold-related breathing difficulty episode; laceration of the nose on the rough mesh wall surface on the sleeper; and a fall when a sibling pulled on the sleeper, causing it to flip over. One of these infants required repeated visits to a medical professional, but the level of care the other infants received was unspecified.

The remaining 156 incidents reported no injuries, or provided no information about any injury. However, many of the descriptions were similar to incidents in which a serious injury or death occurred. Therefore, CPSC staff indicated the potential for a serious injury or even death.

Forty-nine percent of the incidents involved infants 0 to 5 months of age, and 4 percent involved infants 6 to 12 months of age. The age was unknown in 37 percent of the incidents.

2. Hazard Patterns

Similar to the inclined sleep products, the hazard patterns reported for the flat sleep products varied according to the type and usage pattern of the product. Many of the products are new in the marketplace, and consumers and safety advocates expressed concern about their safety. Staff identified the hazard patterns among the 183 reported incidents (11 fatal and 172

DRAFT

nonfatal) associated with the use of these flat sleep products. We present the staff-identified hazard patterns below in descending order of frequency among the reports.

(a) Lock/Latch problems: One hundred and fifteen of the 183 reports (63 percent) fall in this category. All but one of these reports pertain to different models of a particular stand-alone compact bassinet. The locking/latching mechanism that controls the opening/closing of the cover on the product failed. Some reports describe that the inability of the cover to open completely results in the product not lying flat. The single report about a different product describes a foldable sleeper not remaining flat; the unit reportedly folds up while the baby is in the product. None of the reports mention any injuries.

(b) Comments/Concerns: Twenty-nine of the 183 reports (16 percent) expressed consumers' or safety advocates' concerns about the perceived safety hazard of a product, non-compliance with the relevant standard(s) for which a product is being labeled, and/or misleading marketing statements about a product. None of the reports indicate that an incident actually occurred.

(c) Falls/Containment issues: Twelve of the 183 incidents (7 percent) report an infant falling out of the product or an infant not being kept contained within the product. Examples include infants rolling out of a sleeper onto an adult bed and then onto floor; an infant falling out of a sleeper when a sibling jumped onto the couch containing the sleeper; an infant crawling/rolling (unwitnessed) out of a sleeper and getting entrapped between an adult bed frame and mattress. This category includes one death, one hospital admission, and nine ED visits.

(d) Instability issues: Twelve of the 183 reported incidents (7 percent) describe problems with the product not remaining stable. The incident reports describe some products with legs lifting up higher or leaning on one side; other products have slipped off or flipped over

DRAFT

from the adult beds/couches on which they were resting. This category includes two reported injuries, one involving an ED visit.

(e) Asphyxiation/Suffocation hazard: Nine of the 183 incidents (5 percent) fall into this category. The products were compact bassinets/travel beds, baskets, as well as in-bed sleepers, one being used inside a standard bassinet and another, inside a play yard. All but one of the infants had rolled over from their initial position—either fully or partially; positional information is not available for one infant. Eight of the incidents were fatalities due to suffocation or positional asphyxia; one was a near-suffocation episode, with a parent nearby to rescue the infant.

(f) Miscellaneous product-related issues: Three of the 183 incident reports (2 percent) are about mold or quality of the product material. Two of the three products were in-bed sleepers, and the third was a compact bassinet/travel bed. All three report an injury.

(g) Undetermined issues: In three of the 183 incident reports (2 percent), staff could not definitively identify the issue involved. Two of the incidents were fatalities; in both cases, CPSC Field investigation reports indicate that the cause of death is undetermined. The third incident resulted in a hospitalization due to unspecified breathing difficulties suffered by the infant.

C. Safety Alerts, Press Releases, and Product Recalls

The Commission issued two safety alerts involving infant inclined sleep products. A May 31, 2018 safety alert¹⁶ 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

¹⁶ <https://www.cpsc.gov/content/cpsc-consumer-alert-caregivers-urged-to-use-restraints-with-inclined-sleep-products>.

DRAFT

can roll over. An April 5, 2019 safety alert¹⁷ advised consumers to stop using the inclined sleep product when an infant reaches 3 months of age, or as soon as an infant exhibits rollover capabilities. Since issuing the 2019 SNPR, the Commission issued two press releases regarding infant inclined sleep products. A January 16, 2020 press release warned the public about the risk of suffocation associated with the Summer Infant SwaddleMe By Your Bed Sleeper, an infant inclined sleeper. The release advised consumers to stop using the product immediately.¹⁸ An October 31, 2020 press release warned consumers that infant inclined sleep products were not safe for infant sleep based on the results of the Mannen Study, and advised caregivers to stop using infant sleep products with an inclined seat back of more than 10 degrees.¹⁹

The Commission also conducted numerous recalls involving infant inclined sleep products. The 2019 SNPR stated that from May 10, 2000 to August 20, 2019, CPSC conducted 13 consumer-level recalls involving infant inclined sleep products. 84 FR at 60953-54. CPSC conducted recalls in response to hazards involving strangulation, suffocation, falls, 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. *Id.* Tab G in the October 2019 Staff SNPR Briefing Package contains a detailed chart outlining recalls involving infant inclined sleep products up through August 20, 2019.

Since the issuance of the 2019 SNPR, CPSC conducted six additional recalls for a suffocation hazard involving infant inclined sleep products. These six recalls affected approximately 268,300 units. Tab F of Staff's Final Rule Briefing Package contains a chart

¹⁷ <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>.

¹⁸ <https://www.cpsc.gov/Newsroom/News-Releases/2020/CPSC-Warns-Consumers-to-Stop-Using-Summer-Infant-USA-Inc-s-SwaddleMe-By-Your-Bed-Sleeper>.

¹⁹ <https://www.cpsc.gov/Newsroom/News-Releases/2020/CPSC-Cautions-Consumers-Not-to-Use-Inclined-Infant-Sleep-Products>.

DRAFT

outlining these recalls. CPSC did not conduct any recalls for flat sleep products from August 2019 through January 2021.

IV. Overview of CPSC Sleep Standards

The final rule would require that any “infant sleep product,” defined as a product marketed or intended to provide a sleeping accommodation for an infant up to 5 months old, and that is not already subject to one of CPSC’s mandatory standards for infant sleep, must meet the requirements of the mandatory standard for bassinets and cradles, 16 CFR part 1218, *Safety Standard for Bassinets and Cradles*, including conforming to the definition of a “bassinet/cradle.” Currently, the five mandatory CPSC sleep standards are:²⁰

- 16 CFR part 1218 – *Safety Standard for Bassinets and Cradles*
- 16 CFR part 1219 – *Safety Standard for Full-Size Baby Cribs*
- 16 CFR part 1220 – *Safety Standards for Non-Full-Size Baby Cribs*
- 16 CFR part 1221 – *Safety Standards for Play Yards*, and
- 16 CFR part 1222 – *Safety Standard for Bedside Sleepers*.

The Commission considers products that fall within the scope of a CPSC sleep standard to generally follow safe sleep principles. Additionally, caregivers can expect that regulated products intended for infant sleep are tested for compliance to the applicable standard, as well as to any other applicable CPSC rule, such as lead in paint and lead content. Pursuant to section 14 of the CPSA, products within the scope of a children’s product safety rule, which includes all of CPSC’s sleep standards, must be tested for compliance to the standard by a CPSC-accepted third party laboratory, and such compliance must be certified by the manufacturer or importer of the product. Staff regularly participates in ASTM subcommittees for these products, and routinely

²⁰ Tab E of Staff’s Final Rule Briefing Package contains a description of each CPSC sleep standard and the associated voluntary standard the rule is based upon.

DRAFT

updates incident data associated with regulated products, to address identified hazards through the ASTM process. If a voluntary standard that has been adopted by the Commission is revised to address identified hazards, section 104(b)(4)(B) of the CPSIA provides an update process, whereby the revised voluntary standard becomes the new mandatory standard.²¹ Additionally, section 104(b)(2) of the CPSIA requires the Commission to periodically review and revise rules issued under section 104, to ensure that such rules provide the highest level of safety for such products that is feasible. Table 3 summarizes CPSC sleep standards applicable to regulated infant sleep products.

Table 3: Regulated infant sleep products and applicable standards

Product	Voluntary Standard	Mandatory Standard
Bassinet/Cradle	ASTM F2194-16ε1 ²²	16 CFR 1218
Full-Size Crib	ASTM F1169-19	16 CFR 1219
Non-Full-Size Crib	ASTM F406-19	16 CFR 1220
Play Yard	ASTM F406-19	16 CFR 1221
Bedside Sleeper	ASTM F2906-13	16 CFR 1222

Some products currently marketed or intended for infant sleep are not regulated by one of the five existing CPSC sleep standards. Additionally, new products continue to enter the market for infant sleep, but some are also not within the scope of an existing CPSC sleep standard. Such products may not follow safe sleep principles, and are not tested for compliance to a CPSC sleep standard. These unregulated sleep products collectively include products such as: infant inclined

²¹ Under section 104(b)(4)(B) of the CPSIA, the organization must notify the Commission of a revised voluntary standard, and the revised standard becomes a consumer product safety standard issued by the Commission unless within 90 days after notification, the Commission determines that the revised standard does not improve the safety of the consumer product covered by the standard, and the Commission is retaining the existing consumer product safety standard. The revised voluntary standard will become the mandatory standard, effective 180 days after the Commission received notification of the revision (or a later date specified by the Commission in the *Federal Register*). 15 U.S.C. 2056a(b)(4)(B).

²² CPSC's mandatory standard, 16 CFR part 1218, Safety Standard for Bassinets and Cradles, incorporates by reference ASTM F2194-13, *Standard Consumer Safety Specification for Bassinets and Cradles*, with modifications to make the standard more stringent. In 2016, ASTM revised the voluntary standard to include the modifications set forth in the mandatory standard. Accordingly, ASTM F2194-16ε1 is substantially similar to the mandatory standard, and we assess this version of the voluntary standard in this preamble, to simplify our analysis.

DRAFT

sleep products, in-bed sleepers, baby boxes, compact/travel bassinets without handles or handholds, and infant travel tents. Hand-held bassinet/cradles are regulated as part of 16 CFR part 1225, *Safety Standard for Hand-Held Infant Carriers*, but part 1225 does not address hazards associated with infant sleep. Accordingly, hand-held carriers are unregulated if marketed or intended for infant sleep.

The final rule seeks to address hazards associated with infant sleep products, both inclined and flat. Products that already meet a CPSC sleep standard are, by definition, outside the scope of the rule. The final rule addresses hazards associated with infant sleep products by requiring them to meet the requirements of the bassinet and cradle standard, 16 CFR part 1218, including conforming to the definition of a “bassinet/cradle.”

V. Voluntary Standards Overview—ASTM F3118 and ASTM F2194

A. *Infant Inclined Sleep Products – ASTM F3118*

1. History

As a result of incidents associated with the use of 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 2017. This is the fourth revision of the standard since it was first published in May 2015. ASTM F3118-17a states that it is intended to address hazards from falls, positional asphyxiation, and obstruction of nose and mouth by bedding.

DRAFT

2. Description

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 2019 SNPR proposed 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 infant 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 final rule makes substantial modifications to ASTM F3118-17a.

3. CPSC Staff’s Work Within the ASTM Process

CPSC staff’s work on the infant inclined sleep product voluntary standard arose from staff’s work through the ASTM process on the voluntary standard for bassinets and cradles in approximately 2011, in preparation for a proposed rule on bassinets and cradles. ASTM began developing the infant inclined sleep products voluntary standard to address hammocks and inclined sleep products, whose product characteristics at that time did not appear to align with bassinets, because the bassinets standard requires a sleep surface of 10 degrees or less, while the inclined product category at that time included products with an incline of 10 to 30 degrees. Staff has been actively participating in the development of the voluntary standard for inclined sleep products since then.

DRAFT

CPSC staff participated in the ASTM process by attending meetings,²³ working on task groups, commenting on ballots,²⁴ and providing incident data. CPSC staff provided incident data and hazard pattern analysis associated with inclined sleep products for the 2017 NPR and the 2019 SNPR, and updated this information in this final rule preamble. Additionally, staff last provided ASTM with incident data associated with inclined sleep products in May 2018.

Since the SNPR published on November 12, 2019, ASTM has not updated ASTM F3118-17a to address hazards associated with inclined products. Staff's SNPR Briefing Package was posted on the Commission's website on October 16, 2019, before ASTM held fall meetings on voluntary standards for juvenile products, and before the Commission voted on the SNPR, so that ASTM members and other stakeholders could review the package, including the Mannen Study, before the ASTM meetings, and so that staff could discuss the package and the Mannen Study with ASTM members. The ASTM Agenda for Infant Inclined Sleep Products meeting that occurred on October 21, 2019, included a link to Staff's SNPR Briefing Package. CPSC staff discussed the 2019 SNPR Briefing Package at the ASTM meetings in October 2019, including the ASTM subcommittees for infant inclined sleep products, in-bed sleepers, and bassinets, discussing the Mannen Study findings, as well as addressing the fact that flat sleep products were covered by the SNPR. Dr. Mannen attended the subcommittee meeting for infant inclined sleep products via telephone, to discuss the Mannen Study and to answer questions.

After the SNPR published in the *Federal Register* on November 12, 2019, CPSC staff urged the ASTM subcommittee for ASTM F3118 to meet and discuss how to address issues

²³ Meeting logs detailing CPSC's work with ASTM on the infant inclined sleep product voluntary standard can be found here: https://www.cpsc.gov/Newsroom/FOIA/ReportList?field_nfr_date_value%5Bvalue%5D%5Bmonth%5D=&field_nfr_date_value_1%5Bvalue%5D%5Byear%5D=&field_nfr_type_value=meeting&title=incline&=Apply.

²⁴ CPSC staff's correspondence with ASTM since issuing the 2017 NPR regarding these products can be found on www.regulations.gov under supporting materials: <https://www.regulations.gov/docket/CPSC-2017-0020/document?documentTypes=Supporting%20%26%20Related%20Material>.

DRAFT

presented in the 2019 SNPR. However, the F3118 subcommittee did not meet again until August 26, 2020, following a July 16, 2020 letter from CPSC staff.²⁵ After staff's letter, the ASTM F3118 subcommittee established a task group to revise the infant inclined sleep standard's title, introduction, and scope, to be more in line with the proposal in the 2019 SNPR. In December 2020, the ASTM subcommittee introduced ballot F15-18 (20-1) to change the standard's title, introduction, and scope to include all infant sleep products (and not just inclined sleep products). The ballot sought to:

- Remove the word “inclined” throughout the standard.
- Include in the scope, products intended for infants up to 12 months old.
- Include in the scope, products marketed or intended to provide sleeping accommodations.
- Change the scope to include all infant sleep products that do not fall within the scope of an existing infant sleep product standard:
 - Full-Sized Cribs (F1169)
 - Bassinets (F2194)
 - Bedside Sleepers (F2906)
 - Non-Full-Size Cribs/Play Yards (F406)
- Exempt crib mattresses from the scope of the standard.
- Limit the sleep surface in all positions to be 10 degrees or less.

However, in January 2021, the ballot did not pass due to six negative votes. The negative votes objected to a variety of different aspects of the ballot, including four broad categories:

1. That the proposal would discourage innovation and be too broad;
2. That the ballot appeared to allow products that fall under other sleep standards to

²⁵ Available at: <https://www.cpsc.gov/s3fs-public/IISPLettertoASTM-07162020.pdf?6ntZUkyau.r2mlrQnM31s0B3g1EkUg.9>.

DRAFT

opt to meet ASTM F3118 instead;

3. That the voter could not support changing the title, introduction, and scope without seeing the underlying requirements; and

4. Editorial comments.

The ASTM F3118 subcommittee discussed the ballot results at a meeting on January 27, 2021. During this meeting, ASTM members disagreed on the intent and consequences of changes to the voluntary standard, and the meeting ended without a consensus on a path forward. However, CPSC staff participates on an ASTM task group to review safe sleep requirements across infant sleep product standards (the comparison task group), and reports that this task group has met at least four times since the January 27, 2021 meeting. Based on the ballot results and the discussions in these ASTM meetings, staff advises that it is unlikely that ASTM will be able to move forward with changes to ASTM F3118 that address safe sleep requirements in the near term.²⁶

Recently, on April 22, 2021, at an ASTM task group meeting on the title, introduction, and scope of the voluntary standard, task group members discussed balloting the proposed regulatory text in the 2019 SNPR for the voluntary standard, to prevent the sale of infant inclined sleep products that purport to certify to ASTM F3118-17a, meaning products with an incline above 10 degrees, while ASTM works to revise the voluntary standard to be more in line with the 2019 SNPR. However, the task group does not plan to ballot the 2019 SNPR requirement that infant sleep products meet the requirements of the bassinet standard, because ASTM is working to create minimum safe sleep requirements in a revised ASTM F3118 standard. Staff is

²⁶ The ASTM task group approach is different than CPSC's approach in this final rule, because ASTM is attempting to put safe sleep requirements in ASTM F3118, rather than rely on the performance and labeling requirements in the bassinets and cradles standard. The Commission determines in this final rule that the performance and labeling requirements in the bassinet standard are the minimum safe sleep requirements for infant sleep products. Thus, it remains unclear whether ASTM's approach can be successful. However, if the ASTM committee revises ASTM F3118-17a and notifies the Commission, the staff will evaluate the revised voluntary standard at that time.

DRAFT

participating in this effort as well, but staff has advised the task group that staff's expertise does not suggest that requirements that are different and less stringent than the requirements in the bassinet standard will adequately address the risk of injury associated with infant sleep products. Additionally, staff's conclusion that the Safety Standard for Bassinets and Cradles contains the minimum safe sleep requirements for these products is supported by the assessment presented in Staff's Final Rule Briefing Package and in this final rule.

B. Bassinets and Cradles – ASTM F3194

1. History and Description

The voluntary standard for bassinets and cradles, ASTM F2194, was first approved and published by ASTM in 2002, as ASTM 2194, *Standard Consumer Safety Specification for Bassinets and Cradles*. The voluntary standard was revised several times between 2002 and CPSC's promulgation of a mandatory standard for bassinets in 2013. CPSC's mandatory standard for bassinets and cradles, codified at 16 CFR part 1218, incorporates by reference ASTM F2194-13, with the following modifications to the voluntary standard:

1. Clarify the scope of the standard to include multi-mode products in which a mode meets the definition of a "bassinet/cradle" (seat incline is 10 degrees or less from horizontal)
2. Modify the stability test procedure to require the use of a newborn CAMI dummy, rather than an infant CAMI dummy.
3. Add stability requirements for removable bassinet beds
4. Add more stringent mattress flatness performance requirements to limit measured angle to 10 degrees (versus 14 degrees allowed in ASTM F2194-13).
5. Exempt bassinets that are less than 15 inches across from the mattress flatness requirement.

In 2016, ASTM approved and published the most recent version of the standard, ASTM

DRAFT

F2194-16ε1, with new requirements to bring the voluntary ASTM standard in line with the mandatory standard for bassinets in 16 CFR part 1218. In developing ASTM F2194-16 ε1, ASTM harmonized the voluntary standard with all modifications specified in part 1218. In addition to including all modifications contained in part 1218, ASTM added:

1. additional clarification that strollers with a removable bassinet must be tested to the bassinet standard,
2. minor formatting and editorial changes, and
3. an additional warning statement to be applied to bassinet bed products that are removable from the base/stand without the use of tools and that contain a lock/latch mechanism that secures the bassinet bed to the base/stand.

Staff assessed the additional changes to the voluntary standard, beyond harmonization with 16 CFR part 1218, and advises that the changes are either non-substantive, or an improvement in safety. We evaluate and discuss ASTM F2194-16ε1 in this preamble to the final rule, and CPSC will update the reference in part 1218 to ASTM F2194-16ε1 as soon as feasible.

The more significant requirements of ASTM F2194 include:

- Scope—describes the types of products intended to be covered under the standard.
- Spacing of rigid-side components—is intended to prevent child entrapment between both uniformly and non-uniformly spaced components, such as slats.
- Openings for mesh/fabric—is intended to prevent the entrapment of children’s fingers and toes, as well as button ensnarement.
- Static load test—is intended to ensure structural integrity even when a child three times the recommended (or 95th percentile) weight uses the product.
- Stability requirements—is intended to ensure that the product does not tip over when pulled on by a 2-year-old male.

DRAFT

- Sleeping pad thickness and dimensions—is intended to minimize gaps and the possibility of suffocation due to excessive padding.
- Tests of locking and latching mechanisms—is intended to prevent unintentional folding while in use.
- Suffocation warning label—is intended to help prevent soft bedding incidents.
- Fabric-sided openings test—is intended to prevent entrapments.
- Rock/swing angle requirement—is intended to address suffocation hazards that can occur when latch/lock problems and excessive rocking or swinging angles press children into the side of the bassinet/cradle.
- Occupant restraints—is intended to prevent incidents where unused restraints have entrapped and strangled children.
- Side height requirement—is intended to prevent falls.
- Segmented mattress flatness—is intended to address suffocation hazards associated with “V” shapes that can be created by the segmented mattress folds.

The voluntary standard also includes: (1) torque and tension tests to prevent components from being removed; (2) requirements for several bassinet/cradle features to prevent entrapment and cuts (minimum and maximum opening size, small parts, hazardous sharp edges or points, and edges that can scissor, shear, or pinch); (3) requirements for the permanency and adhesion of labels; (4) requirements for instructional literature; and (5) corner post extension requirements intended to prevent pacifier cords, ribbons, necklaces, or clothing that a child may be wearing from catching on a projection. 78 FR 63019, 63020-21 (Oct. 23, 2013).

2. CPSC Staff’s Work Within the ASTM Process

CPSC has been working with ASTM on the voluntary standard for bassinets and cradles since before publication of the original voluntary standard in 2002. CPSC began rulemaking

DRAFT

under section 104 of the CPSIA, to create a mandatory standard for bassinet and cradles based on the voluntary standard, in approximately 2009, following passage of the CPSIA. CPSC issued a notice of proposed rulemaking in 2010 (75 FR 22303 (Apr. 28, 2010)), a supplemental notice of proposed rulemaking in 2012 (77 FR 64055 (Oct. 18, 2012)), and a final rule in 2013 (78 FR 63019 (Oct. 28, 2013)). The final rule is codified at 16 CFR part 1218, Safety Standard for Bassinets and Cradles. The final rule incorporated by reference the then-current voluntary standard, ASTM F2194-13, with modifications to make the standard more stringent.

CPSC staff has continually participated in the ASTM process, including attending subcommittee meetings,²⁷ participating in task groups,²⁷ commenting and voting on ballots to revise the voluntary standard,²⁸ and providing incident data, when requested. This has included ASTM's recent efforts to address hazards associated with currently unregulated flat sleep products, such as compact bassinets, baby boxes, and in-bed sleepers, since approximately 2015. ASTM has not yet been successful in adding any of these flat sleep products to the bassinet standard.

CPSC staff's correspondence with ASTM states that staff is opposed to removing or reducing the requirements of the bassinet and cradle voluntary standard to create new requirements specifically for these products, when such requirements are inconsistent with safe sleep principles already required in the bassinet standard. Accordingly, for example, in a December 12, 2019 letter to both the inclined sleep and bassinet subcommittees, CPSC staff reiterated concerns with weakening the safe sleep requirements in the voluntary standard for

²⁷ CPSC meeting logs associated with staff's work with ASTM can be found here:

https://www.cpsc.gov/Newsroom/FOIA/ReportList?field_nfr_date_value%5Bvalue%5D%5Bmonth%5D=&field_nfr_date_value_1%5Bvalue%5D%5Byear%5D=&field_nfr_type_value=meeting&title=bassinet&=Apply

²⁸ CPSC correspondence with the ASTM Subcommittee for Bassinets and Cradles can be found here:

https://cpsc.gov/s3fs-public/VoteCommentToASTMBassinet_10162020.pdf?NbTgq8p5FBJ12mr1IAQeG0weJUDh_6ZI

DRAFT

bassinets and cradles in order to accommodate unregulated products, such as in-bed sleepers, compact bassinets, and baby boxes.²⁹ Additionally, on October 16, 2020, staff voted negatively on an ASTM ballot to modify the bassinet standard to include less stringent stability and side height requirements for compact bassinets, versus traditional bassinets.³⁰ To ensure safe sleep, staff's negative ballot vote urged ASTM to maintain the same side height and stability requirements for compact bassinets that are required of bassinets.

In June 2019, ASTM began to develop a separate in-bed sleeper voluntary standard. Staff provided data to ASTM regarding in-bed sleepers in 2017, and has participated in ASTM meetings for in-bed sleepers since June 2019, as well as working with performance and labeling task groups.³¹ Task groups working on the in-bed sleeper standard have been unable to reach consensus on performance requirements for in-bed sleepers, and have been focusing on developing warning labels for these products. CPSC staff continues to participate in all of these ASTM efforts, and to urge ASTM members to retain safe sleep principles in standards development. For example, in a July 8, 2020 letter to the Subcommittee Chairman for ASTM's in-bed sleeper committee, CPSC staff stated:

We would like to be clear that based on our evaluation of incident data related to in-bed sleepers, we have great concerns regarding the safety of in-bed sleepers and the feasibility of developing any safety standard that fully addresses potential hazards. Based on the 12 deaths discussed with the In-bed Sleeper Data Task

²⁹ Available at: https://www.cpsc.gov/s3fs-public/LetterToASTMBassinet_IISP_121219.pdf?uMq_ImMYhtrDmFkoDH9I6vdwNI0hsm00

³⁰ Available at: https://www.cpsc.gov/s3fs-public/VoteCommentToASTMBassinet_10162020.pdf?NbTgq8p5FBJ12mr1IAQeG0weJUDh_6ZI. CPSC's website, at <https://www.cpsc.gov/Regulations-Laws--Standards/Voluntary-Standards>, contains information on staff activities as well as correspondence with voluntary standards organizations.

³¹ Meeting logs describing ASTM meetings are available on CPSC's website: https://www.cpsc.gov/Newsroom/FOIA/ReportList?field_nfr_date_value%5Bvalue%5D%5Bmonth%5D=&field_nfr_date_value_1%5Bvalue%5D%5Byear%5D=&field_nfr_type_value=meeting&title=in-bed&=Apply

DRAFT

Group members, CPSC staff cannot foresee how these products can be designed and regulated to ensure safe use for infants. Staff is not confident that an in-bed sleeper voluntary standard that differs from the current bassinet standard will result in a safe sleep product.³²

VI. Assessment of the Voluntary Standards to Address Identified Hazard Patterns Associated with Infant Sleep Products

A. Inclined Sleep Products

The 2019 SNPR assessed the adequacy of ASTM F3118-17a to address the risk of injury associated with inclined sleep products. 84 FR 60955-56. The assessment relied, in part, on the Mannen Study regarding the safety of inclined sleep surfaces for infant sleep, attached as Tab B to Staff’s SNPR Briefing Package, and also summarized in the 2019 SNPR. *Id.* at 60954. Based on the Mannen Study, CPSC staff advised that a flat sleep surface, meaning one that does not exceed 10 degrees from the horizontal, is the safest sleep surface for infants. *Id.* Accordingly, the Commission proposed in the 2019 SNPR to remove the term “inclined” in CPSC’s mandatory standard, and to require that all sleep products not otherwise subject to a CPSC sleep standard (full-size cribs, non-full-size cribs, play yards, bedside sleepers, and bassinets and cradles), meet the requirements of 16 CFR part 1218, Safety Standard for Bassinets and Cradles, which, among other requirements, mandates a seat back/sleep surface angle intended for sleep to be 10 degrees or less from horizontal. *Id.*

Here, we summarize the results of the Mannen Study again, summarize the assessment of ASTM F3118-17a in the 2019 SNPR, and update our assessment to determine whether the voluntary standards, ASTM F3118-17a, or ASTM F2194-16e1, are adequate to address the

³² See July 8, 2020 Letter from C. Kish to ASTM Subcommittee for In-bed Sleepers, available at: https://www.cpsc.gov/s3fs-public/InbedSleepers_07082020ASTM%20Letter.pdf?3SpzS3cG3zvPjCLFamcCz.9FxNjpUu2s

DRAFT

incidents associated with inclined sleep products, including the 71 new incidents reported since the 2019 SNPR.

Based on the following analysis, the Commission determines that ASTM F3118-17a is inadequate to address the risk of injury associated with inclined sleep products, and that more stringent requirements are necessary in the final rule to further reduce the risk of injury associated with infant inclined sleep products. Specifically, the Commission determines that the performance requirements in the mandatory standard, 16 CFR part 1218, Safety Standard for Bassinets and Cradles, would adequately address the risk of injury associated with these products.

1. Mannen Study Summary

During the development of the 2019 SNPR, staff reviewed 450 incidents, 59 were deaths that occurred while in infant inclined sleep products. 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. The Mannen Study examined how the degree of a seatback angle affects an infant's ability to move within the products and whether those designs directly impact safety or present a risk factor that could contribute to the suffocation of an infant. The testing compared infants' muscle movement and oxygen saturation on a flat crib mattress at 0 degrees, 10 degrees, and 20 degrees, versus seven different inclined sleep products. The Mannen Study concluded that none of the inclined sleep products tested were safe for infant sleep. *Id.*

The Mannen Study concluded that muscle activity for infants who rolled over in inclined sleep products with a 20-degree incline sleep surface was significantly different than in products with a 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 rolling

DRAFT

from a supine to prone position. The Mannen Study also concluded that inclined sleep products with a 10-degree or less sleep surface incline do not significantly impact infant motion or muscle activity. Based on the Mannen Study, staff recommended that 10 degrees is the maximum sleep surface angle that should be allowed for any product intended for infant sleep, similar to the requirements found in the EN 1130:2019 *children's cribs*, EN 1466:2014 *carry cots*, and the AS/NZS 4385:96 *infant rocking cradles* international standards. *Id.*

2. Hazard Pattern Categories

In the 2019 SNPR, CPSC reviewed 451 reported incidents involving inclined sleep products, which included 59 fatalities and 96 injuries. CPSC identified seven hazards that involved deaths and injuries (for this analysis, we did not consider patterns, such as consumer comments, that did not involve injuries or deaths):

- *Design issues* (31 percent). This hazard involved 19 deaths, 17 resulting from infants rolling over into a prone (face down) position. An additional 71 injuries were reported in this category, including five hospitalizations and four emergency department visits. Thirty-three percent of the reported incidents involved infants rolling from their original supine (on their back) position.
- *Electrical issues* (28 percent). This hazard involved no deaths and two reports of injuries.
- *Undetermined* (8 percent). This hazard involved 28 deaths and six injuries. Among the 28 deaths, staff was unable to determine the product's role, but often unsafe sleep environment was cited as a co-contributing condition to sudden infant death syndrome (SIDS).
- *Structural Integrity* (6 percent). This hazard involved no deaths and two injuries.
- *Insufficient information* (4 percent). This hazard involved eight deaths and six injuries.

The reports did not provide information on the circumstances of deaths and injuries involved unspecified falls.

DRAFT

- *Other Product-Related Issues* (3 percent). This hazard involved no deaths and nine injuries. The category includes reports of instability (product tipping over) and inadequacy of restraints, and most of the injuries involved falls.

- *Infant placement issues* (1 percent). This hazard involved four deaths and no injuries. Three of the four deaths involved infants placed in a prone position.

Id. at 60952-53.

Since the 2019 SNPR, CPSC received a total of 71 new incident reports related to inclined sleep products. While the distribution of the data in this update varies somewhat, staff advises that the broader hazard categories are very similar. The 71 new reports included 10 fatalities and 17 injuries. Of the 10 fatalities, three deaths involved an infant who rolled from a supine position, one death involved an overturned sleeper, one death involved an infant placed with a blanket, and five deaths without reports containing information on the circumstances of the death. Of the 17 injuries 12 involved design issues, two involved structural integrity, and two involved unspecified falls.

3. Assessment of ASTM Standards in Addressing Hazards

Below we summarize the hazard patterns associated with deaths and injuries from all 522 incident reports related to inclined sleep products CPSC received and reviewed since the 2017 NPR. CPSC did not consider patterns, such as consumer comments, that did not involve injuries or deaths. The 522 incidents involved 69 deaths and 113 injuries. We assesses the adequacy of the voluntary standard for infant inclined sleep products (ASTM F3118) and the adequacy of the voluntary standard for bassinets (ASTM F2194) in addressing hazards associated with injuries and deaths.

In the 2019 SNPR, CPSC determined that the voluntary standard for infant inclined sleep products, ASTM F3118-17a, is inadequate to address the risk of injury associated with the

DRAFT

incline of sleep products, because the standard allows for products with a seatback angle greater than 10 degrees. *Id.* at 60955-56. The majority of deaths (in which the circumstances were known) were due to suffocation after the infant rolled over in the product, and the same hazard pattern was reported in nonfatal incidents. For the mandatory standard, CPSC proposed to modify ASTM F3118-17a to limit the seatback angle for all infant sleep products to 10 degrees or less, and to replace the performance requirements with the performance requirements in 16 CFR part 1218, Safety Standard for Bassinets and Cradles, which incorporates by reference ASTM F2194-13 *Standard Consumer Safety Specification for Bassinets and Cradles*, with modifications. With the modifications in the mandatory standard, the standard is substantially similar to ASTM F2194-16e1, which we use for the assessment here.

(a) Hazard: Design Issues

When combining the data from the 2019 SNPR with new incident data received since the SNPR, the “design issues” hazard is associated with 22 deaths and 83 injuries. At least 20 deaths involved infants rolling into a prone position (face down) and suffocating. More than one-third of the incidents also reported that infants rolled over—fully or partially—from their original supine (on their back) position.

In the 2019 SNPR, we concluded that a flat sleeping surface that does not exceed 10 degrees from horizontal offers infants the safest sleep environment. This conclusion was based on findings from the Mannen Study. 84 FR at 60955-56. Although some comments to the 2019 SNPR stated that more testing should be done to determine if the maximum angle for safe sleep may be between 10 degrees to 20 degrees, the Mannen Study suggested if future work were done on safe sleep angles, one area of study would be additional biomechanical testing to determine “which, if any, angles between 10-and 20-degrees may be safe for infant sleep.”

DRAFT

The Mannen Study recommendations do not imply that an incline angle between 10 and 20 degrees may be safe for infant sleep, merely that if higher angles are considered, additional biomechanical testing is required. The Mannen Study also stated that its testing of awake infants was a limitation because “while the muscle use and motion may be similar, it is likely that infants who find themselves in a compromised position in an inclined sleep product during a nap or overnight sleep may not have enough energy or alertness to achieve self-correction and may succumb to suffocation earlier or more easily than infants who are fully awake.”

Given the vulnerability of newborn infants and infant fatalities who were most likely asleep at the time of incidents in inclined products, we conclude that additional research of inclines above 10 degrees is unnecessary for the final rule. Based on the biomechanical results of the Mannen Study, and its conclusion that 10 degrees is likely a safe incline for infant sleep, which supports the 10 degrees stated in the scope of ASTM F2194-16 ϵ 1, the Commission concludes that 10 degrees is the maximum sleep surface angle that should be allowed for any product intended for infant sleep for young infants up to 5 months old. Additionally, other research³³ has demonstrated a discernable difference in infant ability between 5, 7, and 10 degrees in a side-to-side tilt, which formed the basis of the 7-degree maximum sleep surface angle in Health Canada’s regulations. Staff advises that additional research at angles higher than 10 degrees is unlikely to alter their assessment that 10 degrees is the maximum safe incline for infant sleep.

The current voluntary standard for infant inclined sleep products, ASTM F3118-17a, defines an “inclined sleep product,” in part, as having a seatback angle greater than 10 degrees and not exceeding 30 degrees. Based on the Mannen Study and the other factors discussed

³³ Beal SM, Moore L, Collett M, Montgomery B, Sprod C, Beal A. The danger of freely rocking cradles. *J Paediatr Child Health*. 1995 Feb;31(1):38-40. doi: 10.1111/j.1440-1754.1995.tb02910.x. PMID: 7748688.

DRAFT

above, we conclude that ASTM F3118-17a does not adequately address the risk of injury related to a sleep surface incline greater than 10 degrees, because the voluntary standard does not limit the sleep surface to a safe incline angle. In comparison, the voluntary standard for bassinets, ASTM F2194-16ε1, defines a sleep surface as being less than or equal to 10 degrees, and includes performance requirements for mattress flatness that limit measured angles to 10 degrees or less.³⁴ Therefore, for the mandatory standard specified in this final rule, with respect to sleep surfaces, all infant sleep products, including inclined sleep products, must meet the more stringent sleep surface angle requirement of the voluntary standard for bassinets, ASTM F2194-16ε1, as codified in 16 CFR part 1218, to further reduce the risk of death from suffocation.

(b) Hazard: Undetermined Product Issue

This hazard category is associated with 28 deaths and six injuries. Among the 28 deaths and six injuries, staff was unable to determine the product's role. Without information on the product's role in deaths or injuries, we are unable to assess whether the voluntary standard for infant inclined sleep, ASTM F3118-17a, or the voluntary standard for bassinets, ASTM F2194-16ε1, would adequately address the hazards in this category.

(c) Hazard: Insufficient Information

This hazard category is associated with 13 deaths and eight injuries. The reports did not provide information on the circumstances of deaths and injury reports involving unspecified falls. Without information on the circumstances of deaths or injuries, staff is unable to assess if the voluntary standard for infant inclined sleep, ASTM F3118-17a, or the voluntary standard for bassinets, ASTM F2194-16ε1, would adequately address the hazards in this category. Falls are discussed in more detail in "Other Product-Related Issues," below.

³⁴ In the final rule for bassinets, the Commission stated they intended to limit the scope of the bassinet standard to exclude all inclined products "when the incline is more than 10 degrees from horizontal." 78 *Fed. Reg.* 63,021.

DRAFT

(d) Hazard: Infant Placement

This hazard category is associated with five deaths and no injuries. Three of the deaths involved infants placed in a prone position, and one death involved an infant placed in a supine position with a blanket covering the face. Based on the Mannen study, sleep surfaces with a 20-degree incline significantly increased the demand on abdominal muscles and could lead to increased fatigue and suffocation if an infant is unable to reposition themselves after rolling from a supine to prone position. In three of the deaths in this hazard category, the infant was placed in the prone position and the inclined sleep surface may have contributed to suffocation if the angle of the sleep surface led to fatigue that prevented the infant from rolling to a supine position.

While infants can die in flat products when placed to sleep in the prone position, based on the Mannen Study, an inclined surface could further contribute to deaths in the prone position. A sleep surface limited to a 10-degree or less incline, as required in the bassinet standard (ASTM F2194-16ε1), could reduce the risk of injury associated with the prone position, when compared to an inclined sleep product. Therefore, with respect to sleep surfaces, for the mandatory rule, all infant sleep products, including inclined sleep products, must meet the more stringent sleep surface angle requirement of the voluntary standard for bassinets, ASTM F2194-16ε1, as set forth in 16 CFR part 1218, to further reduce the risk of death from suffocation.

(e) Hazard: Other Product-Related Issues (instability, restraints, etc.)

This hazard category includes reports of instability (product tipping over) and containment; the category is associated with one death and nine injuries. One death occurred when a foam-type reclined product tipped over and fell from the adult bed to the floor, trapping the infant underneath. Most of the injuries involved falls and at least 10 reports (with no injury reported) related to nearly or completely flipped over products.

DRAFT

The death, and most likely the injuries, relate to the stability of the product and how easy it is to tip the product over into a hazardous situation. The voluntary standard for infant inclined sleep products, ASTM F3118-17a, includes two stability performance requirements that apply to “Compact Inclined Sleep Products” and “Infant or Newborn Inclined Sleep Products.” For the “Compact Inclined Sleep Products,” the product must remain upright when placed on a 20-degree inclined test platform. For the “Infant or Newborn Inclined Sleep Products,” a 23-lb. vertical force and 5-lb. horizontal force are applied to the product’s side with a newborn CAMI dummy occupant to simulate an older sibling pulling up on the side to view the infant in the bassinet, and the product must remain upright containing the CAMI dummy. The “Compact Inclined Sleep Products” are exempt from the 23- and 5-pound force requirements, with the rationale that the compact products are intended to sit on a floor and are unlikely to have an older sibling attempt to pull up to see the infant inside.

The current voluntary standard for bassinets, ASTM F2194-16 ϵ 1, includes an identical stability requirement that applies a 23-lb. vertical force and a 5-lb. horizontal force to the product with a newborn CAMI dummy occupant, and this requirement applies to all products; it does not provide exemptions for “Compact Inclined Sleep Products” to meet only the less stringent 20-degree inclined test platform test. The rationale in ASTM F2194 states the dual application of forces simulates a 2-year-old male pulling on the side of the product; staff advises that sibling interaction is a reasonable scenario which may cause the product to tip over. Due to the portability of some of the unregulated compact sleep products, incident data confirm that the products are used on raised surfaces from which infants and product may fall. Therefore, regarding the product’s stability, in the final rule, all infant sleep products, including inclined products, must meet the more stringent stability requirement of the voluntary standard for

DRAFT

bassinets, ASTM F2194-16ε1, as codified in 16 CFR part 1218, to further reduce the risk of injury from tip over of the product.

(f) Hazard: Structural Integrity

This hazard category includes reports of some component failures on the product such as buckles/straps, hardware coming loose, hub/rail/leg coming loose, or other unspecified components breaking. This hazard category involved no deaths and four injuries. All injuries were related to falls, and include one hospitalization and three emergency department visits.

The voluntary standard for infant inclined sleep products, ASTM F3118-17a, includes performance requirements to assess the integrity of inclined sleep products. The requirements specify a dynamic test in which an 18-lb. load, consisting of a 6- to 8-inch steel shot bag, is dropped 50 times from a height of 1.0 inch onto the seat surface. The requirements also specify a static test in which a 50-lb. load or three times the product's maximum recommended weight, whichever is greater, is gradually applied through a 6-inch square wooden block to the seat surface for 60 seconds. The current voluntary standard for bassinets, ASTM F2194-16ε1, has a performance requirement to address structural integrity that specifies a static load test that applies a 54-lb. load or three times the manufacturer's recommended weight, whichever is greater, through a 6-inch aluminum block to the sleep surface for 60 seconds. The rationale in ASTM F2194 states 54 lbs. is three times the weight of the 95th percentile of a 3- to 5-month-old infant.

Although the voluntary standard for infant inclined sleep products, ASTM F3118-17a, requires a dynamic test for structural integrity, its effectiveness in evaluating the product's strength is minimal, compared to the static test. The load in the dynamic test being one-third of the static load, the low drop height, short test timeframe, and presence of energy-absorbing material (shot bag and flexible product material), combine to minimize the effect of this test on

DRAFT

the product's structural integrity. In contrast, the static test applies a much larger load, three times the heaviest infant in the product, with a rigid applicator applied continuously for 60 seconds. Therefore, staff advises that the static test is the more stringent evaluator of product integrity than the dynamic test.

The static load in ASTM F2194-16 ϵ 1 is 54 lbs., which is a more stringent load compared to the static load of 50 lbs. in ASTM F3118-17a. Therefore, to further reduce the risk of injury associated with structural defects, for the final rule, the Commission concludes that the static load test in ASTM F2194 is adequate to assess structural integrity of infant sleep products, and is more stringent than the static load test in ASTM F3118-17a. The final rule requires that all infant sleep products, including inclined sleep products, meet the more stringent structural integrity requirement of the voluntary standard for bassinets, ASTM F2194-16 ϵ 1, as codified in 16 CFR part 1218.

(g) Hazard: Electrical Issues

This hazard category involved no deaths and two reports of injuries related to electric shock. Non-injury incidents reported overheating/melting of components and issues with batteries. As noted in the 2019 SNPR, the infant inclined sleep products standard, ASTM F3118-17a, does not include any performance requirements for electrical components. 84 FR at 60956. The voluntary standard for bassinets, ASTM F2194-16 ϵ 1, also does not address electrical hazards. However, CPSC staff advises that they raised this issue with ASTM, and that the ASTM Ad Hoc task group is developing performance requirements to address electrical hazards across juvenile products. As these electrical requirements are added during the ASTM voluntary standard updates, CPSC can review the updated voluntary standard pursuant to the update provision in Pub. L. No. 112-28, and determine whether to revise the mandatory standard based on a revised voluntary standard.

DRAFT

4. Assessment of International Standards

(a) *EN1466:2014 Carry cots*

The BS EN 1466:2014 *Child use and care articles- Carry cots and stands- Safety requirements and test methods* European standard applies to products intended for carrying a child in a lying position using a handle or stand. This standard applies to children who cannot sit unaided or roll over or push up on their hands and knees and is a maximum weight of 19.84 pounds.

i. Side height

For cots on a stand, EN 1466:2014 standard requires an internal height of at least 7.87 inches (200 mm) from the top of a mattress, compressed by a 19.84-pound (9kg) steel plate, to the lowest point of the upper edge of the sides. For carry cots not on a stand, the standard requires an internal height 5.9 inches (150mm) to 7.09 inches (180mm), depending on the length of the cot, using the same test method. This requirement measures the internal side height when an occupant of the maximum weight compresses the mattress. This standard has a side height requirement similar to the ASTM F2194-16 ϵ 1 *bassinet* standard, which requires a minimum side height of 7.5 inches from an uncompressed mattress. For bassinets on a stand, if the mattress compresses more than 3/8 of an inch, ASTM F2194-16 ϵ 1 requires a higher side. For bassinets not on a stand, ASTM F2194-16 ϵ 1 has a higher side height of 7.5 inches from an uncompressed mattress, compared to the EN 1466:2014 requirement, which is 7.09 inches from a compressed mattress. Additionally, ASTM F2194-16 ϵ 1 requires a consistent side height no matter the configuration.

DRAFT

ii. Sleep surface angle

The EN 1466:2014 standard requires a maximum sleep surface angle of 10 degrees. This requirement is similar to the ASTM F2194-16ε1 *bassinet* standard, which requires a maximum sleep surface angle of 10 degrees.

iii. Latching requirements

The EN 1466:2014 standard requires products with a folding stand mechanism not to collapse after the latch is operated (closed and opened) 300 times, and after a 44.96 pound-force (200N) is applied in the area of the stand most likely to cause the product to fold. The EN 1466:2014 standard's latching requirement only simulates the action of unintentionally folding the stand without the carry cot or box assembled on the stand. In contrast, the ASTM F2194-16ε1 *bassinet* standard tests both the stand and the bassinet as a fully assembled product.

The ASTM F2194 -16ε1 *bassinet* standard requires products without a latching or locking device not to fold when a 20 pound-force is applied to the top edge of the bassinet in the direction most likely to cause it to fold. The ASTM F2194 -16ε1 *bassinet* standard requires a lower force than the EN standard, but the force is applied at a higher location (top side of the bassinet) than the EN standard (force applied to the stand). The higher location of the force can create a higher torque at the latch due to the longer lever arm. For bassinets with a locking hinge or latch, the locking mechanism must withstand a 10-pound force in the direction most likely to release it. Determining which latching requirement is more stringent is difficult because the test parameters are not directly comparable. Staff assesses that testing the product fully assembled, as required by ASTM, is a better test because it simulates realistic use of the product.

The ASTM standard also includes a *Removable Bassinet Bed Attachment to Base/Stand* requirement and testing to address latching and locking devices intended to secure removable bassinet beds to the base/stand. These requirements and test are unique because they address

DRAFT

known incidents of false latching of a removable bassinet bed. By considering the latching, unintentional folding, and bassinet bed attachments to the stand requirements in total, staff assesses that the ASTM F2194-16 ϵ 1 *bassinet* standard's latching requirements are adequate.

iv. Stability requirements

The EN1466:2014 standard requires products with an occupant test mass of 15.43 pounds not to tip over when placed on a 20-degree surface. EN1466:2014 rationalizes this test by stating: "Carry cots shall be designed so that they do not tip over when they are placed on slightly sloping ground or when the child leans against one side of the carry cot." This is different compared to the ASTM F2194-16 ϵ 1 *bassinet* standard that requires the product (with simulated newborn occupant) to withstand a 23-lb. vertical force and 5-lb. horizontal force along its side, without tipping. The rationale in ASTM F2194 states the dual application of forces simulates a 2-year-old male pulling on the side of the product; staff advises that this is a reasonable scenario in which the product may tip over. Determining which stability requirement is more stringent is difficult, because both standards' torque arms depend upon the product's geometry. Using a 10-inch wide by 10-inch tall sidewall box on a 10-inch stand as a reference product for comparison, staff determined the reference product would fail the ASTM F2194 *bassinet* standard's test and pass the EN 1466 standard's test. Therefore, staff assesses that the ASTM 2194-16 ϵ 1 *bassinet* standard's stability requirement is more stringent for this reference product.

v. EN1466:2014 Summary

The EN 1466:2014 carry cots standard has a side height and sleep surface angle requirement similar to ASTM F2194-16 ϵ 1's *bassinet* standard. However, the ASTM F2194-16 ϵ 1 standard has a potentially more stringent stability requirement.

DRAFT

(b) *EN 1130:2019 Children's Cribs and Cradles*

The European Standard, EN 1130-1: 2019 “Furniture – Cribs and Cradles for Domestic Use” has several requirements not found in ASTM F2194-16ε1. Most of these additional requirements address hazards associated with cribs intended for use with older children (in excess of the 5-month recommended maximum age for bassinets); and thus, these requirements are not applicable to bassinets.

i. Side Height

The EN 1130:2019 standard requires a side height of at least 7.87 inches (200 mm) when a 19.84-pound (9kg) steel plate is placed on the compressed mattress. This measures the crib's internal side height with a 19.84-pound occupant is compressing the mattress. This standard has a side height requirement similar to the ASTM F2194-16ε1 *bassinet* standard, which requires a minimum side height of 7.5 inches from an uncompressed mattress. If the mattress compresses more than 3/8 of an inch, ASTM F2194-16ε1 requires a higher side.

ii. Sleep Surface Angle

The EN 1130:2019 standard requires a maximum sleep surface angle of 10 degrees. This standard has a sleep surface angle requirement similar to the ASTM F2194-16ε1 *bassinet* standard, which requires a maximum sleep surface angle of 10 degrees.

iii. Latching Requirements

The EN 1130:2019 standard requires folding products to contain a dual-action locking mechanism, and to unlock with a tool, and to fold only when the crib is lifted, or not collapse after the latch is operated (closed and opened) 300 times, and at least an 11.24-pound force (50N) is required to unlock it. The EN 1130:2019 standard's latching requirement only simulates the action of unintentionally folding the product's folding or adjustable legs, while the

DRAFT

ASTM F2194-16ε1 *bassinet* standard tests both the standard and the bassinet as a fully assembled product.

The ASTM F2194 -16ε1 *bassinet* standard requires products without a locking mechanism to withstand a 20-pound force applied to the top edge of the bassinet in the direction most likely to cause it to fold. For products with a locking hinge or latch, the locking mechanism must withstand a 10-pound force in the direction most likely to release it. Staff's assessment is that testing the product fully assembled, as required by ASTM, is a better test because it simulates realistic use of the product.

The ASTM standard also includes a *Removable Bassinet Bed Attachment to Base/Stand* requirement and testing to address latching and locking devices intended to secure removable bassinet beds to the base/stand. These requirements and the test are unique because they address known incidents of false latching of a removable bassinet bed. By considering the latching, unintentional folding, and bassinet bed attachments to the stand requirements in total, staff assesses that the ASTM F2194-16ε1 *bassinet* standard's latching requirements are adequate.

iv. Stability Requirements

The EN1330:2019 standard requires products not to tip over when a 19.87-pound weight is placed on one side of the crib, while on the opposite side's top rail, a 6.74 pound-force is horizontally applied towards the weight. This test is similar to the ASTM F2194-16ε1 *bassinet* standard with reasonably similar forces. EN1330:2019 rationalizes the test, stating the product "should remain stable when the child moves in the crib or when the crib swings along the amplitude permitted by the suspension device." ASTM F2194-16ε1 is based on U.S. incident data of a 2-year-old sibling pulling over a bassinet, which is a more severe condition than an

DRAFT

infant moving within the product. Therefore, staff concludes the ASTM F2194-16 ϵ 1 *bassinet* standard's stability requirements are adequate.

v. EN 1130:2019 Summary

The EN 1130:2019 children's cribs and cradle standard has side height, sleep surface angle, and stability requirements similar to the ASTM F2194-16 ϵ 1 *bassinet* standard; however, the ASTM F2194-16 ϵ 1 standard has a more extensive and stringent latching requirement.

(c) *AS/NZS 4385:1996* Infant's Rocking Cradles

The Australian/New Zealand standard (AS/NZS 4385:1996) contains requirements for rocking and swinging angles used to develop some of the ASTM F2194-12 requirements. The ASTM rock/swing rest angle performance requirement is more stringent because the occupant surrogate, a CAMI dummy, is placed against the sidewall, resulting in higher rest angles.

i. Side Height

The AS/NZS 4385:1996 standard requires a minimum side height of 11.81 inches (300 mm) between the top of the mattress support to the top edge of the lowest rocking cradle's side. The maximum mattress thickness the AS/NZS standard permits is 2.95 inches (75mm). Therefore, the minimum side height between the top of the mattress and the top edge of the lowest side is 8.85 inches. This is similar to the ASTM F2194-16 ϵ 1 *bassinet* standard, which requires a minimum side height of 7.5 inches between the top of the mattress and the top of the lowest sidewall.

ii. Sleep Surface Angle

The AS/NZS 4385:1996 standard requires the mattress angle on rocking cradles without a self-leveling device not to exceed 5 degrees and 10 degrees on rocking cradles with a self-leveling device. This is similar to the ASTM F2194-16 ϵ 1 *bassinet* standard, which requires a maximum sleep surface angle of 10 degrees.

DRAFT

iii. Latching Requirements

The AS/NZS 4385:1996 standard does not contain any latching requirements to address the unintentional folding hazard. The ASTM F2194-16 ϵ 1 *bassinet* standard is more stringent because it requires products without a locking mechanism to withstand a 20-pound force without folding, or a 10-pound force for hinges with locking mechanisms. The ASTM F2194-16 ϵ 1 also addresses the false latching of a removable bassinet bed with requirements including an automatic locking latch or a false latch indicator.

iv. Stability Requirements

The AS/NZS 4385:1996 standard requires a product not to tip over when a 19.84-pound (9 kg) weight is on the mattress and a 4.49-pound force (20N) is applied horizontally to the uppermost rail. This test is similar to the ASTM F2194-16 ϵ 1 *bassinet* standard, which requires the product (with simulated newborn occupant) to withstand a 23-pound vertical force and 5-lb. horizontal force along its side, without tipping. The rationale in ASTM F2194 states the dual application of forces simulates a 2-year-old male pulling on the side of the product; staff concludes that this is a reasonable scenario in which the product may tip over.

v. AS/NZS 4385:1996 Summary

The AS/NZS 4385:1996 infant's rocking cradle standard has a side height, sleep surface angle, and stability requirement similar to the ASTM F2194-16 ϵ 1 *bassinet* standard. However, the ASTM F2194-16 ϵ 1 *bassinet* standard has a more stringent latching requirement.

(d) Canadian Standard (SOR/2016-152) *Cribs, Cradles, and Bassinets*

The Canadian standard (SOR/2016-152) includes requirements for cribs, cradles, and bassinets. Staff focused their analysis on the requirements for "bassinets," which are defined as providing sleeping accommodations for a child with sides to confine the child, and a sleep surface area less than or equal to 4000 cm² (620 in²).

DRAFT

i. Side Height

The Canadian standard requires a minimum side height of 230 mm (9.05 inches), measured from the mattress support. Because ASTM F2194 – 16 ε1 allows a bassinet mattress of 1.5 inches, measuring from the upper surface of the mattress support to the upper surface of the side would be 1.5 inches greater than measuring from the upper surface of an uncompressed mattress. Therefore, staff advises that the 7.5-inch side height, from the upper surface of an uncompressed mattress, is functionally equivalent to the 9-inch side height, measured from the upper surface of the mattress support in the Canadian standard.

ii. Sleep Surface Angle

The Canadian standard requires the sleep surface angle not to exceed 7 degrees, which is based on a 1995 study that demonstrated a discernable difference in infant ability between 5, 7, and 10 degrees in a side-to-side tilt. Staff advises they understand that Health Canada selected 7 degrees and applied it to all sides of the product, regardless of head-to-toe or side-to-side tilt. The ASTM F2194-16ε1 *bassinets* standard allows for a side-to-side resting angle of 7 degrees for rocking cradles, and limits head-to-toe angle to 10 degrees. As discussed in section VI.A.3(a) of this preamble, based on the Mannen Study and other factors, the Commission concludes that a flat sleeping surface that does not exceed 10 degrees from horizontal offers infants the safest sleep environment.

iii. Latching Requirements

The Canadian standard requires folding products to contain an auto-locking mechanism that requires a dual-simultaneous action to disengage and that does not fold when a 52.91-pound (24kg) load is applied on any area most likely to damage the mattress support. While the Canadian standard requires an auto-locking mechanism that requires a dual-simultaneous action to disengage, it also tests the latching strength by loading the mattress support. The ASTM

DRAFT

F2194-16ε1 *bassinet* standard requires that products without a latching or locking device not fold when a 20-pound force is applied to the top edge of the bassinet in the direction most likely to cause it to fold. The ASTM F2194-16ε1 *bassinet* standard requires a lower force than the Canadian standard, but the force is applied at a higher location (top side of the bassinet) than the Canadian standard (force applied to the mattress support). The higher location of the force could create a greater torque at the latch, due to the longer lever arm. For bassinets with a locking hinge or latch, the locking mechanism must withstand a 10-pound force in the direction most likely to release it. Determining which latching requirement is more stringent is difficult because the test parameters are not directly comparable.

The ASTM standard also includes a *Removable Bassinet Bed Attachment to Base/Stand* requirement and testing to address latching and locking devices intended to secure removable bassinet beds to the base/stand. These requirements and test are unique because they address known incidents of false latching of a removable bassinet bed. By considering the latching, unintentional folding, and bassinet bed attachments to the stand requirements in total, staff assesses that the ASTM F2194-16ε1 *bassinet* standard's latching requirements are adequate.

iv. Stability Requirements

The Canadian requirement in Schedule 11, Test for Stability of Cradles, Bassinets, and Stands, of their regulation is substantially equivalent to the requirement in ASTM F2194-16ε1. The requirement specifies that the product (with a simulated newborn occupant) must withstand a 10-kg (approximately 22 pounds) static vertical load over a period of 5 seconds and a 22 N (approximately 4.9 pounds) horizontal force, without tipping. Staff advises that this test evaluates the same stability hazard and is substantially equivalent to the ASTM F2194-16ε1 *bassinets* standard, differing slightly due to conversions to metric.

DRAFT

v. SOR/2016-152 Summary

The Canadian standard has a side height and stability requirement similar to the ASTM F2194-16ε1 *bassinet* standard. While the Canadian standard has a more stringent sleep surface angle requirement, the ASTM F2194-16ε1 *bassinet* standard has a more extensive latching requirement. Staff concludes that the requirements in the ASTM standard are adequate to address the risk of injury demonstrated in the incident data.

*B. Flat Sleep Products*³⁵

CPSC received public comments on the 2019 SNPR regarding the safety of currently unregulated flat infant sleep products available in the marketplace. In response, for the final rule CPSC staff completed a review of CPSC's epidemiological databases, CPSRMS and NEISS. CPSC received a total of 183 incident reports from January 1, 2019 through December 30, 2020, related to flat sleep products available in the marketplace that are currently not under the purview of any mandatory or voluntary standard that addresses sleep hazards. These flat sleep products include: in-bed sleepers, baskets (that can function as hand-held carriers as well), baby boxes, compact bassinets, most of which are portable for travel, and travel tents. All of these unregulated sleep products are flat (sleep surface has no incline) and most come with mattress pads (with the exception of some baby travel tents).

Based on the following analysis, the Commission determines that the performance and labeling requirements of the voluntary standard for bassinets and cradles, ASTM F2194-16ε1, as codified in 16 CFR part 1218, Safety Standard for Bassinets and Cradles, are adequate to address the risk of injury associated with flat infant sleep products, and furthermore, finds that requiring flat products to conform to these requirements would also further reduce the risk of injury

³⁵ Tab C of Staff's Final Rule Briefing Package contains CPSC staff's assessment of the adequacy of ASTM F2194-16ε1 to address incidents associated with flat sleep products.

DRAFT

associated with flat sleep products.

1. Hazard Pattern Categories

Of the 183 reported incidents, 11 are fatalities; among the remaining 172 nonfatal incidents, 16 reported an injury. Seven of the 11 fatalities involved suffocation. We identified six hazards related to the risk of injury or death (we did not consider patterns that did not relate to injuries or deaths, such as consumer comments). The hazard patterns identified among the 183 incidents are: lock/latch problems, falls/containment issues, instability, asphyxiation/suffocation, product-related issues, and undetermined causes.

Engineering staff analyzed whether the voluntary standard for bassinets, ASTM F2194-16 ϵ 1, would address the identified hazards for flat sleep products. The voluntary standard for bassinets, ASTM F2194-16 ϵ 1, is more applicable to these flat products than ASTM F3118-17a, because these products have a sleep surface less than 10 degrees, and because, as set forth below, the standard addresses the identified hazards associated with these products. The current voluntary standard for infant inclined sleep products, ASTM F3118-17a, is not applicable to these flat sleep surface products, and it does not address hazards associated with flat sleep surfaces.

In the 2019 SNPR, the Commission proposed expanding the scope of ASTM F3118-17a for the mandatory rule, to include all infant sleep products (inclined and flat) that are not covered by another CPSC sleep standard, including the bassinets, cribs (full-size and non-full size), play yards, or bedside sleepers standards. The 2019 SNPR proposed to require that all products marketed or intended for infant sleep have a seatback angle of 10 degrees or less, and meet 16 CFR part 1218, Safety Standard for Bassinets and Cradles, which includes the performance requirements of ASTM F2194-16 ϵ 1 *bassinets*. The following are the identified hazards for flat sleep products are discussed below.

DRAFT

(a) Hazard: Lock/Latch Issue

One hundred fifteen of the 183 incidents, and no deaths, were related to latches that control the opening/closing of the cover on the product failed. Although these latch incidents did not relate to a product folding or collapsing, they illustrate, nevertheless, that these products have latch failures. From analyses on other products, staff is aware that failure of a product's latch can cause the product to fold or collapse unintentionally and pose a suffocation hazard to the infant. The ASTM F2194-16 ϵ 1 *bassinets* standard addresses hazards posed by a lock/latch failure with an unintentional folding requirement. The requirement specifies that if a folding product does not have a latching or locking device, then it shall not fold when a 20-lb. force is applied in the direction most likely to fold the product (with simulated infant occupant). The requirement also specifies if a folding product does have a single-action latch, then it shall not fold when a 10-lb. force is applied in the direction most likely to fold the product. Staff assesses that this requirement adequately simulates the action of unintentionally folding the product, and therefore, to address this risk of injury, we conclude that all flat sleep products with a lock or latch should at least meet the ASTM F2194-16 ϵ 1 *bassinets* standard's unintentional folding requirement.

The ASTM F2194-16 ϵ 1 *bassinets* standard also includes a "*Removable Bassinet Bed Attachment to Base/Stand*" performance requirement. A removable bassinet bed attaches to the bassinet stand and is secured with a latch/lock. This requirement states a removable bassinet bed shall:

- not be supported by the bassinet stand in an unlocked/latched configuration;
- automatically lock to the bassinet stand and can't be placed in an unlocked position on the bassinet stand;
- clearly and obviously be unstable when the product is unlocked/latched by placing the

DRAFT

sleeping surface at a 20-degree incline;

- have a false latch/lock visual indicator designed to visually alert caregivers when the bed is not properly locked to the stand; or

- have a lock/latch mechanism that is not needed to pass the stability requirement.

The purpose of this requirement is to ensure that bassinets that can be removed from their stand are securely latched to the stand when in use. Staff assesses that the ASTM F2194-16 ϵ 1 *bassinets* standard's requirement adequately simulates the action of a bassinet unintentionally unlatching from its stand. Staff also assesses that the ASTM F2194-16 ϵ 1 *bassinets* standard's requirement is more stringent compared to the ASTM F3118-17a *infant inclined sleep products* standard, which lacks a requirement for products that can be removed from a stand. Therefore, the final rule requires that flat sleep products meet the ASTM F2194-16 ϵ 1 *bassinets* standard's "unintentional folding requirement" and the "Removable Bassinet Bed Attachment to Base/Stand requirement," if applicable, to address the risk of injury associated with locks and latching features on these products.

(b) Hazard: Falls/Containment Issue

Twelve of the 183 incidents were related to falls or an infant otherwise not being kept contained within the product. Of the 12 incidents, one resulted in a death, one required hospital admission, and nine required ED visits. Failure to contain occupants in an infant sleep product can lead to infants falling or climbing out of the infant sleep product into a hazardous area.

Typically, regulated sleep products do not allow an active occupant restraint system for occupant containment. Active restraint systems are only effective when the caregiver actively uses them and adjusts them correctly; however, in a sleep environment, active restraints can create an entanglement and asphyxiation hazard.

The ASTM F2194-16 ϵ 1 *bassinets* standard does not allow the use of restraints, and

DRAFT

instead addresses containment-related hazards posed with a side height requirement, a passive safety feature. The requirement specifies that the product's interior side height with an uncompressed mattress shall be at least 7.5 inches.

In 2012, the ASTM F2194-12 *bassinets* standard first required a minimum 7.5-inch side height based on the Canadian standard.³⁶ The side height is measured from the upper surface of the uncompressed mattress to the upper surface of the lowest side. This requirement remains in effect in the most recent version of the *bassinets* standard, ASTM F2194-16ε1. Canada requires a side height of 230 mm (9 inches), measured from the mattress support. Because ASTM F2194-16ε1 allows a bassinet mattress of 1.5 inches, measuring from the upper surface of the mattress support, which is underneath the mattress, to the upper surface of the side would be 1.5 inches greater than measuring from the upper surface of an uncompressed mattress. Therefore, staff assesses that the 7.5-inch side height, from the upper surface of an uncompressed mattress is functionally equivalent to the 9-inch side height, measured from the upper surface of the mattress support in Canada.

Products that CPSC staff identified as flat sleep products are not currently subject to a voluntary or mandatory standard that specifies a minimum side height. Flat sleep products that are considered hand-held carriers under 16 CFR part 1225, *Safety Standard for Hand-Held Infant Carriers*, and ASTM F2050-19, *Standard Consumer Safety Specification for Hand-Held Infant Carriers*, can be defined as a “hand-held bassinet/cradle” product intended for sleep, but “hand-held bassinet/cradles” are not subject to a side height requirement in the mandatory or voluntary standard. Products without a minimum side height could fail to contain occupants, which can lead to infants falling or climbing out of the product into a hazardous area.

³⁶ 78 *Fed. Reg.* 63,109 (Oct. 23, 2013).

DRAFT

Table 4 shows the side height requirements for each sleep product standard. Sleep products that have a minimum side height requirement range from 2-inches for the voluntary standard for infant inclined sleep products, to 9-inches for cribs. Bassinets, bedside sleepers, and infant inclined sleep products are intended for infants from birth to 5-months old. Cribs are intended for newborns up to children 35-inches tall, which is equivalent to a 95th percentile in stature 21-month-old.

Table 4. Side Height Requirements for Sleep Products

Standard	Side Height Requirement	Age range
16 CFR 1218 – Safety Standard for Bassinets and Cradles ASTM F2194-16ε1, <i>Standard Consumer Safety Specification for Bassinets and Cradles</i>	7.5 inches	0-5 months, or sit up
16 CFR 1219 – Safety Standard for Full-Size Baby Cribs ASTM F1169-19, <i>Standard Consumer Safety Specification for Full-Size Baby Cribs</i>	9 inches	0-35 inches tall (95 th percentile 21-month old)
16 CFR 1220 – Safety Standards for Non-Full-Size Baby Cribs 16 CFR 1221 – Safety Standards for Play Yards ASTM F 406-19, <i>Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards</i>	9 inches	0-35 inches tall (95 th percentile 21-month old)
16 CFR 1222 – Safety Standard for Bedside Sleepers ASTM F2906-13, <i>Standard Consumer Safety Specification for Bedside Sleepers</i>	4 inches on side next to adult bed. 7.5 inches for other 3 sides.	0-5 months, or sit up
ASTM F3118-17a, <i>Standard Consumer Safety Specification for Infant Inclined Sleep Products,</i>	3 inches	0-5 months or sit up
	2 inches	0-3 months
16 CFR part 1225 <i>Safety Standard for Hand-Held Infant Carrier</i> ASTM F2050-19 <i>Standard Consumer Safety Specification for Hand-Held Infant Carrier</i>	No requirements	

Inclined sleep products covered in ASTM F3118-17a can meet the standard with a minimum side height of 3-inches, for products intended for newborns, to 5-month of age and a minimum side height of 2-inches, for products intended for newborns up to 3-months old.

Upon review of applicable standards, CPSC staff determined that the ASTM F2194-16ε1 *bassinets* standard’s 7.5-inch side height requirement provided the greatest safety for the intended use for newborns to 5-months of age. Staff assesses that the minimum side height

DRAFT

requirement of 2-inches and 3-inches in ASTM F3118-17a is inadequate to address the incidents of infants failing to be contained in low-sided products, and the 3-inch side height is lower than the center of gravity of a 5-month-old infant on its side. Staff determined that because most flat sleep products are intended for infants under 5 months, who cannot sit upright unassisted, the side height requirement in ASTM F2194-16 ϵ 1 is adequate to address containment incidents. Based on staff's analysis, the Commission determines that flat sleep products with no side height requirements pose a potential fall hazard, as reflected in the incident data.

Staff's analysis demonstrates that the ASTM F2194-16 ϵ 1 *bassinets* standard's 7.5-inch side height requirement is appropriate and would adequately address the falls/containment hazard in flat sleep products for infants up to 5 months old or who cannot sit up unassisted. Therefore, consistent with the 2019 SNPR, the final rule requires that all infant sleep products, inclined and flat, meet the side height requirement of the ASTM F2194-16 ϵ 1 *bassinets* standard, as provided in 16 CFR part 1218, to address fall/containment hazards.

(c) *Hazard: Instability*

Twelve of the 183 incidents were related to the instability of the product. An unstable product can lead to tip-over incidents. Of the 12 incidents, two resulted in injuries, one involved an ED visit. The data summarized in Tab B of the Staff's Final Rule Briefing Package includes at least one incident in a small, portable infant sleep product involving a sibling interaction resulting in a fall. Specifically, the NEISS report states: "7WKOF WITH HEAD INJURY, FELL FROM PORTABLE BASSINET THAT WAS ON COUCH, APPROX 1.5FT, YOUNGER BROTHER PULLED THE BASSINET AND IT FLIPPED ONTO THE PLAYMAT, PT LANDED ON RT SIDE OF HEAD." This sibling interaction-type incident is addressed by the bassinet standard, as discussed below.

Unregulated flat sleep products are not required to have a stand. Therefore, these

DRAFT

products can be placed directly on the floor or on potentially hazardous or unstable elevated surfaces, such as tables, countertops, soft mattresses, or couches. The ASTM F2194-16 ϵ 1 *bassinets* standard addresses this hazard scenario by requiring bassinets to have a stand/base/frame. ASTM F2194-16 ϵ 1 defines a “bassinet” as a small bed “supported by free standing legs, a stationary frame/stand, a wheeled base, a rocking base, or which can swing relative to a stationary base.” This requirement to have a stand, and be raised off the floor, increases the stability of a portable product by discouraging or preventing use of the product on other, less stable, surfaces, such as elevated surfaces or soft surfaces (couches and adult beds). Therefore, with respect to this hazard scenario, and as proposed in the 2019 SNPR, the final rule requires that all infant sleep products, flat and inclined, meet the ASTM F2194-16 ϵ 1 *bassinets* standard’s requirements, including requiring products to have a stand, to further reduce the risk of injury from a product placed on a hazardous elevated surface or an unstable surface, such as a couch or adult bed. This requirement in the final rule is codified by requiring products to meet the definitional requirement of a “bassinet/cradle.”

Additionally, the ASTM F2194-16 ϵ 1 *bassinets* standard addresses hazards posed by the product’s instability with a stability requirement. The requirement specifies that the product (with simulated newborn occupant) withstand a 23-lb. vertical force and 5-lb. horizontal force along its side, without tipping. The rationale in ASTM F2194 states the dual application of forces simulates a 2-year-old male pulling on the side of the product; staff assesses that this is a reasonable scenario in which the product may tip over. Incident data also demonstrate that these compact products are used on elevated surfaces, such as beds and couches, from which the infant and product fell. Therefore, with respect to the product’s stability, the final rule requires that all infant sleep products meet the stability requirement of the voluntary standard for bassinets, ASTM F2194-16 ϵ 1, as provided in 16 CFR part 1218, to further reduce the risk of injury

DRAFT

associated with product tip-over.

The Canadian requirement in Schedule 11, Test for Stability of Cradles, Bassinets and Stands, of their regulation is substantially equivalent to the requirement in ASTM F2194-16ε1. The requirement specifies that the product (with a simulated newborn occupant) withstand a 10-kg (approximately 22 pounds) static vertical load over a period of 5 seconds and a 22 newton (approximately 4.9 pounds) horizontal force without tipping. Staff advises that this test is substantially equivalent to the ASTM test, differing slightly due to conversions to metric.

(d) *Hazard: Asphyxiation/Suffocation*

Nine of the 183 incidents were related to infants that partially or fully rolled over from their initial position in infant sleep products. Of the nine incidents, eight resulted in a death, and one resulted in a near-suffocation prevented by a nearby parent.

The voluntary standard for bassinets, ASTM F2194-16ε1, addresses the asphyxiation/suffocation hazard with the following general/performance requirements:

- *5.10 Corner Posts:* This requirement addresses corner post extensions that can entangle ribbons, pacifier cords, necklaces, or occupant clothing. Entanglement of any of these items could lead to the asphyxiation of the occupant. This requirement limits the extension of a bassinet's corner post from extending more than .06 inches above the upper edge of an end or side panel. Corner posts that extend at least 16 inches above the top of a side rail are exempt because they are deemed inaccessible to the occupant. These are the same requirements found in the regulated ASTM F406-19 (*non-full-sized cribs*) and ASTM F1169-19 (*full-sized cribs*) standards that CPSC staff previously concluded adequately address the corner post entanglement hazard.

DRAFT

- *6.1 Spacing of Rigid-Sided Bassinet/Cradle Components.* This requirement limits the distance between slats to less than 2 3/8 inches to mitigate the suffocation hazard from feet-first head entrapment.

- *6.2 Openings for Mesh/Fabric-Sided Bassinets/Cradle.* This requirement tests openings in the bassinet's mesh for entrapment of fingers, toes, and snaring buttons, often used on infant clothing. The snaring of a button entraps the button and could lead to asphyxiation as the infant becomes entangled and entrapped. In this performance requirement, the mesh-sided bassinet's openings cannot allow a 1/4-inch rod to fit through.

- *6.5.3 Pad Dimensions.* This requirement mitigates the hazard of suffocating when entrapped in the space between the edge of the mattress and the bassinet's sidewall, by limiting the available space to less than 1 inch.

- *6.7 Bassinets with Segmented Mattress: Flatness Test.* This requirement limits sleep surface variability of a segmented or folding mattress to 10 degrees or less. This angle was determined to reduce the likelihood of an infant's face becoming engulfed by a small "V" shape formed by the creases in a folded mattress, potentially present in a bassinet that uses a folding play yard mattress as the bassinet mattress.

- *6.8 Fabric-Sided Enclosed Openings.* This requirement addresses the hazard of a feet-first head entrapment through the openings of fabric-sided bassinets. This requirement limits the openings in a fabric-sided bassinet to prevent the 5th percentile 0 to 2-year-old torso probe from passing through. This requirement prevents a child's torso from fitting through any openings in the fabric sidewalls; therefore, staff concludes this requirement would prevent a feet-first head entrapment.

- *6.9 Rock/Swing Angle.* This requirement limits the bassinet's sleeping surface angle to less than 20 degrees when rocked, and seven degrees when the bassinet is at rest. In the 2019

DRAFT

SNPR, and in this final rule, the Commission determined that a flat sleep surface that does not exceed 10 degrees offers infants the safest sleep environment. This conclusion is based on the Mannen Study.

In total, these requirements address known suffocation hazards with infant sleep and create a minimally safe sleep environment. Therefore, for the final rule, with respect to the asphyxiation/suffocation hazard, we finalize the 2019 SNPR proposal, by requiring that all infant sleep products meet general and performance requirements of the voluntary standard for bassinets, ASTM F2194-16e1, as provided in 16 CFR part 1218, to further reduce the risk of death from suffocation.

(e) Hazard: Product-Related Issues

Three of the 183 incidents were related to mold or quality of the product material. Two of the three products were in-bed sleepers, while the third was a compact bassinet/travel bed. All three reported an injury. None of the voluntary standards currently address conditions such as mold that manifest due to the conditions under which a product is used. A moisture-resistant requirement has been discussed in the ASTM task group for baby boxes (which is under the bassinet subcommittee), but the task group has not reached a consensus on appropriate performance requirements to address mold and moisture resistance. CPSC staff will continue to work with this task group.

(f) Hazard: Undetermined Issues

Three of the 183 incidents did not have enough reported information for us to determine the issue involved. Two of the incidents were fatalities; in both cases, CPSC Field investigation reports indicate that the cause of death is undetermined. The third incident resulted in a hospitalization due to unspecified breathing difficulties suffered by the infant. The reports did not provide sufficient information on the circumstances of deaths, and injury reports involved

DRAFT

unspecified falls. Without information on the circumstances of deaths or injuries, we are unable to assess whether the voluntary standard for bassinets, ASTM F2194-16 ϵ 1, would adequately address the hazards in this category.

2. Assessment of International Standards

(a) *EN12790:2009 Reclined Cradles*

The scope of the European Standard, EN 12790-2009 “Child use and care articles – Reclined cradles” includes inclined bassinets/cradles, car seat carriers, hammocks, and bouncers. Some of the general requirements could apply, but because the scope of the products that fall within this standard is not the same as the final rule, most of the requirements are not applicable to infant sleep products.

i. Side Height

The EN 12790:2009 standard does not have a side height requirement, but it includes a three-point restraint to address the containment hazard. The ASTM F2194-16 ϵ 1 *bassinet* standard is more stringent by requiring a minimum side height of 7.5 inches. Restraints are an active safety feature that might not always be used, while the side height requirement is a passive safety feature.

ii. Sleep Surface Angle

The EN 12790:2009 standard requires a seatback angle between 10 degrees and 80 degrees, while the ASTM F2194-16 ϵ 1 *bassinet* standard is more stringent by requiring a maximum sleep surface angle of 10 degrees. The EN 12790:2009 standard was written for products that may or may not be intended for sleep, such as car seats, a scope that is broader than the scope of the ASTM bassinet standard. The Mannen Study concluded that a seatback angle of 10 degrees or less is safe. Accordingly, the sleep surface requirement in the final rule remains consistent with the Mannen Study findings, and as already codified in 16 CFR part 1218.

DRAFT

iii. Latching Requirements

The EN 12790:2009 standard specifies that infant rocking cradles must have at least one automatic locking latch mechanism, and that the locking mechanisms:

- Require 50N (11.24 pounds-force) to unlatch after operating the latch 300 times;
- Require a tool to unlatch;
- Require two consecutive actions to unlatch; or
- Require two independent and simultaneous actions to unlatch.

The EN 12790:2009 standard's latching requirement simulates the action of unintentionally folding the product. The ASTM F2194-16 ϵ 1 *bassinets* standard similarly includes requirements that address the unintentional folding hazard and requirements that address the false latching of a removable bassinet bed. Therefore, staff assesses that the ASTM F2194-16 ϵ 1 *bassinets* standard's latching requirements are adequate.

iv. Stability Requirements

The EN 12790:2009 standard requires products with a test mass not to tip over when placed on a 15-degree surface. The test mass for cradles designed for occupants up to 13.22 pounds is 19.84 pounds. The test mass for cradles designed for occupants up to 19.87 pounds is 33.06 pounds. This standard simulates the stability of an occupied reclined cradle on an uneven surface. This is different compared to the ASTM F2194-16 ϵ 1 *bassinets* standard, which requires the product (with simulated newborn occupant) to withstand a 23-lb. vertical force and 5-lb. horizontal force along its side, without tipping. The rationale in ASTM F2194 states the dual application of forces simulates a 2-year-old male pulling on the side of the product; staff concludes that this is a reasonable scenario in which the product may tip over.

DRAFT

v. EN 12790:2009 Summary

The EN 12790:2009 reclined cradle standard is less stringent than the ASTM F2194-16ε1 *bassinets* standard by not requiring any minimum side height for containment and permits a more inclined sleep surface angle for products that include reclined cradles and car seats for children up to 19.84 pounds.

C. Applicability of ASTM F2194-16ε1 to Flat Sleep Product Hazards

Table 5 summarizes the hazards associated with flat sleep products and how each hazard category is addressed by the voluntary standard for bassinets, ASTM F2194-16ε1. Table 5 demonstrates that four hazard categories (shaded) are addressed by ASTM F2194-16ε1: Latching, Falls/Containment, Instability, and Asphyxiation/Suffocation.

Table 5: Flat Sleep Product Hazards Addressed by Bassinets Voluntary Standard

Product	Applicable Voluntary Standard	Infant Sleep Hazards					
		Latching	Falls/Containment	Instability	Asphyxiation/Suffocation	Miscellaneous product-related	Undetermined
Flat Sleep Products (flat and inclined)		115 incidents Not currently addressed	12 incidents: 1 death Not currently addressed	12 incidents: 2 injuries Not currently addressed	9 incidents: 8 deaths; not currently addressed	3 mold-related incidents; not currently addressed	3 incidents: two deaths Too little information to determine addressability
Bassinet/Cradle	ASTM F2194-16ε1	Unintentional folding requirement	Side height requirement	Stability requirement	Max sleep surface angle defined in definition; Restraints not allowed; Flatness/hazardous Vs identified; Pad dimensions; Corner posts; fabric sided enclosed openings; Spacing; Mesh openings	Not currently addressed; task group work	Too little information to determine addressability

Based on this assessment of the hazards associated with flat sleep products, and consistent with the 2019 SNPR, the final rule requires that all infant sleep products not already

DRAFT

regulated by a CPSC sleep standard meet the requirements in the ASTM F2194-16^{ε1} *bassinets* standard, as provided in 16 CFR part 1218, to address the risk of injury associated with these sleep products. Specifically, the final rule requires that infant sleep products, meaning products that are marketed or intended as a sleeping accommodation for an infant up to 5 months of age, and that are not subject to a CPSC sleep standard (bassinets and cradles, cribs (full-size and non-full-size), play yards, or bedside sleepers), meet the requirements of 16 CFR part 1218, including conforming to the definition of a “bassinet/cradle.”

VII. Response to Comments

The Commission collected comments on the 2017 NPR, which proposed to incorporate by reference the then-current voluntary standard for infant inclined sleep products, ASTM F3118-17, with a modification to the standard’s definition of “accessory.” 82 FR 16964 (April 7, 2017). The Commission also collected comments on the 2019 SNPR, which proposed to incorporate by reference the current voluntary standard for infant inclined sleep products (ASTM F3118-17a), with modifications to make the standard more stringent, to further reduce the risk of injury. 84 FR 60949 (Nov. 12, 2019). The 2019 SNPR proposed to expand the scope of the rule to include all unregulated infant sleep products, including inclined products and non-inclined, flat products. The 2019 SNPR invited the public to submit written comments during a 75-day comment period, beginning on the SNPR publication date, and ending on January 27, 2020. In response to a request for an extension of the comment period, the Commission extended the comment period by 30 days, closing on February 26, 2020. 85 FR 4918 (Jan. 28, 2020).

Below we consolidate the Commission’s responses to comments on the 2017 NPR and the 2019 SNPR. In response to the 2017 NPR, the Commission received seven comments. In response to the 2019 SNPR, the Commission received 56 comments within the comment period. We also considered two late-filed documents, one received on February 2, 2021, and one

DRAFT

received on April 30, 2021. We organized the comments by rulemaking notice (2017 NPR or 2019 SNPR), and then by topic.

Numerous commenters on the 2019 SNPR, such as the American Academy of Pediatrics (AAP), consumer groups, and individual parents, supported the SNPR, because the products covered in the final rule will be required to follow the AAP safe sleep guidelines. Based on consideration of the comments received, for the final rule, the Commission will maintain the proposed 12-month effective date, and make several clarifications, as listed in section I.F of this preamble.

A. Comments on the 2017 NPR

1. Safety of Inclined Products

Comment 1: Three commenters disagreed with the 2017 NPR, stating that infant sleep products with a 30-degree seat back angle are not safe and contradict the AAP's safe sleep recommendations. One commenter also indicated that the Commission should:

- conduct more research on the 30-degree seat back angle;
- conduct more research on developmental implications when an infant is restrained while sleeping;
- provide performance requirements to address product misassembly;
- make the side height requirement match the 7.5 side height requirement in the bassinets and cradles standard;
- develop performance or design changes for compact units so they cannot be placed on a raised surface, in crib, or on soft surface;
- add seat back height requirement for infant products like newborn products;
- add requirements for hammocks to increase stability;
- add requirements for flat sleep products, so an infant cannot move into an unsafe chin to

DRAFT

chest position;

- add pictograms to warnings like slings and hand-held carriers;
- include “marking” on products to show compliance with new regulations;
- conduct market surveillance after a regulation becomes effective; and
- have a 6-month effective date for the final rule.

Response 1: We agree, based on the Mannen Study, that infant sleep products, as defined in the final rule, should not have a seat back/sleep surface angle greater than 10 degrees. The Commission proposed to address many of the commenter’s in-scope recommendations noted above in the 2019 SNPR, and is now finalizing the requirements, by requiring inclined and flat sleep products that are marketed or intended to provide a sleeping accommodation for an infant up to 5 months old, to meet the bassinet standard. Due to the expected significant economic impact on some manufacturers, the Commission will maintain the proposed 12-month effective date for the final rule.

2. Definition of “Infant Inclined Sleep Product”

Comment 2: A commenter stated that the phrase, “primarily intended and marketed to provide sleeping accommodations,” in the proposed definition of an “infant inclined sleep product,” is not needed, because “incorporating a manufacturer’s marketing intentions into a definition of a product which impacts the safety standard of that product opens the door to potential conflicts of interests.” The commenter reasoned that a child’s age and the product incline are objective factors, while a manufacturer’s intent is more subjective, and could allow manufacturers to market the product in a way to avoid meeting the requirements of the rule.

Response 2: Although the definition the commenter refers to in the standard no longer includes the term “inclined,” we respond here to the concept of including the phrase “marketed or intended” in the definition of “infant sleep product” in the final rule. A manufacturer’s

DRAFT

intended use of the product and marketing guide informs caregivers about the product's safe use. Manufacturers of products that are not designed or marketed for use as an infant sleep product should provide caregivers with instructions and warnings regarding safe use of the product. Including a manufacturer's marketing and intent in the definition also assists the Commission to enforce the regulation, because it provides objective criteria for CPSC staff to apply to a product's name, packaging, warnings, labeling, and marketing materials about whether the product falls within the scope of the rule. CPSC staff has experience using marketing materials to enforce CPSC's regulations, and CPSC is required to use such materials in some cases. For example, section 3 of the CPSA provides factors for determining whether a product is a "children's product," and includes several factors that require reviewing labeling, promotion, and advertising, to determine whether a product is "designed or intended primarily for children 12 years of age or younger." 15 USC 2052(a)(2). Products that have no use other than infant sleep, based on the product's design, cannot be labelled as not intended for infant sleep to avoid meeting the requirements of the final rule.

3. Comments Superseded by the 2019 SNPR

Comment 3: Two commenters agreed with the modification of the "accessory" definition in the 2017 NPR, and with the 12-month effective date. One commenter had a specific comment related to restraint requirements in the NPR.

Response 3: The 2019 SNPR supersedes the 2017 NPR. The proposed modification to the definition of "accessory" is no longer at issue in the final rule, because this definition has been removed, along with other requirements related to inclined sleep products. The Commission will maintain the 12-month effective date for the final rule, to provide manufacturers and importers sufficient time to come into compliance. Allowance of a restraint requirement in an infant sleep product was unique to inclined sleep products to contain the infant

DRAFT

in the product. Consistent with the 2019 SNPR, the Commission removed the restraint requirement in the final rule, because restraints can create a strangulation hazard. The passive containment provision in the bassinet and cradle standard, which requires a product side height of 7.5 inches and a flat (below 10 degree) sleep surface, follows safe sleep practices for containment: a bare, flat, infant sleep surface.

B. Comments on the 2019 SNPR

1. Scope of the Final rule

(a) All products marketed, promoted, or otherwise indicated for sleep

Comment 4: A commenter suggested: “[t]he new standard should apply not just to those infant products intended by the manufacturer for sleep or certified as being for sleep, but also any product that is marketed, promoted, or otherwise indicated—or may be reasonably interpreted as indicating—as being for any kind of sleep, including products described using substitute language for sleep, such as ‘nap’ or ‘snooze.’”

Several other commenters expressed concern that various terms used in the 2019 SNPR were vague, and recommended that more precise definitions be provided for “sleep” and “sleeping accommodations.” In addition, commenters requested clarification regarding which products are included in the definitions.

Response 4: In response to this comment, the preamble and regulation text for the final rule: (1) clarify that the scope of the rule includes products with inclined and flat sleep surfaces, and (2) more precisely explain the definition of an “infant sleep product.” For example, to clarify that the scope of the rule includes inclined and flat sleep products, the scope of CPSC’s regulation text in § 1236.2, and the scope of the revised voluntary standard in section 1.3, explain that the scope of the infant sleep products rule includes products with inclined and flat sleep surfaces. The final rule also broadens the definition of an “infant sleep product” to include the

DRAFT

term “marketed”: which is “a product marketed or intended to provide sleeping accommodations for an infant up to 5 months old that is not subject to any of the following . . .” The definition then lists CPSC’s five infant sleep standards, to ensure that all infant products marketed or intended for infant sleep meet the requirements of a CPSC sleep standard, so that all products meet minimum safe sleep requirements. Staff modified the introduction, scope, and definitions in the final rule to clarify the applicability of the rule to any infant sleep product not covered by another CPSC sleep standard.

While newborns can and do fall asleep in many products, because young infants sleep for extended hours throughout the day, certain products are designed, marketed, and intended for infant sleep. Therefore, “sleep” and “sleeping accommodations” refer to products that are marketed or intended for both extended, unattended sleep, and also napping, snoozing, and other types of sleep in which a parent may or may not be present, awake, and attentive. Additionally, if a product name implies the product is for use as an infant sleep product, such as use of the terms “bed,” “bassinet,” or “crib,” but does not already comply with the bassinet or crib regulation, the product falls within the scope of the final rule. If a product, through marketing, pictures, and written description, indicates that the product is being sold as an infant sleep product for infants up to 5 months old, that product will be covered by this regulation if it is not already subject to a CPSC sleep standard.

The 2019 SNPR included four definitions, “infant sleep products,” “newborn sleep products,” “compact sleep products,” and “accessory sleep products.” However, this distinction is not necessary and creates confusion when identifying infant sleep products, because there are no unique requirements in this rule based on these definitions. Accordingly, for the final rule, to clarify which infant sleep products are subject to the rule, the Commission removed the separate definitions of “newborn,” “compact,” and “accessory” sleep products, and will rely solely on the

DRAFT

definition of an “infant sleep product”:

3.1.7 infant sleep product, n – a product marketed or intended to provide a sleeping accommodation for an infant up to 5 months of age, and that is not subject to any of the following:

- 16 CFR part 1218 – Safety Standard for Bassinets and Cradles
- 16 CFR part 1219 – Safety Standard for Full-Size Baby Cribs
- 16 CFR part 1220 – Safety Standard for Non-Full-Size Baby Cribs
- 16 CFR part 1221 – Safety Standard for Play Yards
- 16 CFR part 1222 – Safety Standard for Bedside Sleepers

(b) Distinguishing Non-Sleep Products

Comment 5: A commenter stated that infant car seats, swings, and rockers typically have seatback angles greater than 30 degrees, adding that these products have use patterns very similar to products that fall within the scope of ASTM F3118. The commenter requested clarification of the distinguishing features or characteristics that differentiate these two types of products with very similar usage patterns.

Response 5: The purpose of the final rule is to regulate all products marketed or intended for infant sleep for infants up to 5 months old. Accordingly, the products within the scope of the final rule are all marketed and intended for sleep, and do not include car seats, swings, or rockers, unless a product is marketed or intended for sleep. Newborns can and do fall asleep in many products, because young infants typically sleep 16 to 17 hours a day, 1 to 2 hours at a time. By 3 months, infants can sleep 4 to 5 hours during the day and 9 to 10 hours during the night.³⁷ However, products such as car seats, swings, and rockers typically are not marketed for use as an

³⁷ <https://www.stanfordchildrens.org/en/topic/default?id=infant-sleep-90-P02237>.

DRAFT

infant sleep product; these products are intended for use while the child is awake. Moreover, regarding car seats, CPSC has jurisdiction only for use outside of an automobile, when the product is being used as an infant carrier; while the National Highway Traffic Safety Administration (NHTSA) has jurisdiction over car seats being used in an automobile, including the car seats' angle and design for safe use in an automobile.

Comment 6: Several commenters stated that the scope of the 2019 SNPR was too broad, and expressed concerns that non-sleep products would be included. Some of the comments requested specific exclusions or inclusions to the scope of the final rule.

Response 6: The final rule does not apply to products that are not marketed or intended for infant sleep, such as bouncer seats, swings, infant chairs, or other similar durable infant or toddler products that are marketed for use while a child is awake. In addition, the Commission is specifically excluding crib mattresses that fall within the scope of the voluntary standard for crib mattresses, ASTM F2933, from the scope of the final rule. A crib mattress, alone, does not meet the definition of an “infant sleep product,” and is always used in conjunction with a sleep product, such as a crib or play yard, which are within one of the five existing CPSC sleep standards. The Commission issued a notice of proposed rulemaking for crib mattresses in 2020, and we intend to finalize a separate rule on crib mattresses this fiscal year.

The purpose of the rule is to set minimum safe sleep requirements for products that are marketed or intended for infant sleep up to 5 months old. The Commission is aware that infant sleep products share hazard patterns that can be addressed by performance and labeling requirements; but currently, a gap exists between regulated and unregulated products. Therefore, the scope of the final rule includes all infant sleep products not already covered by a mandatory CPSC sleep standard (bassinets, full-sized cribs, non-full-sized cribs, play yards, or bedside sleepers), and requires the product to be tested to the bassinet standard as a default, so that all

DRAFT

infant sleep products follow a mandatory safety standard for infant sleep, specifically (and minimally) the standard for bassinets and cradles. Based on staff's evaluation, following the requirements of the bassinet and cradle standard would address the hazard patterns found in the incident data for unregulated inclined and flat sleep products (see section VI of this preamble and Tab B and C of Staff's Final Rule Briefing Package).

The Commission is also concerned about new infant sleep products that come on the market and that do not follow any CPSC sleep standard. The concern is that caregivers may view these products as safe because they are on the market, even though these products may not address known infant sleep hazards or may not be tested to an appropriate standard.

Accordingly, the final rule requires all products marketed or intended for sleep for infants up to 5 months old to follow core safe sleep principles, which the Commission, in agreement with AAP, states are: place infants alone, on their back, and on a flat, firm surface with no restraints or loose fabric nearby.

Rather than list specific inclusions and exclusions, other than excluding crib mattresses, the scope and definitions in the final rule address potential confusion about which infant sleep products are covered. For example, the definition of an "infant sleep product" states:

3.1.7 infant sleep product, n – a product marketed or intended to provide a sleeping accommodation for an infant up to 5 months of age, and that is not subject to any of the following:

- 16 CFR part 1218 – Safety Standard for Bassinets and Cradles
- 16 CFR part 1219 – Safety Standard for Full-Size Baby Cribs
- 16 CFR part 1220 – Safety Standard for Non-Full-Size Baby Cribs
- 16 CFR part 1221 – Safety Standard for Play Yards
- 16 CFR part 1222 – Safety Standard for Bedside Sleepers

DRAFT

Comment 7: Several commenters asked for clarification regarding whether products, similar in design to inclined sleepers but marketed as a “soother,” “rocker,” or “lounger,” are in-scope for the rule, and suggested that such products should be in-scope due to the potential for consumer confusion as to intended uses. We also received a comment asking that inclined products for activity and transport, such as a bouncers, strollers, and swings, be excluded from the scope of the rule.

Response 7: Infant products, inclined or flat, do not fall within the scope of the final rule as long as they are not intended for sleep, and they are marketed conspicuously as not for sleep by infants up to 5 months old. This means that the product packaging, marketing materials, inserts, and instructions cannot indicate that the product is for sleep, or imply through pictures of sleeping infants that sleeping in the product is acceptable. In addition, if “attended” or “supervised” sleep is indicated, then the product would be considered within the scope of the final rule. The product name, description, and instructions also cannot include references to sleep, snooze, dream, or nap. CPSC staff would consider decorations on the product that include pictures of sleeping animals or sleeping cartoon figures to imply the product is intended for sleep. Additionally, the product must not be described as a bed. Some of these products, such as stroller accessories, are already required by the mandatory standard for that product type to meet the bassinet standard when the product is in bassinet mode.

Comment 8: One commenter acknowledged that the scope of the rule does not include sleep positioners and requested “the CPSC to better enforce the ban on sleep positioners.”

Response 8: Neither CPSC, nor FDA, has a “ban on sleep positioners”; however, both agencies advise consumers not to use them with infants due to the risk of suffocation. Sleep positioners are considered accessories, and not an “infant sleep product” under the definition proposed in the 2019 SNPR or as clarified in the final rule. Similar to crib mattresses, sleep

DRAFT

positioners are not intended to be used as the sole product for sleep; instead, they are used in conjunction with a sleep product, for example, to hold an infant in a position while inside a crib. Therefore, sleep positioners do not fall within the final rule because they are not intended to provide a sleeping accommodation for an infant. The Commission declines to explicitly exclude sleep positioners from the final rule at this time.

(c) Upper Age Limit for Infants Up to 5 Months Old

Comment 9: The 2019 SNPR posed a question regarding whether the Commission should remove the upper age limit from the scope of the mandatory standard, to accommodate a broad scope of infant sleep products. Several commenters stated that the final rule should remain applicable to products intended for infants up to 5 months old. Otherwise, the commenters said new requirements addressing containment, stability, and side height would need to be added to the bassinet standard for products intended for ages 6 to 12 months, noting that the existing bassinet requirements are designed only for infants up to 5 months old.

Response 9: After further consideration, the Commission agrees that changing the scope of the final rule to remove the upper age limit, or to include products intended for infants up to 12 months old (as suggested at an ASTM task group meeting), would require new performance, labeling, and testing requirements in the bassinet standard. As the commenters noted, the bassinet standard only applies to infants up to 5 months of age. Therefore, a number of requirements in the ASTM F2194-16 ϵ 1 *bassinet* standard, would need to be changed to address older, larger, and more mobile and active infants, including changes to the scope in section 1.3, the stability requirement in section 6.4, and the side height requirement in section 6.5.4.

Additionally, the final rule focuses on hazards to young infants associated with infant sleep products because infants under 5 months old are the most vulnerable, due to their limited mobility and young, developing respiratory system. Requiring currently unregulated inclined

DRAFT

and flat sleep products to meet the bassinet standard sets minimum requirements for safe sleep. Bassinets are designed for children who are not yet mobile, and the final rule addresses the hazards seen in this population. Older infants, *i.e.*, 6 to 12 months old, have different needs for sleep, and the existing standards for this older age group are designed to address those needs. By 6 months of age, infants have developed enough mobility that they can perform such actions as rolling back and forth and pulling themselves up. The Commission agrees with CPSC staff's assessment that it is unsafe for 6 to 12 month olds to be in a confined space, such as a bassinet, for sleeping, as they may roll out of the product, or pull themselves out of the product.

The unregulated products on the market with which CPSC has concerns, *e.g.*, in-bed sleepers, baby boxes, and compact bassinets, are intended for this younger, more vulnerable population. In addition, CPSC data indicate that 34 percent of the incidents involving inclined sleep products and 49 percent of the incidents involving unregulated, flat, sleep products happened to infants 0 to 5 months of age. Infants 6 to 12 months old were involved in 9 percent of inclined sleep products and 4 percent of unregulated, flat sleep product incidents, respectively. Therefore, consistent with the 2019 SNPR, the final rule limits the scope of the standard to infants up to 5 months of age. Due to the size and design of these unregulated compact/travel products, older infants should not be placed to sleep in these products, and older infants are not included within the scope of the final rule.

(d) Consumer Registration Rule

Comment 10: A commenter expressed no objection to requiring product registration cards for products within the scope of the rule, but suggested that the Commission “remain open

DRAFT

to innovation as to the specific methods of achieving optimum product traceability, particularly now that so many products are linked to internet devices.”

Response 10: In the 2009 NPR for the consumer registration rule (74 FR 30986 (June 29, 2009)), the Commission said it: “intends to encourage innovation in the use of the Internet for product registration,” and the methods of registration online are encouraged, whether through a website or email. The Commission is open to innovation in this area, but we note that section 104(e) of the CPSIA sets forth a process the Commission must follow to allow new technology for product registration, in lieu of the product registration card requirements in part 1130.

Comment 11: A commenter supported the Commission’s amendment of the consumer registration rule, 16 CFR part 1130, to identify infant sleep products as durable infant or toddler products subject to the product registration requirements, so that freestanding sleep products without a frame, are included within the scope of part 1130.

Staff Response 11: To avoid confusion, and to ensure that all infant sleep products fall within the requirements of part 1130, the final rule updates the list of durable infant or toddler products in part 1130 to explicitly identify “infant sleep products” as durable infant or toddler products, as a subcategory of bassinets and cradles.

2. Incident Data

(a) Inclusion of Flat Sleep Products

Comment 12: Multiple commenters expressed concern about in-bed sleepers, baby boxes, and compact bassinets being subject to the standard. Concerns included:

- In-bed sleepers, baby boxes, and compact bassinets are not identified in CPSC data;
- Bed-sharing is a common practice in the United States and abroad;
- Potential disparity in safety among in-bed sleepers versus a potential ban of in-bed sleepers;

DRAFT

- Interest in increased advocacy regarding bed-sharing; and
- Differences among products necessitates different requirements based on demonstrable hazard data.

Commenters objected to including non-inclined sleep products in this rulemaking, including objecting to replacing the term “infant inclined sleep products,” with the more general “infant sleep products.” Instead, these commenters urged the Commission to focus on inclined products for this rulemaking and to review requirements for non-inclined products in separate rulemaking efforts. A commenter stated that it is inappropriate to require all products not subject to an existing standard to comply with the bassinet standard.

Response 12: The Commission recognizes that bed-sharing is a common practice of parents, both in the United States and abroad. However, we cannot recommend bed-sharing as a safe sleep practice, due to the increased risk of SIDS, overlay, and other hazards. AAP safe sleep recommendations encourage infants to room-share with parents, but to provide infants with their own firm, flat space, near the parents, but not in the same bed. For a more detailed discussion on bed-sharing, please see CPSC human factor’s staff memorandum at Tab D of Staff’s Final Rule Briefing Package.

As discussed in section III of this preamble, in response to the comments, the Directorate for Epidemiology staff identified 183 incident reports related to non-inclined, flat products marketed as infant sleep products, such as in-bed sleepers, and compact bassinets. The incident data, reported to have occurred during the period from January 1, 2019 through December 31, 2020, identified 11 fatalities and 16 injury reports. Seven of the 11 fatalities described a suffocation death. The other deaths involved the infant rolling over to a prone position, or rolling out of the product and becoming entrapped. The final rule identifies the flat sleep products that fall within the scope of the rule, provides incident data, describes hazard patterns,

DRAFT

analyzes the effectiveness of the bassinet standard to address the hazards, and compares the performance requirements in international standards to demonstrate that these products have similar hazard patterns that can be addressed by the requirements in the bassinet standard.

Comment 13: Several commenters urged the Commission to work with ASTM to develop product-specific safety standards for each of the identified flat products, such as in-bed sleepers, baby boxes, and compact bassinets, and to do so in a separate effort.

Response 13: The ASTM process for developing the voluntary standard for infant inclined sleep products took close to 5 years before the standard was published. The bassinet subcommittee also has been working about 5 years to add “compact bassinets” to the standard, which has not been completed. CPSC staff has participated in these efforts and provided incident data to the ASTM committees and task groups. Throughout all this time, inclined and compact infant sleep products have entered the retail market without meeting any safe sleep testing, voluntary or mandatory. The incident data discussed in section III of this preamble (Tab B of Staff’s Final Rule Briefing Package), and the engineering and human factors analysis in section VI of this preamble (Tabs C and D of Staff’s Final Rule Briefing Package), demonstrate that inclined, compact, and in-bed sleep products pose risks to infants and therefore, should not be allowed to be sold as infant sleep products without meeting one of CPSC’s mandatory sleep standards.

Comment 14: A commenter stated that no data indicate that overlay injuries or fatalities exist while using an infant in-bed sleeper.

Response 14: As part of CPSC staff’s participation with ASTM voluntary standards groups, in fall 2017³⁸ and summer 2019,³⁹ CPSC staff provided the ASTM in-bed sleeper

³⁸ October 2, 2017 email from Hope Nesteruk to Lisa Trofe and Meredith Thomas, JPMA contacts for ASTM meetings.

³⁹ Email dated June 4, 2019, from Hope Nesteruk to Meredith Thomas, JPMA contact for ASTM meetings.

DRAFT

working group with incident data that identified fatal and nonfatal incidents involving in-bed sleepers. This data demonstrated 11 fatalities and 22 nonfatalities associated with in-bed sleepers. The primary hazard patterns, consistent with the incident data discussed in this final rule, involved infants falling out of in-bed sleepers, rolling into the side, bedsharing, and consumer complaints.

An overlay hazard typically occurs during bed-sharing, when a parent lays over their infant, and typically does not realize they have done so because they are asleep. Accordingly, during task group and subcommittee meetings, staff expressed additional concerns with low side height, soft-sided, in-bed sleepers, because use of such products may provide parents with a potentially false sense of security when bed-sharing. Based on this information, and bed-sharing concerns generally, CPSC has substantial concerns that a low, soft-sided, in-bed sleeper may not prevent a parent from inadvertently laying over an infant and suffocating the baby. CPSC data for in-bed sleepers is anecdotal in nature, and therefore, we may not have received overlay incidents that involve an in-bed sleeper, but the large number of overlay incidents reported to the CPSC generally indicate that bed-sharing can be hazardous.

Comment 15: A commenter stated that the 2019 SNPR is well-intentioned, but that it is premature, and that the scope of the rule ultimately may harm consumer safety, because consumers will use soft bedding and other tools to replace an entire category of products that effectively are banned under the SNPR. The commenter stated that the data necessary to support the rule is either missing or incorrect. Another commenter stated that the data on in-bed sleepers, and the existing CPSC sleep standards, do not support CPSC's approach in the 2019 SNPR, noting that babies die in all types of infant sleep products despite having an existing standard, citing bassinets, cribs, and play yards. Infants die for reasons not associated with the product, the commenter asserted, adding that CPSC has not presented data to warrant all infant sleep products

DRAFT

without a standard to comply with the bassinet standard. This commenter maintained that CPSC is using a “back-door method” to remove infant products from the market without the data to support or justify this action. The commenter opined that CPSC should write safety standards that will ensure safe sleep for each product type, and not funnel various products into one standard, bassinets and cradles, which was not intended for these products.

Response 15: In coordination with a range of stakeholders, CPSC has carefully developed safety regulations for five infant sleep products (cribs: full-size and non-full-size, bassinets, play yards, and bedside sleepers), and we encourage consumers to use these products for infant sleep. The Commission is aware that deaths occur in these products, but as noted, infant deaths are not always associated with the product. We particularly urge consumers to follow the AAP safe sleep recommendations when using any product intended for infant sleep. CPSC data, in section III of this preamble (Tab B of Staff’s Final Rule Briefing Package), and evaluated in section VI of this preamble (Tabs C and D of Staff’s Final Rule Briefing Package), show that deaths and injuries occur in untested and unregulated infant sleep products, including inclined and flat sleep products, and sometimes these incidents involve a use contrary to AAP recommendations. However, CPSC’s evaluation of the incidents in section VI of this preamble demonstrates that requiring currently unregulated infant sleep products to meet the requirements of the bassinet standard will further reduce the risk of death and injury associated with these products (Tab C of Staff’s Final Rule Briefing Package).

The argument that parents will use soft bedding and other tools to replace products taken off the market is the same argument used in support of creating a separate voluntary and mandatory standard for infant inclined sleep products, and infants died in these products that did not meet AAP safe sleep guidelines. Accordingly, to further reduce the risk of death and injury, the final rule requires that all products marketed or intended as a sleeping accommodation for

DRAFT

infants up to 5 months old be tested and certified to an existing CPSC sleep standard, and that CPSC, the AAP, and the industry, continue to promote and educate caregivers about safe sleep practices for infants.

(b) Statistically Significant Data

Comment 16: One commenter questioned whether the data presented in the 2019 SNPR are statistically significant for inclined sleep products, or are the deaths due to SIDS?

Response 16: The analysis presented in the 2019 SNPR and in this final rule is based on reported incidents, and therefore, anecdotal in nature. This means that the data do not constitute a statistical sample representing all incidents related to inclined and flat sleep products; nor do the data represent a complete set of incidents that may have occurred involving the products. As such, no statistical inference is possible. However, the data do provide at least a minimum count for the number of incidents related to each type of product reviewed.

Many of the fatality reports contain unclear, conflicting, and/or inconsistent information. For example, for some deaths, medical examiners may have concluded the cause of death to be SIDS or Sudden Unexpected Infant Death (SUID), but they also may mention co-contributing conditions, such as an unsafe sleep environment (*e.g.*, soft bedding, inclined sleep surface) or other pre-existing medical condition(s). This can confound CPSC's ability to determine a predominant factor in the fatality. Staff used a consensus-based decision-making process to review incident data. If an unsafe sleep environment or a product design was one of the factors, staff classified the death under that category. Otherwise, staff classified the reported incident under the "undetermined" category, when no one factor stood out, or staff classified the incident under the "insufficient information" category, when staff did not have enough information to classify the incident in another category to avoid overestimating the risk.

DRAFT

3. Degree of Incline

(a) Additional Testing for Inclines Between 10 and 20 Degrees

Comment 17: Several commenters stated that the Commission should conduct additional research on the safety of inclines between 10 and 20 degrees for infant sleep products. A commenter stated that CPSC has failed to provide relevant data to support the 2019 SNPR’s approach regarding inclined sleep products, to limit the seat back angle to 10 degrees or less, and not to conduct additional study on the 10 to 20 degree angle, or to provide information or incidents to support this decision.

Response 17: During the development of the 2019 SNPR, Commission staff contracted with Dr. Erin Mannen to examine how the degree of a seat back angle affects an infant’s ability to move within inclined sleep products, and if the incline angle directly impacts safety or presents a risk factor that could contribute to the suffocation of an infant.⁴⁰ The Mannen Study findings showed that infants in products with a seat back angle greater than 20 degrees exhibit increased demand on their abdominal muscles. The Mannen Study concluded that this could lead to increased fatigue and suffocation, if an infant is unable to reposition themselves after an accidental roll from supine to prone. The Mannen Study concluded that a sleep surface that is 10 degrees or less, is comparable to a crib mattress surface and can be considered a safe sleep surface. The Mannen Study suggested if future work were done on safe sleep angles, one area of study would be additional biomechanical testing to determine “which, if any, angles between 10- and 20-degrees may be safe for infant sleep.”

The Mannen Study recommendations do not imply that an incline angle above 10 degrees may be safe; rather, the Mannen Study merely suggests that if higher angles are considered,

⁴⁰ [Read the full report from Dr. Mannen beginning on page 91, Tab B, of CPSC Staff’s SNPR Briefing Package: https://cpsc.gov/s3fs-public/SupplementalNoticeofProposedRulemakingforInfantSleepProducts_10_16_2019.pdf](https://cpsc.gov/s3fs-public/SupplementalNoticeofProposedRulemakingforInfantSleepProducts_10_16_2019.pdf).

DRAFT

additional biomechanical testing is required. We are not aware of existing research that suggests that an inclined sleep surface between 10 and 20 degrees is safe, nor is CPSC currently conducting similar research. The Mannen Study also stated that its testing of awake infants was a limitation because “while the muscle use and motion may be similar, it is likely that infants who find themselves in a compromised position in an inclined sleep product during a nap or overnight sleep may not have enough energy or alertness to achieve self-correction and may succumb to suffocation earlier or more easily than infants who are fully awake.” Given the vulnerability of newborn infants and the precedence of fatalities of infants who were most likely asleep in inclined products at the time of incidents, additional research of inclines above 10 degrees is unnecessary for the final rule.

Additionally, other research⁴¹ has demonstrated a discernable difference in infant ability between 5, 7, and 10 degrees in a side-to-side tilt, which formed the basis of the 7-degree maximum sleep surface angle in Health Canada’s regulations and the 5-degree limit in the Australian requirement. The 10-degree sleep surface limit in the final rule is a slightly higher allowed sleep surface angle than other countries. Based on the Mannen Study and the research that supports sleep surface angles in international standards reviewed by CPSC staff, staff believes that it is unlikely that additional research at angles higher than 10 degrees will demonstrate that an angle greater than 10 degrees is safe for infant sleep. Accordingly, for the final rule, infant sleep products must be tested for a seat back or sleep surface angle of 10 degrees or less from horizontal, and they must meet the requirements of the bassinet and cradle standard.

⁴¹ Beal SM, Moore L, Collett M, Montgomery B, Sprod C, Beal A. The danger of freely rocking cradles. *J Paediatr Child Health*. 1995 Feb;31(1):38-40. doi: 10.1111/j.1440-1754.1995.tb02910.x. PMID: 7748688.

DRAFT

(b) Adopt Canadian Standard of 7 Degrees

Comment 18: One commenter stated that Canada only allows up to 7-degree seat back angle in sleep products, and suggested CPSC should consider adopting the Canadian standard. Another commenter supported the SNPR proposal that infant sleep surfaces be no more than 10 degrees from horizontal.

Response 18: The Mannen Study concluded that a seatback angle of 10 degrees or less is safe. This seatback angle is consistent with CPSC’s Safety Standard for Bassinets and Cradles, which also requires a 10 degree or less incline. We recognize that Health Canada is using a 7-degree maximum incline; however, that requirement is based on a side-to-side tilt study of infants in rocking cradles published in 1995. The 2019 Mannen Study compared infant muscle and breathing behavior on a flat crib mattress and on a crib mattress, head-to-toe 10 degrees from horizontal, and determined that infant responses were essentially the same on both sleep surfaces. Accordingly, based on the Mannen Study findings, to provide a safe sleep surface, the final rule is consistent with the current requirement in the bassinet and cradle standard, requiring that infant sleep products must have a head-to-toe incline angle of 10 degrees or less.

(c) Highest Seat Back Angle Clarification

Comment 19: A commenter requested that CPSC replace the phrase: “the manufacturer’s recommended highest seat back angle position intended for sleep,” with “the seat back angle position that is the highest position intended for sleep or that is the highest position that a reasonable consumer would consider as being for infant sleep, whichever is higher.”

Response 19: The commenter’s suggestion, by focusing on the “seat back” of an infant sleep product, illustrates some confusion with terminology. The 2019 SNPR applied to infant sleep products, and required all infant sleep products to be 10 degrees or less from horizontal—the same as the sleep surface in bassinets. However, the safe sleep principle requirement from the

DRAFT

Mannen Study, and already reflected in the bassinet standard, is that infants should sleep flat on their backs. Accordingly, the SNPR term “seat back” created confusion, because the term implies that infant sleep products are for “sitting” in a device with a “seat.” Thus, to reduce this confusion in the final rule, we replace the term “seat back” with the term “*Seat Back/Sleep Surface.*”

4. Safe Sleep Principles

(a) Request to Ban Infant Inclined Sleep Products

Comment 20: Approximately 25 commenters requested that CPSC “ban” or “remove” infant inclined sleep products from store shelves. Of those commenters, three indicated that their child died while sleeping in an inclined sleep product.

Response 20: Many products with an incline greater than 10 degrees from horizontal have been removed from the market through CPSC recalls. To address newly manufactured products, the final rule does not “ban” all infant sleep products with an angle, but addresses the hazards associated with inclined sleep products by requiring that any product marketed or intended for sleep for infants up to 5 months old must not have a sleep surface angle greater than 10 degrees, and that any currently unregulated infant sleep product meet the bassinet standard. The purpose of these requirements is to ensure that all infant sleep products meet minimum safe-sleep principles, including the sleep surface angle, as addressed through an existing CPSC sleep standard.

(b) Aligning with AAP Safe Sleep Practices

Comment 21: One commenter acknowledged that the 2019 SNPR aligns with the AAP’s safe sleep recommendations, and encourages CPSC to ensure that the proposed rule sends a clear message addressing safe sleep practices.

DRAFT

Response 21: The Commission is committed to addressing safe sleep practices in this rulemaking and ensuring that all products marketed, intended, promoted, or otherwise indicated as being for any kind of infant sleep for infants up to 5 months old are addressed. Therefore, the final rule requires that all infant sleep products, including inclined and flat products, be subject to 16 CFR part 1218, Safety Standard for Bassinets and Cradles, because part 1218 includes safe sleep requirements. Additionally, CPSC’s website provides extensive information regarding best practices for safe sleep through its CPSC’s Safe Sleep Campaign and Baby Safety information at: <https://www.cpsc.gov/SafeSleep>.

(c) Use of Unsafe Products by Sleep Deprived Parents

Comment 22: One commenter expressed concern that parents, particularly those who are sleep deprived, cannot reasonably be expected to use a product that is unsafe by design in a safe manner.

Response 22: Lack of sleep may have a detrimental effect on a parent’s judgment when using an infant sleep product. Research demonstrates that fatigue can negatively affect memory, concentration, and decision making.⁴² The final rule is the most effective method of ensuring that infant sleep products for infants up to 5 months of age are safe for use.

5. Definitions

(a) Remove “Intended” from Definitions

Comment 23: A commenter requested that the word “intended” be struck from the definitions of infant and newborn sleep products.

Response 23: We disagree with the request to remove “intended” from the definitions. Manufacturer’s intent, which can be evaluated through stated warning messages, marketing photos, product instructions and other factors, must remain a factor for staff’s consideration. As

⁴² <https://www.sleepfoundation.org/sleep-deprivation>.

DRAFT

the commenter noted, some products are marketed for swinging or bouncing. If infant products are not intended for sleep and are not marketed in ways that imply they are for sleeping or napping, they are not subject to the infant sleep product standard. CPSC will evaluate a manufacturer's intent using all available materials, including marketing. Accordingly, the final rule maintains the word "intended" and also broadens the definition of an "infant sleep product" to include the word "marketed."

(b) Define or Clarify "Free Standing" Infant Sleep Products

Comment 24: One commenter contended that "free standing" is an ambiguous term.

Response 24: A "free-standing" infant sleep product is a sleep product that can be used by itself, without the need of another product, such as a portable play yard. ASTM F3118 – 17a contains a separate definition for "accessory inclined sleep product," which applies to products that are supported by another product, such as a play yard. The term "free-standing" is used without issue in other ASTM and CPSC standards. For the final rule, the definition of "infant sleep product" is broadened to cover all inclined and flat products marketed or intended as a sleeping accommodation, regardless of whether the product is free-standing or attached to another product. Accordingly, we removed the term "free-standing" from the definition of "infant sleep product" in the final rule, to reduce confusion about which infant sleep products are subject to the rule.

6. Warnings and Instructions

(a) Provide Information About Scoliosis and Torticollis

Comment 25: One commenter recommended that information about deformities, such as scoliosis and torticollis, be included on an insert with all infant sleep products.

Response 25: Providing parents with information and resources regarding various infant deformities is beneficial, and manufacturers are not prevented from including this information if

DRAFT

they desire. However, as indicated in the 2019 SNPR, increases in the number of children with plagiocephaly may actually be attributed to the AAP's recommendation to place infants to sleep on their backs to decrease the risk of SIDS. The final rule does not contain any modifications to the voluntary standard to address this issue.

(b) Placement of Warnings

Comment 26: One commenter recommended that warnings should be placed on the outside and inside of the packaging, as well as on the product. The commenter also recommended that packaging should be labeled, easily visible, and easy to read/understand.

Response 26: Consistent with the 2019 SNPR, the final rule requires that infant sleep products not already subject to a CPSC sleep standard, be subject to the warning requirements set forth in the bassinet standard, ASTM F2194-16e1, which requires that warning labels be present on the product and its packaging, and that warning information be present in the instructional literature. ASTM F2194-16e1 also requires that the warnings be conspicuous, permanent, and easy to read/understand.

7. Economic Analysis

Comment 27: A commenter suggested that CPSC conduct an exposure study to research the relative risks of these different sleep products. This commenter also suggested that CPSC perform a full cost-benefit analysis of the final rule.

Response 27: CPSC is continuing research topics related to safe sleep, which may potentially involve types of infant sleep products. Although an exposure study is an effective means to estimate exposure, we can estimate exposure by comparing annual sales of products to the number of live births, and staff identifies the hazard patterns from the incident data. The Commission is not required to conduct cost-benefit analyses under section 104 of the CPSIA, and has not done so for any durable infant or toddler rulemaking. We are uncertain what the

DRAFT

purpose of such an analysis would accomplish for a rule promulgated under section 104 of the CPSIA, where cost/benefit considerations are not germane to the Commission's rulemaking authority.

8. Effective Date

Comment 28: Commenters both supported and opposed the 12-month effective date. Some opposing commenters supported a 6-month effective date instead, because additional time for the rule to become effective puts infants at risk, while other opposing commenters wanted a longer effective date, or an indefinite delay until ASTM completes additional standards for specific products. The 2019 SNPR proposed that the effective date would apply to products manufactured or imported after the final rule effective date. We received multiple comments that the effective date should apply to products sold after the final rule effective date instead of the "sold by date," to prevent stockpiling and remove the hazards as soon as possible.

Response 28: For the final rule, the Commission will maintain the 2019 SNPR proposed effective date of 12 months after the date of publication in the *Federal Register*. A 6-month effective date may seem reasonable because suppliers have had ample lead time to prepare for this rule since the SNPR was published in 2019, and many of the products within the scope of the final rule have been withdrawn from the market or redesigned, particularly for inclined sleep products. However, for manufacturers of other unregulated flat sleep products that remain in the market, there will likely be a significant economic impact as a result of this final rule. While some suppliers can reduce the impact of this rule by relabeling their products as not for infant sleep, not all manufacturers can simply remarket the product if the physical form of the product demonstrates that it is intended for sleep. For some of these products, manufacturers could relabel them as intended for infants older than five months, or, in some cases, for pets. However, the demand for infant sleep products for pet use is probably limited.

DRAFT

The final rule is considered a consumer product safety standard issued under the Commission's authority in section 104 of the CPSIA. Section 104(b)(1)(B). We are unclear regarding what the commenters' "sold by" date references. The Consumer Product Safety Act (CPSA) sets forth requirements for manufacturers and importers once a rule becomes effective. Section 19(a)(1) of the CPSA states:

(a) It shall be unlawful for any person to—

(1) sell, offer for sale, manufacture for sale, distribute in commerce, or import into the United States any consumer product, or other product or substance that is regulated under this Act or any other Act enforced by the Commission, that is not in conformity with an applicable consumer product safety rule under this Act, or any similar rule, regulation, standard, or ban under any other Act enforced by the Commission;

15 USC 2068(a)(1). Accordingly, the CPSA provides that, as of the effective date of the final rule, it is unlawful to "sell, offer for sale, manufacture for sale, distribute in commerce, or import into the United States," any infant sleep product, as defined in the rule, that is not in conformity with the final rule.

9. Procedural Comments

(a) Products Subject to the Final Rule

Comment 29: A commenter stated that the proposed rule would apply to domestic products, and not to products made overseas. The commenter stated that the rule should apply to products made overseas and sold in the United States, for "optimal consumer safety."

Response 29: The commenter appears to misunderstand the scope of products subject to the final rule. If finalized, the rule would make it unlawful to sell, offer for sale, manufacture for sale, distribute in commerce, or import into the United States, an infant sleep product that is not

DRAFT

in conformity with this rule, regardless of whether the product was manufactured in the United States or overseas.

(b) Incorporation by Reference

Comment 30: A commenter states that the Commission should publish the legal standard for infant sleep products, rather than incorporate the standard by reference. The commenter stated:

- Publishing the legal standard “will advance fundamental principles of fair notice and due process by ensuring that the public has open and unimpeded access to the law.”
- The law belongs to the people, regardless of who drafts the law, and thus citizens have a fundamental right to know what the law contains.
- When the public is not informed about relevant legal standards, this has the potential for arbitrary or discriminatory enforcement.
- People cannot comply with a law if they do not know the substance of the law.

Response 30: Section 104 of the CPSIA directs the Commission to issue standards for durable infant or toddler products that are “substantially the same as,” or more stringent than, applicable voluntary standards. Thus, unless the Commission determines that more stringent requirements are necessary to further reduce the risk of injury, the Commission’s rules must be, for the most part, the same as the applicable voluntary standard. In this case, the final rule would incorporate by reference ASTM F3118-17a, with substantial modifications to make the standard more stringent, to further reduce the risk of injury associated with infant sleep products. This final rule would set forth in the Code of Federal Regulations (CFR): definitions, one test for the seatback/sleep surface angle of an infant sleep product, and otherwise require infant sleep products that do not already meet a CPSC sleep standard to meet the requirements of the bassinet standard, to further reduce the risk of injury associated with inclined and flat infant sleep

DRAFT

products. CPSC's bassinet standard, 16 CFR part 1218, currently incorporates by reference performance and labeling requirements in ASTM F2194-13, with modifications set forth in the CFR. CPSC's mandatory standard is substantially similar to ASTM F2194-16e1.

ASTM's voluntary standards are protected by copyright, which the Commission (and the federal government generally) must observe. The United States may be held liable for copyright infringement. 28 U.S.C. § 1498. Accordingly, the Commission cannot violate copyright law by publishing ASTM's voluntary standards in the CFR. The Office of the Federal Register (OFR) has established procedures for incorporation by reference that seek to balance the interests of copyright protection and public accessibility of material. 1 CFR part 51. OFR's regulations are based on Freedom of Information Act provisions that require materials to be "reasonably available" when incorporated by reference with approval of the Director of the Federal Register. 5 U.S.C. § 552(a)(1). Under the OFR's requirements, an agency may incorporate by reference specific publications, including standards, if they are "reasonably available to and usable by the class of persons affected." 1 CFR § 51.7. To ensure the material is "reasonably available," an agency must summarize the material it will incorporate by reference and discuss how that material is available to interested parties in the *Federal Register* notice. *Id.* §§ 51.3(a), 51.5(a).

Manufacturers and importers of infant sleep products represent the class of persons affected by the final rule. Although any interested person has access to the content of CPSC's regulations through *Federal Register* notices of proposed and final rules, the CFR, and the content of voluntary standards on ASTM's website, under the statutory scheme set forth in the CPSIA, it is those manufacturers and importers who want to "sell, offer for sale, manufacture for sale, distribute in commerce, or import into the United States," any durable infant or toddler product, that must conduct testing using a third party conformity assessment body (lab) and

DRAFT

certify their product as compliant with the applicable consumer product safety rule. 15 U.S.C. § 2063(a)(2).

The Commission complies with the requirement that publications, including standards, are “reasonably available to and usable by the class of persons affected,” whenever incorporating material by reference. For example, when the Commission proposes a rule under section 104 of the CPSIA, the Commission describes and summarizes the requirements of the rule, including the voluntary standard, in the preamble of the rule printed in the *Federal Register*, and explains that ASTM’s copyrighted voluntary standards are available to review online for free during the comment period at <https://www.astm.org/CPSC.htm>. Once a rule becomes effective, ASTM provides a read-only copy of the standard for review on the ASTM website at:

<https://www.astm.org/READINGLIBRARY/>. As always, any person can purchase a voluntary standard from ASTM, or may schedule a time to review a voluntary standard (for free) at the Commission’s headquarters in Bethesda, MD, or at the National Archives and Records Administration (NARA). Accordingly, citizens who are interested in the content of the law have unimpeded access to the regulation, and have several avenues for free access to the text of voluntary standards incorporated by reference into a mandatory CPSC standard for a durable infant or toddler product.

Comment 31: A commenter states that CPSC’s practice of incorporating voluntary standards by reference into law forces citizens to either visit the agency in person, or pay for access, to view the proposed law. The commenter contends that CPSC’s actions to allow public access to the proposal, including summarizing the proposed requirements in the preamble to the proposed rule, making the voluntary standard available for review at CPSC’s offices, or reading the standard on ASTM’s website free of charge, are all problematic, as the regulations are not “reasonably available” to the class or persons affected. The commenter states that ASTM’s

DRAFT

restrictions on downloading or printing the standard (unless the standard is purchased) are an impediment to accessing the law, and describes the Commission's access to the proposed law as "limited" and insufficient to "ensure robust public access to the law." Specifically, the commenter notes that without the ability to download graphs and charts in the ASTM standard, the graphs are unreadable in portrait view. The commenter states that "reasonably available" is not defined in the APA, but should be interpreted broadly "to promote fundamental constitutional values...."

Response 31: We disagree with the commenter that CPSC's efforts to make voluntary standards "reasonably available" are "limited." For rules issued under section 104 of the CPSIA, stakeholders have several ways to access the content of the voluntary standard proposed to be incorporated by reference, and after the standard is incorporated by reference into a regulation, including reading a summary of the requirements of a voluntary standard in a proposed or final rule (free), reviewing voluntary standards in person at CPSC's offices (free), reviewing read-only copies of the voluntary standard on ASTM's website (free), and by purchasing a copy of the standard. The OFR's regulations do not require free access to the contents of copyrighted materials. In developing a regulation, the OFR considered whether to require free access to materials that are incorporated by reference into regulations, and specifically declined to do so. 79 FR 66267 (Nov. 7, 2014). The OFR found that adopting requirements to summarize the content of the material incorporated, and explaining to stakeholders how to obtain the material, was adequate to make the material "reasonably available." *Id.* at 66,270. Accordingly, CPSC's efforts to make copyrighted materials reasonably available exceed the OFR's requirements.

Comment 32: A commenter states that incorporation by reference, without providing free access to the law, undermines due process because it may limit public input and exclude meaningful participation by some stakeholders. The commenter explains, for example, that to

DRAFT

participate in ASTM standards development, one must be an ASTM member, which costs \$75 per year. The commenter notes that the regulated community can afford this and participate, while members of the public cannot meaningfully participate.

Response 32: Stakeholders have several options to review the content of a voluntary standard for free, as described in response to comments 30 and 31. ASTM typically seeks a cross section of stakeholders to participate in standards development. While ASTM requires membership to vote on balloted items to create or revise a voluntary standard, ASTM does not require membership to participate in ASTM meetings where stakeholders discuss standards development for durable infant or toddler products. Thus, if a consumer wanted to participate in an ASTM meeting, they could do so without membership. Additionally, if a consumer wanted to become an ASTM voting member and cannot afford the membership fee, that person can contact ASTM to learn about additional options for membership. For example, students can be ASTM members free of charge.

We further note that CPSC's regulation at 16 CFR part 1031 does not allow staff to participate in voluntary standards meetings that are not open to the public. CPSC staff's participation in ASTM meetings discussing durable infant or toddler products are posted on CPSC's calendar (on CPSC's website) at least a week in advance. The meeting notice provides the date, time, purpose of the meeting, the staff attending, and contact information for staff (to obtain ASTM login information) so that any person who wants to participate in the ASTM meeting may do so. Moreover, CPSC staff creates a written meeting log for each ASTM meeting where staff participates, which summarizes the meeting content.

We encourage members of the public to meaningfully participate in standards development efforts for durable infant or toddler products through the ASTM process and by commenting on CPSC's proposed rules.

DRAFT

Comment 33: A commenter describes a recent holding by the Eleventh Circuit finding that annotations to a Georgia statute were “sufficiently law-like” to require free public access. The commenter also describes two district court cases challenging PACER system fees, but notes the cases are in the early stages of litigation, but “the underlying principles of free public access to the law and legal proceedings are directly relevant here.”

Response 33: As described in response to comments 30 and 31, CPSC exceeds the OFR’s regulation requiring that voluntary standards that are incorporated by reference be made reasonably available to the class of persons affected, because the voluntary standards incorporated by reference by CPSC in rules under section 104 of the CPSIA are available for review by all interested parties. ASTM provides access to review voluntary standards incorporated by reference before and after a rulemaking, free of charge, on ASTM’s website. Additionally, any person can schedule a time to review a voluntary standard (for free) at the Commission’s headquarters in Bethesda, MD, or at the National Archives and Records Administration (NARA).

(c) Alleged Notice and Comment and Section 104 Procedural Defects

Comment 34: A commenter states that the rulemaking process for including flat products within the scope of the 2019 SNPR, such as in-bed sleepers, is procedurally deficient and does not follow the procedure for rules issued under section 104 of the CPSIA, because the Commission’s 2019 SNPR did not include sufficient data demonstrating the need for a rule to cover non-inclined sleep products. The commenter states that the data set for non-inclined products is incomplete and insufficiently reviewed, suggesting that the Commission did not review incident data for non-inclined products with the ASTM committee. The commenter states that the Commission’s failure to publish a revised SNPR to include CPSC staff’s concerns with compact bassinets, baby boxes, and in-bed sleepers, as described in a December 12, 2019

DRAFT

letter from staff to several ASTM subcommittees, which the commenter states did not appear in the 2019 SNPR, and to instead provide a 30 day extension of the comment period, was insufficient notice to all interested parties, and may result in a flawed standard that is unable to withstand judicial scrutiny.

Response 34: The 2019 SNPR provided notice to stakeholders that unregulated, non-inclined, flat infant sleep products were included in the proposal, by proposing to remove the term “inclined” from the standard, and to include within the scope of the rule currently unregulated infant sleep products, including inclined and non-inclined products. For example, the SNPR states:

- “CPSC’s proposed standard would cover products intended for infant sleep that are not already addressed by another standard.” 84 FR at 60949.
- “CPSC proposes to define ‘infant sleep products’ as products that provide sleeping accommodations for infants that are not currently covered by bassinets/cradles, cribs (full-size and non-full size), play yards, and bedside sleepers...” *Id.* at 60950. Similar statements are also made on pages 60951 (three times), 60956, and in the draft regulatory text (proposed § 1236.1, § 1236.2(b)(4)(D) and § 1236.2(b)(11)(i) at 60962-63).
- “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”
- The request for comments on page 60961 asks for comments on non-inclined products likely to be impacted by the SNPR, including, for example, a request for comment on:
 - “...any additional types of products that commenters believe may be impacted by the Supplemental NPR.”

DRAFT

- "...products with inclines less than or equal to 10 degrees that do not already comply with the bassinet standard."
- removing the upper age limit of 5 months because the SNPR "proposes to address 'infant sleep products' not already covered by traditional sleep product [standards]."
- The Staff's October 16, 2019 SNPR Briefing Package, referenced in the *Federal Register* notice, contains similar statements about the scope of the rule (pages 15, 16, 21, 117, 136), and on page 133 also specifically states (and on page 134, Figure 1 provides a picture of an unregulated flat sleep product):

The draft supplemental proposed rule would also cover products with inclined sleep surfaces greater than 30 degrees and less than 10 degrees, if they are intended or marketed for children under 5 months of age for sleep purposes, and they are not subject to another sleep product standard. For example, the draft supplemental proposed rule would include the hammock-style crib accessory shown in Figure 1. It appears to have an incline of 10 degrees or less, but does not fall under another sleep category.

CPSC's description of the scope of the rule throughout the 2019 SNPR and the Staff's SNPR Briefing Package, and the request for comment on these products, were sufficient to inform stakeholders that these unregulated flat sleep products were included within the scope of the rule.

In addition, ASTM members had actual notice of the contents of the 2019 SNPR before and after publication. Sections V.A.3 and V.B.2 of this preamble discuss staff's work with the ASTM subcommittees and task groups. Staff's SNPR Briefing Package was posted on the Commission's website on October 16, 2019, before ASTM held fall meetings on voluntary standards for juvenile products, and before the Commission voted on the SNPR, so that ASTM

DRAFT

members and other stakeholders could review the package, including the Mannen Study, before the ASTM meetings, and so that staff could discuss the package and the Mannen Study with ASTM members. The ASTM Agenda for the Infant Inclined Sleep Products meeting that occurred on October 21, 2019 included a link to Staff's SNPR Briefing Package. CPSC staff discussed the 2019 SNPR Briefing Package at the ASTM meetings in October 2019, including with the ASTM subcommittees for infant inclined sleep products, in-bed sleepers, and bassinets, discussing the Mannen Study findings, as well as addressing the fact that flat sleep products were covered by the SNPR. Dr. Mannen attended the subcommittee meeting for infant inclined sleep products via telephone, to discuss the Mannen Study and to answer questions.

The SNPR published in the *Federal Register* on November 12, 2019. In a December 12, 2019 letter to both the ASTM inclined sleep and bassinet subcommittees, CPSC staff again reiterated its concerns with weakening the safe sleep requirements in the voluntary standard for bassinets and cradles to accommodate unregulated products, such as in-bed sleepers, compact bassinets, and baby boxes. Thus, the letter represents an additional effort to ensure that the relevant ASTM subcommittees (and thus subcommittee members) were aware of CPSC staff's concerns with these products, as well as the content of the 2019 SNPR, which proposed that flat sleep products would need to meet the requirements of the bassinet standard. Even though this letter was in addition to, and not instead of, the notice provided in the 2019 SNPR, the Commission extended the comment period for an additional 30 days, to accommodate any confusion among stakeholders. The final rule addresses scope and data concerns submitted by commenters on the inclusion of unregulated flat sleep products.

With regard to in-bed sleepers, baby boxes, and compact bassinets specifically, ASTM members, which include manufacturers of these products, have been well aware of CPSC staff's concerns with these products for years, based on activity on the bassinet subcommittee which has

DRAFT

been developing requirements for these products to include in the bassinet standard, but has thus far been unsuccessful. With regard to in-bed sleepers, ASTM created a separate standards development effort for this product, which CPSC staff has participated in, and provided incident data on the products, including notice of the injuries and fatalities associated with these products. Indeed, through staff's participation in the ASTM process, including attending meetings, providing incident data, and providing comments and votes on ballot efforts, staff's concerns with unregulated flat sleep products, and the incident data associated with these products, is not unknown to stakeholders and these commenters.

Comment 35: A commenter states that CPSC statutes require the Commission to defer to voluntary standards under certain conditions, and that CPSC's website states that CPSC follows OMB Circular A-119, but the Commission has done neither in this case. Another commenter states that the 2019 SNPR did not rely on the ASTM consensus-driven process to develop a standard, and that CPSC's data cannot be presented belatedly to ASTM participants, after or at the same time as the SNPR was provided to the Commission. This commenter states that while CPSC claims the process was a collaborative one, for the 2019 SNPR, the process was not.

Response 35: Rulemaking pursuant to sections 7 and 9 of the CPSA requires the Commission to rely on a voluntary standard, rather than promulgate a rule, if: (1) the voluntary standard adequately addresses the risk of injury associated with a product, and (2) there is likely to be substantial compliance with the voluntary standard. If either of these criteria are not met, the Commission may proceed with rulemaking under sections 7 and 9 of the CPSA, if the Commission can make the other required findings. Those criteria are not relevant under section 104 of the CPSIA, which requires the Commission to consult "with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts, examine and assess the effectiveness of any voluntary consumer product safety standards for

DRAFT

“durable infant or toddler products,” and to promulgate rules that are substantially the same as the voluntary standards, or more stringent than the voluntary standards, if the Commission finds that more stringent standards would further reduce the risk of injury.

Although CPSC staff’s standards development work through the ASTM process can colloquially be termed “collaborative,” nothing in section 104 of the CPSIA requires “collaboration” on a rule outside of the rulemaking process. Under section 104, the Commission is not required to “defer” to the voluntary standard, rather, the Commission must promulgate rules, and those rules must be substantially the same as the voluntary standard, or more stringent than the voluntary standard, if more stringent requirements would further reduce the risk of injury. Section 104 requires the Commission to consult regarding the effectiveness of a voluntary standard; the Commission is not required to consult on the timing of a proposed rule, the Commission’s enforcement work, or on the content of a proposed rule outside of the rulemaking process. In the case of bassinets, unregulated flat sleep products, and inclined sleep products, staff has been consulting on the effectiveness of the voluntary standards, or lack thereof, for these products for many years.

Generally, CPSC staff’s work through the ASTM process has improved the safety of durable infant or toddler products. However, nothing in section 104 of the CPSIA requires the Commission to delay addressing risks of harm to the most vulnerable infants in sleep products that parents rely upon as a safe place for an infant, until all ASTM members have reached a consensus on whether and how to create or revise a voluntary standard to address the risk. The Commission would be relinquishing the statutory mandate to protect consumers by ceding product safety to the very industry Congress required the agency to regulate. CPSC met the requirement to consult on the effectiveness of the voluntary standards. The lengthy record of staff’s participation with the infant inclined sleep committee since the 2017 NPR is available on

DRAFT

regulations.gov, as well as through ASTM records. A similarly robust record of staff's participation on the bassinet and cradle committee, outside of the rulemaking process, is available through ASTM, on CPSC's website, and through CPSC's Office of the Secretariat⁴³.

Finally, as review in response to comment 12, the final rule addresses scope and data concerns submitted by commenters on the inclusion of unregulated flat sleep products, by specifically listing the products included within the scope of the final rule in this preamble, reviewing incident data and hazard patterns associated with flat products, and by demonstrating that the requirements in the bassinet standard are adequate to address the risk of injury associated with flat infant sleep products. CPSC's description of the scope of the rule throughout the 2019 SNPR and Staff's SNPR Briefing Package, and the request for comment on these products (including a 30 day comment extension), were sufficient to inform stakeholders that these unregulated flat sleep products were included within the scope of the rule. Moreover, the Commission received comments on the inclusion of flat sleep products within the scope of the rule, demonstrating knowledge of their inclusion.

Comment 36: A commenter states that CPSC had been participating collaboratively with the ASTM committee for ASTM F3118 before the summer of 2019, when the commenter states the Commission rescinded its rulemaking to adopt ASTM F3118 as a mandatory standard, and to modify the standard through the SNPR. The commenter states that the better practice would be to issue an advanced notice of proposed rulemaking (ANPR) while also seeking modifications to ASTM F3118 through the ASTM process, so that stakeholders can "work with urgency" toward addressing CPSC incident data to develop a performance-based standard, versus a design restrictive standard. The commenter also expressed disappointment that CPSC is "subverting" the ASTM process, which has a proven track record for resolving product problems. The

⁴³ <https://cpsc.gov/Regulations-Laws--Standards/Voluntary-Standards>

DRAFT

commenter requests that CPSC “correct its course” and provide the relevant data to the ASTM committee, so that the committee can address the problems associated with inclined sleep products through the ASTM process. The commenter requests that CPSC hold the SNPR in abeyance while proceeding as the commenter has suggested, with an ANPR and working through the ASTM process.

Response 36: Although staff submitted an NPR termination package for infant inclined sleep products to the Commission on June 12, 2019, the Commission never voted on the termination package. Instead, the Commission voted (5-0) on October 25, 2019 to issue the SNPR for infant sleep products.

Generally, CPSC staff’s work through the ASTM process to improve the requirements of voluntary standards to address hazards associated with durable infant or toddler products has improved the safety of these products, and CPSC will continue its work through the ASTM process. Accordingly, CPSC did not, and is not, subverting the ASTM process to address the hazards associated with inclined and flat sleep products. CPSC staff has been participating in the infant inclined sleep product standards development process, as well as the bassinet and cradle standards development committee, for many years, both before and after the Commission issued the 2019 SNPR.

ASTM did not hold subcommittee meetings or task group meetings on inclined sleep products or the SNPR for almost one full year after the October 2019 ASTM meetings, and did not schedule any meetings until after CPSC staff sent a letter to the ASTM subcommittee for infant inclined sleep products on July 16, 2020. After staff’s letter, the ASTM F3118 subcommittee established a task group to revise the infant inclined sleep standard’s title, introduction, and scope, to be more in line with the proposal in the 2019 SNPR. In December 2020, the ASTM subcommittee introduced ballot F15-18 (20-1) to change the standard’s title,

DRAFT

introduction, and scope to include all infant sleep products (and not just inclined sleep products). A more detailed description of this ballot is in section V.A.3 of this preamble. However, in January 2021, the ballot did not pass due to six negative votes. The ASTM F3118 subcommittee discussed the ballot results at a meeting on January 27, 2021. During this meeting, ASTM members disagreed on the intent and consequences of changes to the voluntary standard, and the meeting ended without a consensus on a path forward.

Based on the ballot results and the discussions in these ASTM meetings, staff advises that it is unlikely that ASTM will be able to move forward with changes to ASTM F3118 that address safe sleep requirements in the near term. However, we note that a task group to review safe sleep requirements across infant sleep product standards (the comparison task group) has met four times since the January 27, 2021 meeting. CPSC staff has participated in all of these ASTM efforts, including commenting on ASTM's ballot.

The December 2020 ASTM ballot to revise the title, introduction, and scope of ASTM F3118, and the January 2021 meeting to discuss the negatives on the ballot, demonstrate that ASTM members do not have a consensus on moving forward to address the hazards associated with infant sleep products, despite CPSC's 2019 SNPR and staff's continued participation in the process. Although ASTM task groups continue to work on revisions to the voluntary standard, staff reports that the ASTM process is not close to completing their work, and staff was not confident that ASTM would achieve consensus on revisions to the standard in the near term.

In a recent ASTM task group meeting on revisions to the title, introduction, and scope of the standard (April 22, 2021), task group members discussed balloting the proposed regulatory text in the 2019 SNPR to replace ASTM F3118-17a, to prevent the sale of infant inclined sleep products that purport to certify to ASTM F3118-17a, meaning products with an incline above 10 degrees, while ASTM works to revise the voluntary standard. However, the task group did not

DRAFT

plan to ballot the requirement that all infant sleep products meet the bassinet standard, because an ASTM task group is attempting to identify minimum safe sleep requirements that could apply to infant sleep products to include in F3118. Staff is participating in this effort as well, but, based on the assessment in this final rule, does not believe that requirements that are different and less stringent than the requirements in the bassinet standard will adequately address the risk of injury associated with infant sleep products.

Section 104 of the CPSIA requires CPSC to consult regarding the effectiveness of the voluntary standard; it does not require CPSC to consult on the timing of rulemaking, the content of a rule outside the rulemaking process, or to delay rulemaking until ASTM members achieve consensus. Moreover, stakeholders have now had sufficient time to consider and comment on the Mannen Study, which has been available on CPSC's website as an attachment to Staff's SNPR Briefing Package since October 2019, and how to address hazards associated with products within the scope of the SNPR, through the rulemaking and the ASTM processes. Despite having a year and a half to make progress through the ASTM process, stakeholders have not achieved consensus on how to move forward. When ASTM members do not have, or cannot achieve, consensus on whether or how a voluntary standard can address associated hazards, product safety is not improved.

The Commission's statutory mandate under section 104 of the CPSIA is to ensure that durable infant or toddler product standards provide the highest level of safety for such products that is feasible. Accordingly, CPSC will not delay the final rule, and section 104 of the CPSIA does not require CPSC to delay under the circumstances.

Comment 37: A commenter states that the scope of the 2019 SNPR includes many different types of products, with different sizes, age capacities, breathability, firmness, geometry,

DRAFT

perceived usage, and different warnings. The SNPR did not explain CPSC's rationale to include all of these products under ASTM F3118 and to conclude that all of these products are unsafe.

Response 37: The 2019 SNPR stated that the rule applied to all infant sleep products not subject to a CPSC sleep standard, including products with an incline less than 10 degrees, as outlined in response to comment 34. CPSC staff has been participating on the ASTM committees for bassinets and infant inclined sleep for many years about the hazards associated with products that would fall within the scope of the final rule. The infant inclined sleep product standard and the developing in-bed sleeper standard both evolved from the bassinet standard, and ASTM is currently trying to create new requirements in the bassinet standard to accommodate designs of certain flat sleep products. Accordingly, as provided in response to comment 36 regarding staff's efforts through the ASTM process, stakeholders understand the scope of products addressed in the 2019 SNPR and the final rule, ASTM's efforts to modify the bassinet requirements to accommodate these products, and CPSC staff's objection to modification of the safe sleep requirements in the bassinet standard. To address comments on the 2019 SNPR, the final rule includes additional incident data and analysis to demonstrate that the performance and labeling requirements of the bassinet standard would address the risk of injury associated with currently unregulated flat and inclined sleep products.

Comment 38: A commenter states that CPSC followed the process set forth in section 104 of the CPSIA when it issued the 2017 NPR to incorporate by reference into a mandatory rule, ASTM F3118. The commenter notes that the NPR was substantially the same as the voluntary standard, and that CPSC staff consulted with representatives from consumer groups, juvenile product manufacturers, and independent child product engineers and experts, to examine and assess the effectiveness of ASTM F3118, as required by section 104 of the CPSIA. The commenter states, however, that the 2019 SNPR for infant sleep products did not meet these two

DRAFT

requirements in the CPSIA. Instead of consulting with consumer groups, manufacturers, and product safety experts through the section 104 process, CPSC staff “informed” stakeholders about the Commission’s change in direction at the October 2019 ASTM committee meetings, after the SNPR was already issued. Moreover, although CPSC staff remains engaged in the ASTM F3118 subcommittee, their engagement is in support of the SNPR. The commenter maintains that the 2019 SNPR was not a collaborative effort, and that CPSC did not consult with stakeholders before issuing the SNPR. The commenter states: “The stakeholder community, impacted and potentially impacted manufacturers, are in the very unfortunate position of being subject to a mandatory rule that they had no part in helping to craft, by way of the ASTM development process.” The commenter also suggests that CPSC staff has acted in an “ultra vires manner to sanitize from incline sleep products” that are otherwise subject to an existing standard and to the rulemaking. The commenter recommends that the Commission issue another SNPR to clarify the scope of the rulemaking and evaluate and mitigate any unintended consequences, and to allow time for stakeholders and CPSC staff to work through the ASTM process to examine the impact of the proposed rule. Another commenter similarly urges the Commission to proceed in accordance with section 104 of the CPSIA by working with ASTM to develop a standard with a clearly defined scope, clear definitions, and creation of performance requirements based on specific product types within the infant sleep product category. This approach would require working with ASTM, and then reissuing an SNPR, before proceeding with a final rule.

Response 38: Section 104(b)(1) of the CPSIA requires the Commission to: “(A) in consultation with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts, examine and assess the effectiveness of any voluntary consumer product safety standards for durable infant or toddler products;” and (B) in accordance with the informal notice and comment rulemaking requirements under section 553 of

DRAFT

the Administrative Procedures Act (APA), “promulgate consumer product safety standards that – (i) are substantially the same as such voluntary standards; or (ii) are more stringent than such voluntary standards, if the Commission determines that more stringent standards would further reduce the risk of injury associated with such products.”

The regulated community participates in the rulemaking process by commenting on a proposed rule. Neither section 104 of the CPSIA nor the APA requires that stakeholders craft a CPSC mandatory rule. CPSC is required to consult regarding the effectiveness of the voluntary standard and to promulgate rules. As set forth in section V.A.3 and V.B.2 of this preamble, CPSC staff has been consulting about the effectiveness of the voluntary standards at issue, infant inclined sleep products and bassinets and cradles, for many years, through participation with the relevant ASTM subcommittees and task groups. For example, since ASTM began development of an infant inclined sleep product standard in or around 2011, CPSC has participated in the development of the standard. Similarly, CPSC staff has participated in the development and revisions to the bassinet and cradle standard since at least 2002. For both standards, CPSC staff has provided incident data, participated in subcommittee and task group meetings, and submitted comments and/or votes on ASTM ballots. For this final rule, CPSC has reviewed the incident data, hazard patterns, and the adequacy of the voluntary standards to address the risk of injury associated with products within the scope of the final rule, unregulated inclined and flat sleep products, and is promulgating a rule that is more stringent than the voluntary standard, as proposed in the 2019 SNPR, to further reduce the risk of injury associated with infant sleep products.

ASTM members have now had ample time to consider the hazards associated with infant sleep products, to comment on the SNPR, and to address associated hazards through revised voluntary standards. ASTM is still working on these issues and staff will continue working with

DRAFT

ASTM to develop a voluntary standard that addresses the risk of injury associated with infant sleep products. If and when ASTM has revised ASTM F3118-17a, it may send the revised standard to CPSC to evaluate, through the update process set forth in section 104 of the CPSIA.

Comment 39: Commenters allege that the 2019 SNPR represents an unprecedented effort by CPSC to issue a mandatory rule that would create a pre-market testing and approval process for an entire product category. Commenters state that creating an omnibus rule that requires infant sleep products to meet the bassinet standard, instead of creating product specific standards, would have the unintended consequence of stifling innovation.

Response 39: As with all of CPSC's regulations to set performance and labeling requirements, CPSC's mandatory rules for durable infant or toddler products set a floor for safe consumer products. CPSC does not require pre-market approval of consumer products, nor does the agency have the authority to do so. However, CPSC does have the authority to create mandatory performance requirements through rulemaking, and to require that all products offered for sale in the United States meet these requirements to protect consumers from injuries or death. When the Commission is aware of a gap in the regulatory framework for infant sleep products, the Commission can use its authority to address the associated hazards.

Mandating a safety standard for infant sleep products offered for sale in the United States that are not already within the scope of another CPSC sleep standard is not "unprecedented" and is no different than standards for other durable infant or toddler products that contain different product types within the same standard, such as strollers and high chairs, each of which include a variety of product types. No company can sell a stroller in the United States that does not comply with the stroller standard, simply based on the type of stroller. Similarly, no company can sell a high chair in the United States unless it complies with the high chair standard. This is not a novel idea. The only difference in these product categories is how the voluntary standards

DRAFT

evolved. The scope of the stroller and high chair standards are broad for the purpose of encapsulating all products. Standards for sleep products evolved on a different track. But the Commission is not required to continue a patchwork regulatory scheme that does not serve the interests of consumer safety. In this case, the Commission seeks to ensure that all products marketed or intended for infant sleep, for infants up to 5 months of age, meet the infant sleep product standard to set a floor for safe infant sleep. CPSC's mission is to protect consumers, and the agency will use its authority to protect the most vulnerable infants, up to 5 months old, and their unsuspecting parents, from sleep surfaces that do not follow known safe sleep principles, as set forth in the existing CPSC sleep standards. Accordingly, the Commission's effort in the 2019 SNPR is consistent with CPSC's statutory mandate to protect consumers, and specifically, under section 104, to promulgate standards for product categories that the Commission determines to be of the highest priority, and to ensure that such standards provide the highest level of safety for such products that is feasible.

Because CPSC staff has been working with ASTM members on the bassinet and cradle subcommittee for years, on both inclined sleep products, as well as unregulated flat infant sleep products, ASTM members should be well aware of staff's efforts and concerns with both product types. Once CPSC issues an NPR, CPSC's docket on Regulations.gov includes a record of staff's participation through the ASTM process, and ASTM records should reflect this participation as well. CPSC's Office of the Secretariat maintains meeting logs summarizing staff's participation with external parties, such as ASTM, outside of the rulemaking process, and these meeting logs are searchable on CPSC's website.

Finally, performance and labeling requirements for consumer products allow for innovation with certain baseline safety requirements. While we understand the concerns that innovation beyond the baseline safety requirements may be discouraged, we note the

DRAFT

development of infant inclined sleep products as a prime example of innovation preceding safety. Infant inclined sleep products were first marketed as an innovative sleep solution for parents; however, no safety standard existed for these products when they were introduced to the market. Commenters to the 2010 NPR and 2012 SNPR for bassinets indicated that hammocks and inclined sleep products should have their own standard because they could not meet the requirements for bassinets, and parents were likely to create their own “unsafe” alternative if a regulated product was not available. The ASTM standards development process for inclined sleep products took many years before the standard was published in 2015, and during that time, manufacturers were designing and selling innovative inclined products. As time went on, the hazards posed by inclined products became apparent in the accumulation of infant deaths and incidents associated with this product category. To avoid a repeat of this process, involving the most vulnerable infants up to 5 months old, the Commission is issuing this infant sleep product standard that contains key elements of safe sleep, so that product innovation does not compromise safe sleep for infants up to 5 months old.

Comment 40: A commenter states that section 104 of the CPSIA does not permit the application of the bassinet standard to an open-ended and undefined scope of products. The commenter contends that section 104 requires the Commission to consider specific product types, characteristics, and hazards. The commenter states that the 2019 SNPR approach is “arbitrary” and “is a reversal of the Section 104 process” for existing and new products that are sleep products, but not bassinets or cradles. The commenter states that CPSC must clearly define the scope of the rule and the products that fall within the scope of the rule.

Response 40: As set forth in response to comment 34, the 2019 SNPR provided notice that the rulemaking included flat infant sleep products. Moreover, the preamble to this final rule identifies product types that fall within the scope of the rule, as well incident data, hazard

DRAFT

patterns, and an analysis of how the requirements in the bassinet and cradle standard address the risk of injury associated with flat infant sleep products. The purpose of the rule is to regulate any product marketed or intended as a sleeping accommodation for an infant up to five months old that is not already regulated by another CPSC sleep standard. Accordingly, the scope of the rule is not “open-ended,” and the final rule demonstrates that the bassinet standard provides minimum safe sleep characteristics for these infant sleep products.

Comment 41: A commenter states that to implement a rule that requires specific products to meet the requirements of the bassinet standard, CPSC must provide a rationale that is supported by “substantial evidence.” The commenter states that the 2019 SNPR did not provide a rationale for the application of the bassinet standard to specific products within the infant sleep product category.

Response 41: As stated in response to comment 37, CPSC and stakeholders have been working through the ASTM process regarding requirements for unregulated flat and inclined sleep products for many years, as part of development of the bassinet standard. Accordingly, based on the 2019 SNPR and this ongoing work with ASTM, staff’s efforts have been to maintain the safe sleep requirements in the bassinet standard and apply them to all sleep products marketed and intended for infants up to 5 months old. In response to comments, the final rule makes clearer the unregulated flat sleep products that fall within the scope of the rule, provides incident data, identifies hazard patterns, analyzes the effectiveness of the bassinet standard to address the hazards, and compares the performance requirements in international standards to demonstrate that products within the scope of the final rule have similar hazard patterns that can be addressed by the requirements in the bassinet standard.

Comment 42: A commenter states that the Commission previously recognized the importance of product specificity in promulgating the consumer registration rule, 16 CFR part

DRAFT

1130. Despite this, the commenter states that the 2019 SNPR failed to discuss which product types would be considered “durable infant or toddler products” for product registration card purposes, and “simply concludes in a circular fashion that infant sleep products are durable infant or toddler products.” The commenter believes that a specific rationale is required for each product to “independently qualify” as a durable infant or toddler product. The commenter concludes that under the APA, CPSC must specifically define products that fall within an “infant sleep product” in another SNPR before it can issue a final rule.

Response 42: The preamble for the final rule identifies product types that fall within the scope of the rule. However, the 2019 SNPR and the final rule purposely do not define product types by name in the regulation text, and instead identify product types by purpose and age limit, to ensure that all infant sleep products meet minimum safe sleep requirements in the bassinet standard, including existing products and future products.

Section 104(f)(1) of the CPSIA does not require any further product type specificity to identify these products as durable infant or toddler products. The statute defines a durable infant or toddler product as “a durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years” and then provides a list of products that are durable infant or toddler products. The Commission’s implementing rule at 16 CFR § 1130.2(a) states:

DEFINITION OF DURABLE INFANT OR TODDLER PRODUCT means the following products intended for use, or that may be reasonably expected to be used, by children under the age of 5 years. The listed product categories are further defined in the applicable standards that the Commission issues under section 104(b) of the Consumer Product Safety Improvement Act of 2008, and include products that are combinations of the following product categories...

DRAFT

Based on this definition in part 1130, a product marketed or intended as a sleeping accommodation for an infant up to 5 months old is a durable infant or toddler product. Because the products are intended for infants up to 5 months old, the products are “intended for use,” and “reasonably expected to be used,” by children under 5 years old. Products intended for infant sleep are similar to products on the statutory list intended for infant sleep, such as cribs, and bassinets and cradles. Additionally, “infant sleep products” are further defined in the final rule. Accordingly, adding “infant sleep products” as a durable infant or toddler product is consistent with the Commission’s approach of adding a durable infant or toddler product category with a mandatory standard to the list of products in part 1130, to clarify that these products must meet the consumer registration rule, and the testing and certification requirements for durable infant or toddler products.

Comment 43: A commenter contends that the creation of specific types of infant sleep products is not by the Commission’s choice, but required by section 104 of the CPSIA. The commenter states that Congress purposely listed different types of infant sleep products separately in section 104, because “differences between these products warrant individual consideration in any rulemaking proceeding,” and that this principle is true with the remaining infant sleep product types.

Response 43: The commenter offers no legislative history to support the idea that Congress listed sleep products separately because product differences warranted individual rulemaking proceedings. The products listed as durable infant or toddler products are examples of durable infant or toddler products that Congress expected the Commission to regulate by issuing a mandatory standard. Most of these products had existing voluntary standards in 2008 when Congress passed the CPSIA. Congress gave CPSC the authority to add products to the list of durable infant or toddler products, gave CPSC the mission to protect consumers, and

DRAFT

instructed CPSC to “periodically review and revise the standards set forth under this subsection to ensure that such standards provide the highest level of safety for such products that is feasible.”

Flat sleep products that are subject to the final rule are not currently defined or covered by any existing ASTM standard. If CPSC could not use its authority to expand the scope of a rule to include such products, especially when staff’s analysis demonstrates that the existing bassinets and cradles standard would address the risk of injury associated with such products, ASTM could dictate when and if durable infant or toddler products are regulated by CPSC. Similarly, when products fall within an ASTM standard, CPSC should not be bound by ASTM’s categorization of such products if CPSC can demonstrate that the voluntary standard is inadequate to address the risk of injury associated with the products, but another voluntary standard would be adequate.

Comment 44: A commenter states that CPSC must not only specifically identify product types that fall within the infant sleep product category, but must also provide the rationale for applying the bassinet and cradle standard requirements to each product type within the category, as well as establishing the product type is a durable infant or toddler product. The commenter contends that this analysis must identify the specific characteristics for each product type and the related hazards, to describe how the bassinet standard would address each hazard pattern. The commenter contends that a requirement that may be applicable to one product type may not be applicable to another product type. The commenter contends that “[n]o broad product category to date has ever been subject to a rule without such specificity.” The commenter states this level of specificity is required to avoid banning existing safe products or chilling future innovation.

Response 44: As set forth in response to comment 34, the 2019 SNPR provided notice that the rulemaking included flat infant sleep products, and multiple other efforts, including those

DRAFT

at ASTM, reinforced this. In response to comments, the preamble to this final rule provides further clarity, identifying product types that fall within the scope of the rule, including inclined and flat sleep products, as well associated incident data and hazard patterns. This final rule also provides an analysis demonstrating that the requirements of the bassinet standard are adequate to address each risk of injury associated with infant sleep products, both flat and inclined product types. As set forth in response to comment 39, we disagree that a rule under section 104 of the CPSIA cannot have a scope that is broader than one product type. For example, many types of carriages and strollers fall within the Safety Standard for Carriage and Strollers. Strollers offered for sale in the United States must meet the requirements in this regulation, regardless of product type.

The Commission's statutory mandate under section 104 of the CPSIA is to ensure that durable infant or toddler product standards provide the highest level of safety for such products that is feasible. Congress specifically included five products intended for infant sleep in the statutory list of durable infant or toddler products (full-size cribs, non-full-size cribs, play yards, and bassinets and cradles), demonstrating intent for CPSC to regulate such products. Currently, multiple flat and inclined sleep products are not subject to a CPSC regulation, but CPSC has the authority to add "infant sleep products" as a durable infant or toddler product, and to regulate this product category. Accordingly, the final rule regulates any product marketed or intended as a sleeping accommodation for an infant up to 5 months old, that is not already regulated by another CPSC sleep standard. In response to comments, the final rule expands the justification from the 2019 SNPR to demonstrate that the bassinet standard provides the minimum safe sleep characteristics for these infant sleep products. Finally, the scope of the final rule is well-defined, and allows a manufacturer to intentionally design and market a product as an infant sleep product, or to choose not to design and market a product as an infant sleep product.

DRAFT

VIII. Final Rule Establishing a Safety Standard for Infant Sleep Products

This final rule establishes 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 and CPSC staff’s analysis of the incident reports, hazard patterns, and adequacy of the voluntary standard, demonstrate that ASTM F3118-17a is inadequate to address the risk of injury associated with inclined sleep products. ASTM F3118-17a is inadequate to address the risk of injury associated with inclined sleep products, because it allows products with a seat back angle greater than 10 degrees, and does not address additional hazard patterns associated with inclined sleep products, such as containing the infant. The Commission determines that more stringent requirements are necessary in the mandatory standard to further reduce the risk of injury associated with inclined sleep products. Staff’s assessment in the 2019 SNPR, and section VI of this preamble, demonstrate that the performance requirements in the current voluntary standard for bassinets and cradles, ASTM F2194, which is incorporated into the Commission’s mandatory standard, 16 CFR part 1218, is adequate to address the risk of injury associated with infant inclined sleep products, and will further reduce the risk of injury associated with inclined sleep products.

As proposed in the 2019 SNPR, the definition of an “infant sleep product” in the final rule also includes flat sleep products, such as in-bed sleepers, baby boxes, compact bassinets, and baby tents, which currently do not fall within the scope of any voluntary or mandatory standard. Staff’s assessment of the incident reports and hazard patterns associated with flat sleep products in this final rule demonstrates that the risk of injury and death associated with flat sleep products are similar, and can be addressed by meeting the requirements in the current voluntary standard for bassinets and cradles, ASTM F2194, which is incorporated into the Commission’s mandatory standard, 16 CFR part 1218.

DRAFT

Accordingly, the final rule incorporates by reference ASTM F3118-17a as the mandatory standard for infant sleep products, both inclined and flat, with the following modifications to the voluntary standard:

- Revise the introduction of the standard, to state the purpose of the standard is to address infant sleep products not already covered by traditional sleep product standards, to reduce deaths associated with known sleep hazards, including but not limited to, a seat back or sleep surface angle that is greater than 10 degrees from the horizontal. This requirement is intended to broaden the purpose of the standard to more clearly address inclined and flat sleep products, including known hazards associated with infant sleep.
- Revise the scope of the standard, to remove the term “inclined” and broaden the scope to include infant sleep products, including inclined and flat sleep surfaces, marketed or intended to provide a sleeping accommodation for an infant up to 5 months old, and that are not already subject to a mandatory CPSC sleep standard:
 - 16 CFR part 1218 - Safety Standard for Bassinets and Cradles, incorporating by reference ASTM F2194, Standard Consumer Safety Specification for Bassinets and Cradles;
 - 16 CFR part 1219 - Safety Standard for Full-Size Baby Cribs, incorporating by reference ASTM F1169, Standard Consumer Safety Specification for Full-Size Baby Cribs;
 - 16 CFR part 1220 - Safety Standard for Non-Full-Size Baby Cribs, incorporating by reference applicable requirements in ASTM F406, Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards;
 - 16 CFR part 1221 - Safety Standard for Play Yards, incorporating by reference applicable requirements in ASTM F406, Standard Consumer Safety Specification

DRAFT

for Non-Full-Size Baby Cribs/Play Yards;

- 16 CFR part 1222 - Safety Standard for Bedside Sleepers, incorporating by reference ASTM F2906, Standard Consumer Safety Specification for Bedside Sleepers.

The purpose of this revision is to more clearly establish the scope of the final rule, which includes all products marketed or intended for infant sleep for children up to 5 months of age, so that these products that are currently unregulated must now meet one of the mandatory standards for infant sleep.

- Revise the scope of the standard to explicitly state that crib mattresses that meet the requirements of ASTM F2933 do not fall within the scope of the standard. This exclusion clarifies that crib mattresses that meet the voluntary standard do not meet the definition of an infant sleep product, and are always used in conjunction with a sleep product, such as a crib or play yard, that falls within one of CPSC’s sleep standards. The final rule also modifies referenced documents in the standard, to add the voluntary standard for crib mattresses, ASTM F2933;
- Modify the definition of “infant inclined sleep product” to remove the term “inclined” and revise the definition to state that an “infant sleep product” is “a product marketed or intended to provide a sleeping accommodation for an infant up to 5 months of age, and that is not subject to any of the following:
 - 16 CFR part 1218 – Safety Standard for Bassinets and Cradles
 - 16 CFR part 1219 – Safety Standard for Full-Size Baby Cribs
 - 16 CFR part 1220 – Safety Standard for Non-Full-Size Baby Cribs
 - 16 CFR part 1221– Safety Standard for Play Yards
 - 16 CFR part 1222 – Safety Standard for Bedside Sleepers

DRAFT

This requirement aligns the definition of “infant sleep product” with the scope of the rule, including the intent of the rule to ensure that all infant sleep products, inclined and flat, are subject to a mandatory CPSC sleep standard, to address the risk of injury associated with infant sleep products.

- Remove the definitions of accessory, compact, and newborn inclined sleep products because they are no longer necessary and have no unique requirements in the standard, because all infant sleep products are subsumed under the definition of “infant sleep product.”
- Modify seat back/sleep surface angle so the maximum allowable angle, as tested per the rule, must be equal to or less than 10 degrees from horizontal in all positions recommended for sleep. Although the bassinet standard also requires a sleep surface equal to or less than 10 degrees, the bassinet standard does not have a test for the sleep surface angle. Accordingly, infant sleep products are required to test for the sleep surface angle, in addition to meeting the bassinet standard.
- Add a new requirement that infant sleep products must meet 16 CFR part 1218, Safety Standard for Bassinets and Cradles, including conforming to the definition of bassinet/cradle. As the final rule analysis demonstrates, conforming to the requirements in the bassinet standard addresses the risk of injury associated with infant sleep products. Requiring products to meet the definition of a bassinet/cradle also ensures that the products meet the requirement to have a stand.
- Remove all the performance requirements except for the above new or modified requirements.
- Remove all test methods except for maximum seat back/sleep surface angle.

DRAFT

The name of CPSC's final rule does not include the term "inclined," and will be codified as 16 CFR part 1236, Safety Standard for Infant Sleep Products. Finally, as proposed in the 2019 SNPR, because infant sleep products must meet the bassinet standard, infant sleep products must also meet the warning requirements in the bassinet and cradle standard, instead of those stated in ASTM F3118-17a. 84 FR at 60956-57. An Appendix to Tab C of Staff's Final Rule Briefing Package contains a redline of the final rule changes, compared to the requirements in ASTM F3118-17a.

IX. 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).

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.

DRAFT

All new NORs for new children’s product safety rules, such as the infant sleep products standard, require an amendment to part 1112. Accordingly, the 2019 SNPR proposed to amend the existing rule that codifies the list of all NORs issued by the Commission, 16 CFR part 1112, to add 16 CFR part 1236, *Standard Consumer Safety Specification for Infant Sleep Products*, to the list of children’s product safety rules for which CPSC has issued an NOR, because a final rule would be a children’s product safety rule that requires third party testing by a CPSC-accepted third party conformity assessment body. 84 FR at 60957. The Commission received no comment on the proposed amendment, and is finalizing the amendment as proposed in the SNPR.

Test laboratories applying for acceptance as a CPSC-accepted third party conformity assessment body to test to the new standard for infant sleep products are 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 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 CPSC’s website at: www.cpsc.gov/labsearch. Part 1236 includes one performance test to check for a seat back/sleep surface angle that is 10 degrees or less, and then requires infant sleep products to meet 16 CFR part 1218, Safety Standard for Bassinets and Cradles.

The new 16 CFR part 1236 for infant sleep products should have sufficient testing capacity by the effective date of the final rule. The test to check the sleep surface angle required in part 1236 involves use of the “Hinged Weight Gage – Infant” identified in F3118-17a. Because the gage is also used for testing to the 16 CFR part 1223, Safety Standard for Infant Swings (incorporating by reference ASTM F2088), labs conducting infant swing testing will

DRAFT

already have the gage. Staff advises that 33 labs are currently CPSC-accepted to test to the bassinet and cradle standard. Of these 33, 19 of the labs are also accredited to test to the infant swings standard, meaning these labs have all of the test equipment required to test to the new part 1236. These labs should be able to more easily become accredited to test to part 1236. Also, labs that already test to part 1218 *bassinets*, must only acquire the test gage, which staff advises is manufactured with readily available metal and is estimated to cost \$800. Moreover, labs that previously tested to the current ASTM F3118-17a for the JPMA certification program have the gage, because F3118 contains a test to measure the seat back angle using the gage. Finally, the effective date of this final rule is 12 months from publication in the *Federal Register*. Accordingly, labs seeking to become accredited to part 1236 have a full year to obtain the necessary test equipment, become ISO accredited, and have CPSC-accept their accreditation to test to part 1236.

The Commission certified in the 2019 SNPR that the proposed NOR for infant sleep products would not have a significant impact on a substantial number of small laboratories. 84 FR 60959. CPSC expects that laboratories that are already accredited to test to the bassinet and cradle standard will find it relatively easy to become accredited to test to this standard, because the primary substantive requirement added by this standard is the sleep surface angle. Moreover, CPSC did not receive any comments regarding the NOR. Therefore, for the final rule, the Commission continues to certify that amending part 1112 to include the NOR for the infant sleep products final rule will not have a significant impact on a substantial number of small laboratories.

X. 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

DRAFT

standards for durable infant or toddler products, section 104 of the CPSIA also directed the Commission to issue a rule requiring that manufacturers of durable infant or toddler products establish a program for consumer registration of those products. Section 104(d) of the CPSIA.

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" to add to the statutory list in section 104(f)(2) of the CPSIA:

- 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).

DRAFT

In the SNPR, the Commission proposed 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 consumer registration rule and section 104 of the CPSIA. CPSC received a comment stating that the SNPR failed to discuss which product types would be considered “durable infant or toddler products” for product registration card purposes, and “simply concludes in a circular fashion that infant sleep products are durable infant or toddler products.” The commenter believes that a specific rationale is required for each product to “independently qualify” as a durable infant or toddler product. The commenter concludes that under the APA, the Commission must specifically define products that fall within an “infant sleep product” in another SNPR before it can issue a final rule.

We disagree with the commenter and finalize the amendment to part 1130, as proposed in the 2019 SNPR, to include “infant sleep products” as a durable infant or toddler product, as a subcategory of bassinets and cradles. Based on the definition of a “durable infant or toddler product” in section 104(f) of the CPSIA, and in § 1130.2, which define the term as products “intended for use, or that may be reasonably expected to be used, by children under the age of 5 years,” “infant sleep products” are a durable infant or toddler product. “Infant sleep products” are defined in the final rule as a product marketed or intended as a sleeping accommodation for an infant up to 5 months old. Accordingly, the products are “intended for use,” and “reasonably expected to be used,” by children under 5 years old. Moreover, products intended for infant sleep are similar to products on the statutory list intended for infant sleep, such as cribs, bassinets and cradles. Moreover, “infant sleep products” are further defined in the final rule. Finally, as discussed in section V of this preamble, the Safety Standard for Infant Sleep Products, for both inclined and flat sleep products, is an outgrowth of efforts to develop a safety standard for

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bassinets and cradles, and may be considered a subcategory of bassinets. To provide greater clarity that inclined sleep products are durable infant or toddler products subject to the consumer registration rule, as well as third party testing and certification requirements for durable infant or toddler products, the Commission finalizes the amendment to 16 CFR § 1130.2(a)(12), as proposed, to explicitly include “infant sleep products” as a subcategory of bassinets and cradles.

XI. Incorporation by Reference

Section 1236.2(a) of the final rule provides that each infant sleep product must comply with applicable provisions of ASTM F3118-17a. The Office of the Federal Register (OFR) has regulations concerning incorporation by reference. 1 CFR part 51. For a final rule, agencies must discuss in the preamble to the rule the way in which materials that the agency incorporates by reference are reasonably available to interested persons, and how interested parties can obtain the materials. Additionally, the preamble to the rule must summarize the material. 1 CFR 51.5(b).

In accordance with the OFR’s requirements, sections VI.A and VIII of this preamble summarize the provisions of ASTM F3118-17a that the Commission is incorporating by reference. ASTM F3118-17a is copyrighted. Before the effective date of this rule, you may view a copy of ASTM F3118-17a at: <https://www.astm.org/cpsc.htm>. Once the rule becomes effective, ASTM F3118-17a can be viewed free of charge as a read-only document at: <https://www.astm.org/READINGLIBRARY/>. To download or print the standard, interested persons may purchase a copy of ASTM F3118-17a from ASTM, through its website (<http://www.astm.org>), or by mail from ASTM International, 100 Bar Harbor Drive, P.O. Box 0700, West Conshohocken, PA 19428; <http://www.astm.org>. Alternatively, interested parties may inspect a copy of the standard free of charge by contacting Alberta E. Mills, Division of the

DRAFT

Secretariat, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone: 301-504-7479; e-mail: cpsc-os@cpsc.gov.

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). CPSC generally considers 6 months to be sufficient time for suppliers of durable infant and toddler products to come into compliance with a new standard under section 104 of the CPSIA. Six months is also the period that the Juvenile Products Manufacturers Association (JPMA) typically allows for products in the JPMA certification program to transition to a new standard once that standard is published.

The 2019 SNPR proposed 12-month effective date after publication of the final rule, for products manufactured or imported on or after that date, because: (1) the Commission was proposing to incorporate by reference, ASTM F3118-17a, a relatively new voluntary standard that covers a variety of products whose manufacturers may not be aware that their product must comply; and (2) the Commission proposed to make substantial modifications to ASTM F3118-17a, and a 12-month effective date would allow time for infant sleep product manufacturers to bring their products into compliance after a final rule is issued. 84 FR 60958. The 2019 SNPR stated that the Commission expects that most firms should be able to comply within the 12-month timeframe. The 2019 SNPR also requested comment on the proposed 12-month effective date, because of the hazards involved with infant inclined sleep products, and stated that the final rule could issue with a shorter effective date, so that safer products would be available sooner. *Id.*

The 2019 SNPR commenters both supported and opposed the 12-month effective date. Some commenters supported a 6-month effective date, urging that additional time for the rule to become effective puts infants at risk. Other commenters requested a longer effective date, or an

DRAFT

indefinite delay of the rulemaking, until ASTM completes additional standards for specific products covered by the final rule.

For the final rule, the Commission will maintain the 2019 SNPR proposed effective date of 12 months after the date of publication in the *Federal Register*. Accordingly, as of the effective date of the final rule, it is unlawful to “sell, offer for sale, manufacture for sale, distribute in commerce, or import into the United States,” any infant sleep product, as defined in the rule, that is not in conformity with the final rule. 15 USC 2068(a)(1).

A 6-month effective date may seem reasonable because suppliers have had ample lead time to prepare for this rule since the SNPR was published in 2019, and many of the products within the scope of the final rule have been withdrawn from the market or redesigned, particularly for inclined sleep products. However, some manufacturers of flat sleep products that remain in the market will likely experience a significant economic impact as a result of this final rule. While some suppliers can reduce the impact of this rule by relabeling their products as not for infant sleep, not all manufacturers can simply remarket the product if the physical form of the product demonstrates that it is intended for sleep. For some of these products, manufacturers could relabel them as intended for infants older than five months, or, in some cases, for pets. However, the demand for infant sleep products for pet use is probably limited. Accordingly, maintaining the proposed 12-month effective date will provide manufacturers and importers time to spread the impact of the rule over a 12 month time period, to reduce the economic impact of the final rule.

XIII. Regulatory Flexibility Act

A. Introduction

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601-612, requires that agencies review a proposed rule and a final rule for the rule’s potential economic impact on small entities,

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including small businesses. Section 604 of the RFA generally requires that agencies prepare a final regulatory flexibility analysis (FRFA) when promulgating final rules, unless the head of the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Staff prepared a FRFA that is available at Tab E of Staff's Final Rule Briefing Package.

The scope of this FRFA and the number of firms impacted is different from the Initial Regulatory Flexibility Analysis (IRFA) that accompanied the 2017 NPR, because the scope of the NPR was inclined sleep products, while the scope of the final rule is infant sleep products, defined in the final rule as products that are marketed or intended to provide sleeping accommodations for an infant up to 5 months of age, and that are not already covered by a mandatory CPSC sleep standard: full-size cribs, non-full-size cribs, play yards, bassinets and cradles, or bedside sleepers. This change in scope from the proposed rule was specified in the 2019 SNPR, and includes inclined and non-inclined (flat) infant sleep products. Some inclined sleep products have been recalled or otherwise voluntarily removed from the market since 2019, so some firms that were forecast to be impacted in the IRFA are not likely to be impacted by this final rule, because the firms have already stopped selling those products. However, a significant economic impact is possible for suppliers of flat sleep products that were not analyzed in the IRFA, as well as remaining suppliers of inclined products. Flat sleep products without inclined sleep surfaces include: baby boxes, compact and travel bassinets that do not meet the bassinet standard, in-bed sleepers, baby tents marketed for infant sleep, baby pods, and baby nests.

Pursuant to the final rule, firms whose infant sleep products do not comply with any CPSC sleep standard will need to evaluate their products, determine what changes would be required to meet an existing CPSC standard, or 16 CFR part 1218, the Safety Standard for Bassinets and Cradles, and decide how to proceed. Noncompliant products would need to be

DRAFT

removed from the U.S. market, modified to meet the mandatory standard as specified in this final rule, remarketed for children older than 5 months, or remarketed as not intended for infant sleep. New infant sleep products introduced to the market would also need to comply with the standard, or one of the other CPSC sleep standards. The final rule defines an “infant sleep product” as a product marketed or intended to provide a sleeping accommodation for an infant up to 5 months of age, and that does not already meet a mandatory CPSC sleep standard. CPSC interprets this definition to include products that are marketed for “napping,” “snoozing,” “dreaming,” or any other word that implies sleeping, or that are called a “bed,” and items marketed with a picture of a sleeping infant, to be an infant sleep product.

Based on the staff’s analysis, the Commission anticipates a possible significant economic impact for twelve small importers and nine small domestic manufacturers that supply infant sleep products to the U.S. market, as well as for hundreds of home-based small businesses that ship from the U.S. We provide a summary of the FRFA below.

B. The Market for Infant Sleep Products

Section II of this preamble describes the infant sleep products within the scope of the final rule, the products excluded from the final rule, and a description of the market for infant sleep products, including a summary of retail prices for various types of infant sleep products.

C. Products and Small Entities to Which the Final Rule Would Apply

1. Overview of Products Covered by, and Excluded From, the Final Rule

Section II.A and B of this preamble describe the products subject to, and excluded from, the final rule. This rule is intended to cover “infant sleep products,” defined in the final rule as products that are marketed or intended to provide a sleeping accommodation for an infant up to 5 months of age, and that are not already covered by a mandatory CPSC sleep standard: full-size cribs, non-full-size cribs, play yards, bassinets and cradles, or bedside sleepers. A detailed

DRAFT

description of the products covered by the final rule is set forth in section II.C of this preamble, and includes:

- *Inclined products*, such as: hard frame inclined sleepers, compact foam inclined sleepers, inclined play yard accessories, and baby hammocks; and
- *Flat products*, such as: soft-sided products (baby pods and baby nests, soft-sided travel bassinets or travel beds, hand-held carriers marketed for sleep, and in-bed sleepers), rigid-sided and rigid-framed compact bassinets, travel bassinets, and similar products (baby boxes, compact, portable, or travel bassinets, or infant travel beds), and baby tents.

None of these products is covered by an existing CPSC sleep standard. CPSC considers that any items marketed for “napping,” “snoozing,” or “dreaming,” or any other word that implies sleeping, or that are called a “bed,” as well as items marketed with a picture of a sleeping infant, to be an infant sleep product.

Products that are subject to another CPSC sleep standard, or to another durable infant or toddler product rule that is not marketed for sleep, such as infant bouncers or swings, are not subject to the final rule. Moreover, a crib mattress, as defined in ASTM F2933-19, is not an infant sleep product covered by the final rule.

2. Suppliers to this Market

Manufacturers of infant sleep products are categorized under many different North American Classification System (NAICS) categories, because there is not a NAICS code specifically for infant sleep products. These items are made by companies that have baby furniture, baby bedding items, mattresses, other durable baby items including strollers or car seats, toys, or general merchandise as their primary business. Businesses are generally considered small per the Small Business Administration (SBA) size standards if they have fewer than 100 employees for importers or wholesalers, or fewer than 500 employees for most of the

DRAFT

relevant types of manufacturers for this rule. The SBA size standard for mattress manufacturing is 1,000 employees. The relevant NAICS codes include:

314999 (All Other Miscellaneous Textile Product Mills)

337910 (Mattress Manufacturing)

339930 (Doll, Toy, and Game Manufacturing)

339999 (All Other Miscellaneous Manufacturing)

423220 (Home Furnishing Merchant Wholesalers)

424330 (Women's, Children's, and Infants' Clothing and Accessories Merchant Wholesalers)

The SBA size standards for “small” for the relevant NAICS codes mean that most suppliers in this product category are considered “small.” A U.S. company that has a factory employing 100 people might be a top 10 supplier in a particular infant sleep product category, but would be considered “small” by SBA standards. Similarly, an importer with a U.S. warehouse staff of 50 people would also be considered “small.”

Prior to the recalls of some infant inclined sleep products, large domestic and foreign companies and the larger “small” companies by SBA size standards were responsible for most of the sales volume for the hard frame inclined sleep products and inclined play yard sleeper accessories. Many of the inclined sleep products were available at big box chain retailers, and a few were available at mattress retailers. The larger companies have recalled or discontinued these products, and most big box stores have stopped stocking them. However, inclined sleep products are still available from small manufacturers and importers, and discontinued items made by large companies are still available from online merchants. Small companies have always accounted for a majority of the suppliers of the unregulated flat-bottomed sleep products and infant hammock categories. A large number of suppliers exist for these products; the market

DRAFT

is fragmented with many sellers. Many of the products covered by the final rule, particularly the soft-sided products and the products sold by small businesses, are only available online.

The majority of the suppliers to which this final rule would apply are small by SBA standards. At least 60 small U.S.-based manufacturers and importers are in this market, as well as 5 large domestic companies, and dozens of foreign companies, some of which ship these items directly to customers in the U.S. via online marketplaces. In addition, more than a thousand home-based businesses supply flat sleep products that would be subject to the final rule, of which hundreds ship from the U.S. Some firms sell these items under multiple brand names and models, including small manufacturers that make “store brands” for larger companies. The number of importers selling flat sleep products is approximate because the proliferation of online retail makes it possible for importers to quickly change their product offerings based on demand for particular products. The number of foreign companies is approximate for the same reason. In addition to the foreign companies that ship from U.S. distribution sites, dozens of third-party sellers are on major internet retail sites that ship products to U.S. consumers directly from a foreign country. The analysis in this FRFA focuses on the impact on small U.S. manufacturers and importers that ship from the U.S., as well as U.S.-based home businesses, but the large and foreign companies will also be impacted by the cost of complying with this rule. The large number of companies in the flat sleep products market covered by this rule reflects both a strong market demand for these products and a competitive market with relatively low margins.

D. Testing and Certification

Under section 14 of the CPSA, once the new infant sleep product mandatory standard become effective, all suppliers will be subject to the third party testing and certification requirements under the CPSA and the Testing and Labeling Pertaining to Product Certification rule (16 CFR 1107), which requires that manufacturers and importers certify that their products

DRAFT

comply with the applicable children's product safety standards, based on third party testing, and subject their products to third party testing periodically. Third party testing costs are in addition to the costs of modifying the infant sleeper products to meet the standard.

For infant sleep products, the third-party testing costs are expected to be about \$1,500 per testing cycle per model, including both the costs of the testing and the costs of the samples to be tested. This is consistent with the IRFA in the SNPR, which estimated a cost of \$1,100 for testing alone, not including the cost of the samples to be tested; we did not receive any comments on the SNPR providing a different estimate. Based on comments received on the bassinet and cradle final rule published in 2013, one-time costs of redesigning a product to meet the standard could be as high as \$500,000 for products requiring major redesign. As allowed by the component part testing rule (16 CFR 1109), importers may rely upon third party tests obtained by their suppliers, which could reduce the impact on importers. In addition, all businesses selling products covered by this rule were already required to certify compliance to general children's product rules for lead, phthalates, and small parts with third party testing, so those third-party testing costs would not be considered new costs of compliance for this rule.

E. Impact of Final Rule by Product Category

The impact on small businesses would vary by product category. We describe each product, provide information on the types of firms that supply the product, and describe the impacts for each product type for complying with this rule or taking action to exit the market sector.

1. Inclined Sleep Products

(a) Hard Frame Inclined Sleepers, Compact Foam Inclined Sleepers, and Play Yard Accessories

Since the NPR was published in 2017, some inclined sleep products have been recalled or otherwise removed from the market. However, while resale of recalled products is prohibited,

DRAFT

discontinued items that were not recalled are still available on the secondary market, as well as additional physically similar products sold by small companies that were not recalled. JPMA has two manufacturers that are certified as compliant to the current ASTM F3118 standard for inclined sleepers. While larger companies have removed most of their inclined products from the market or remarketed them as chairs or loungers, some smaller importers and foreign direct shippers still offer them as sleep products. Some play yards with inclined sleep accessories are still available. To date, the lack of a CPSC mandatory standard means that new entrants are free to enter this market sector with new inclined sleep products that do not comply with the existing ASTM standard, ASTM F3118-17a, or any other ASTM or CPSC sleep standard. Many of the recalled items were still available from smaller Internet merchants in the spring and summer of 2020. Some items that were not recalled, but merely discontinued by the manufacturer, are still available for sale from retailers, at least until the remaining stock is sold.

Once the final rule is published and becomes effective, suppliers of inclined sleep products must either redesign existing products to comply with the standard and conduct third-party testing to demonstrate compliance, stop selling the products, or remarket the products as not intended for infant sleep. The impact of those options will depend upon how much redesign the product requires, and what portion of the company's sales are inclined sleep products. The impact on small companies that sell many different products in different categories, which is relatively common, especially for importers, will likely not be as significant as the impact on small companies that sell only a few types of products or that concentrate on sleep products covered by this rule.

The impact of remarketing products for a different use, such as for an older child, a pet, or not for sleep, will depend on the extent to which consumers demand the product for the different use. Given the proliferation of floor chairs, lounge chairs, rockers, and bouncer seats

DRAFT

on the market, it seems likely that consumers find value in physically similar products that are marketed for a different use, and that remarketing will not reduce demand. U.S. sales of the combined category of bouncer seats, rockers, and sleepers totaled more than 2 million units and \$126 million dollars in 2018.⁴⁴

Suppliers of the hard-plastic framed rocker-type items may choose to redesign their items to meet the requirements of a different mandatory safety standard, particularly the one for infant bouncer seats. Most of the hard-framed products were made by large or foreign companies, although the market volume has shifted to smaller companies as the larger companies have already removed these items from the market or remarketed them as chairs, rockers, or chair/swing combos. Two small domestic companies that make inclined sleep products may experience a significant economic impact⁴⁵ as these were some of their best-selling products, and one of them also supplied the product as a “store brand” to another company. The other sells multiple types of sleepers within the scope of the final rule. Redesigning, relabeling, or discontinuing the products could be a significant impact on these firms. The rest of the small domestic companies that sold this product and small importers will likely not be significantly impacted because they sell many other products that would not be subject to the final rule.

Suppliers of inclined compact foam products will need to redesign their products with an incline of 10 degrees or less and meet other requirements of this standard, remove these products from the market, or relabel them as not being intended for sleep by children under 5 months of age. Some of these products have restraining harnesses to keep the infant from sliding down on

⁴⁴ Baby feeding, care, and travel accessory unit sales in the United States in 2018, by product type - <https://www.statista.com/statistics/891908/baby-feeding-care-and-travel-accessory-unit-sales-by-product-type-us/>
And Baby feeding, care, and travel accessory sales in the United States in 2018, by product type <https://www.statista.com/statistics/891889/baby-feeding-care-and-travel-accessory-sales-by-product-type-us/>

⁴⁵ Please note that the number of companies impacted for each product type sums to more than the total number of impacted companies for the rule as a whole, because several small companies sell products in multiple product categories impacted by this rule.

DRAFT

the slanted product, which is not compliant with any of the existing CPSC sleep standards. Some suppliers have already remarketed the products as loungers or floor chairs without changing the design. Several of the companies that sell these products sell larger wedge pillow products for adults and older children as “body pillows” or sleeping positioners, so the infant sleep products are not their only product line. Redesign or remarketing could have a significant impact for the three small domestic companies and one importer that have such products, as well as other products in the scope of this rule, as a large portion of their product line.

Suppliers of inclined play yard accessories will need to redesign their products with an incline of 10 degrees or less and meet other requirements of this standard, remove these products from the market, or relabel them as not being intended for sleep by children under 5 months of age, if appropriate. Most play yard suppliers have already discontinued or recalled the inclined accessory products and replaced them with flat products instead. The ASTM standard for non-full-size-cribs and play yards, F406-19, already specifies that bassinet, changing table, or similar accessories must comply with the applicable requirements of ASTM standards addressing those product types. Play yard suppliers were already required to comply with the requirement that bassinet accessories meet the bassinet standard. Because the main product is the play yard, not the particular accessories, and suppliers were already required to comply with the bassinet standard for bassinet-type accessories, this rule should not have a significant impact on any of the suppliers of play yards, unless they had “napper” or “inclined sleeper” accessories that did not meet the bassinet standard. The impact could be significant for one small domestic company that still sells inclined play yard accessories, and has other products in the scope of this rule.

(b) Baby Hammocks

Suppliers of baby hammocks are unlikely to be able to redesign their product to meet any of the existing CPSC infant sleep standards. An inclined sleep angle is inherent in the design of

DRAFT

hammocks, which shift shape as the infant moves. Sleeping pads in the bottom of a hammock would still leave the product with sides that shift shape in use. For hammock accessory products sold separately that attach to the corners of a crib or play yard, there is no standard installation that could be tested to meet incline, gap, side heights, or stability requirements: the incline would depend on the size of the crib or play yard and the weight of the infant, and the gaps between the hammock side and the side of the crib or play yard would depend on the size of the crib or play yard. Therefore, relabeling and remarketing baby hammocks as being not for sleep or as being intended only for children at over 5 months of age may be the only compliance option, other than removing the products from the market altogether.

Since the NPR was published, some baby hammocks have been withdrawn from the market by small companies that make and import other types of baby products or adult hammocks. However, many home-based suppliers remain in the market, as well as several small domestic businesses, one of which appears to have infant crib hammocks as its only product. Multiple importers based in the U.S. also sell hammocks with frames made by foreign companies, but those companies will not be significantly impacted because they sell many other products that would not be impacted by the final rule. Several foreign companies that make baby hammocks will have to stop distributing them in the U.S., or conspicuously label them as being for use only by children over 5 months of age.

If baby hammocks are removed from the market, the impact will likely be significant for one small domestic company for which baby hammocks constitute most, if not all, of their product line, as well as possibly significant for several small importers that do not appear to have many other products. The impact will likely be significant for dozens of home-based manufacturers that have crib hammocks or other fabric hammocks without a frame as their main or only product, if they choose to exit the market. However, it is possible that some sellers of

DRAFT

hammocks will simply relabel and remarket them for older children or as toy storage hammocks. The demand for these products for older children or toy storage uses is unknown.

2. Flat Sleep Products

(a) Flat, Soft-Sided Products

Many of the suppliers of flat, soft-sided products would likely be significantly impacted by the final rule. This is because compliance with any of the sleep product standards, particularly the stability, side height, and occupant containment requirements, would be difficult for a product with low, soft sides. A product with low, soft sides cannot meet the bassinet standard by simply adding a stand, nor can it meet the hand-held carrier standard by simply adding handles. Also, adding rigid higher sides may be contrary to the intended product use as in-bed sleepers. Relabeling the products as being not intended for infant sleep might not be an option if the product is clearly intended for infant sleep, and is not large enough for an older child, although these items could be remarketed as pet beds. At least nine small importers and four domestic manufacturers that supply these products have these products as most or all of their product line. There are also potentially hundreds of small, home-based businesses for which such low, soft-sided products appear to be their major product line. The impact for suppliers that have these products as most of their product line would likely be significant. In addition, the many home-based businesses do not currently have warning labels, instruction manuals, or certification to other CPSC or ASTM standards. Some products are already being remarketed as loungers, nappers, or “for tummy time”, but will be required to comply with the final rule if they are marketed for sleep, including napping.

Flat play yard accessories are already required to meet the bassinet or other applicable standard. The ASTM standard for non-full-size-cribs and play yards, F406-19, already specifies that bassinet, changing table, or similar accessories must comply with the applicable

DRAFT

requirements of ASTM standards addressing those accessories. Most flat play yard accessories are hard-framed, not soft-sided, and are discussed in the next section. Because the main product is the play yard, not the particular accessories, and suppliers were already required to comply with the bassinet standard for bassinet-type accessories, this rule should not have a significant impact on any of the suppliers of flat play yard accessories, unless they have “napper” accessories that are not compliant with the bassinet standard. One importer has only one model of play yard with a flat mesh accessory as their main product; that importer could be significantly impacted if their product is not compliant and they cannot find another supplier with a compliant product.

(b) Flat, Rigid-Sided and Rigid-Framed Compact Bassinets, Travel Bassinets, and Similar Products

Compact bassinets with rigid sides or rigid-framed sides but without a stand or legs cannot meet the stability or physical requirements of CPSC’s bassinet and cradle standard or this standard, independent of whether the product has an incline. Suppliers may choose to offer their products with a stand to meet this standard, or add a handle and redesign the product to meet the hand-held carrier standard. In either case, the cost of redesigning the product could be significant. These products usually already have flat sleep surface and rigid sides, as required by the bassinet/cradle standard, but may not meet the side-height requirement of the bassinet/cradle standard. However, the cost to redesign could still be significant, as even a simple re-design could cost hundreds of thousands of dollars per model and require new third-party testing, and all of the product marketing, instructions, and packaging would have to be revised. Adding a stand would also increase the retail price of the product, which would likely reduce sales, assuming that demand is responsive to price and that other products like hand-held carriers are considered by consumers to be reasonable substitutes. Moreover, these products likely cannot be remarketed for another use by infants 5 months and younger, as the physical design suggests the

DRAFT

product is for sleep, although they could be remarketed for older children or for pets, depending on whether the size is appropriate for those uses. For the importers, the impact is likely not significant, as they do not have these products as most of their product line and can therefore either stop selling the product or obtain a compliant product from a different supplier at minimal cost to them. For the two domestic manufacturers of these products that have these products as most of their product line, or sell multiple products covered by this rule, the cost of compliance could be significant.

Baby boxes have similar compliance impacts to the larger category of compact bassinets. Some compact bassinets are marketed as suitable for bed-sharing, so may be considered as rigid in-bed sleepers. Suppliers of baby boxes and in-bed sleepers with rigid or rigid-framed sides may also choose to offer their products with a stand to meet the bassinet standard. Given that these products already have rigid sides and flat sleeping surfaces, the redesign may be relatively minor, but could still cost hundreds of thousands of dollars to implement and test, especially given the need to adapt them to meet stability requirements. These suppliers could also choose to add a handle to these products and make other design, instructions and labeling changes in order to comply with the hand-held carrier standard. Labeling these products as not for infant sleep is likely not an option, as these items are intended for sleep, and are too small to be used by older children. Remarketing as storage boxes is possible, but likely a much lower price point. The impact could be significant for two suppliers of baby boxes.

Flat sleep surface play yard accessories are already required to meet the bassinet or other applicable standard. The ASTM standard for non-full-size-cribs and play yards, F406-19, already specifies that bassinet, changing table, or similar accessories must comply with the applicable requirements of ASTM standards addressing those accessories. Because the main product is the play yard, not the particular accessories, and suppliers were already required to

DRAFT

comply with the bassinet standard for bassinet-type accessories, this rule should not have a significant impact on any of the suppliers of flat rigid-sided play yard accessories, with the possible exception of a few “napper” products from small importers. Those importers should be able to find a new compliant supplier relatively easily, or relabel the items as not for sleep.

(c) Baby Tents

Baby tents cannot meet any of CPSC’s sleep standards, due to the physical form of these products, which includes slanted flexible sides connected to the floor, sometimes with hanging cords and anchoring spikes. Therefore, relabeling these products as not for infant sleep or removing the products from the market are the only compliance options. We assume that most suppliers will choose to remarket their items as not for sleep or for older children, and that this will not reduce sales, because the advertised primary purpose of the product is shade and insect screen. Also, most suppliers in this product sector are importers with many other unrelated products or foreign direct shippers. CPSC believes it unlikely most of the suppliers in this category will experience a significant economic impact as a result of this rule. One small importer does not appear to have any other products that might be significantly impacted if they cannot find a compliant supplier.

F. Summary of Costs and the Economic Impact of the Final Rule

Suppliers that choose to stay in the market for infant sleep products will need to comply with the final rule, or another CPSC sleep standard, and certify compliance through third party testing. Suppliers that choose to relabel their products as bouncer seats or swings will need to meet the standards for those products. Suppliers that relabel their products for use by children over 5 months will still need to meet general testing and certification requirements required for all children’s products, such as testing for lead content and phthalates, as well as small parts, but they were already required to meet those requirements.

DRAFT

Based on costs for compliance with other ASTM and CPSC standards for durable nursery products, the expected cost to comply with third party testing will be about \$1,500 per model tested, including the costs of the samples to be tested. This is for compliance with the specific standard for infant sleep products only; the costs for complying with general requirements for children's products should not be new costs for any suppliers. Some of the companies that are small by SBA standards have up to a dozen models of different products impacted by this rule, each of which will have to be tested for compliance with this standard. This would suggest testing costs of about \$18,000 per testing cycle.

The suppliers of low, soft-sided products and hammocks are unlikely to be able to redesign their products to meet any of the sleep standards, so they will need to decide whether to exit the market or relabel their products for use by older children. The impact is likely to be significant for suppliers of these products if these products constitute a substantial portion of their product line, and they choose to exit the market rather than remarketing the items for older children or pets.

Some manufacturers and importers, both large and small, may be able to minimize the impact of this rule by marketing their products as not for infant sleep, thus effectively putting their products out of scope of this rule. This may involve conspicuously labeling and marketing their items as not for sleep by children under 5 months. Some flat sleep surface rigid-sided products could demonstrate compliance with this standard and the bassinet standard with the addition of a stand or other rigid support. Some non-compliant items might be remarketed for pet use, which has apparently happened with some former children's products, but the market for such products is probably limited. Remarketing these products could still result in significant impact of suppliers if such relabeling results in a substantial reduction in product demand.

DRAFT

While some items can be credibly remarketed as not for infant sleep, such as items that resemble chairs or swings, the design of other items suggest they are intended for infant sleep, including hammock crib accessories, baby boxes, and in-bed sleepers, as are most compact bassinets and anything marketed as a “bed”. Some of these products could be marketed for children over 5 months, depending on the size of the product, but many are too small for a larger child. Suppliers of products where the design and function of the product communicates to the consumer that the product is intended for infant sleep may experience a significant economic impact if those products are a substantial portion of their product line.

Most home-based manufacturers will have the choice of either remarketing their products as not for infant sleep or stopping the sale of the products. The cost of redesigning the product to comply with the standard could be a significant portion of revenue for home-based manufacturers, and redesign might not even be possible for some products commonly sold by home-based manufacturers, such as baby hammocks and low, soft-sided flat products. Additionally, even if redesign were possible, the testing costs alone could be sufficient to induce these home-based manufacturers to withdraw from the market for these products. The economic impact of the rule on these home-based manufacturers is likely to be significant. In some cases, these manufacturers might be able to relabel their products for older children, or for pet use. In the case of hammocks, the items could also be marketed for toy storage. However, the demand for infant sleep products for these types of alternative uses is likely to be limited.

We discussed earlier the impacts for specific types of sleeper markets. In summary, the suppliers of inclined sleepers can redesign their items to meet this standard, remove them from the market, relabel them for use by older children, or remarket them as some type of chair. Some inclined items have already been remarketed as types of chairs or chair/swing combination products. The impact would depend on the demand for these products as chairs; the current

DRAFT

remarketing suggests that companies have found there is indeed demand for these products as chairs. Suppliers of inclined play yard accessories have similar options; it appears that most play yard suppliers have chosen to remove these items from the market and replace them with flat sleep surface accessories instead. Because play yards were already required to comply with the bassinet standard if in bassinet mode, this may not be a significant impact. Suppliers of compact rigid-sided and rigid-framed products without a stand may be able to redesign their products to meet this standard, or remarket them for use by older children. The size of some of these products would be appropriate for use by older children. Some suppliers of soft-sided “travel” and “compact” bassinets are unlikely to be able to redesign their products to comply with this standard, but may be able to remarket them for use by older children. Similarly, suppliers of in-bed sleepers and baby hammocks are unlikely to be able to redesign their products to comply with this rule, but some may be able to remarket them for use by older children or pets, depending on the size of the products, although demand for those uses may be limited.

In general, suppliers of products with limited remarketing options, where the size of the product is not conducive to use by older children, the low, soft sides cannot easily be redesigned to meet this standard, and the physical configuration of the product limits uses other than sleep, are likely to be significantly impacted. Some suppliers may be able to remarket their infant sleep products for alternative uses. However, this market is probably limited; otherwise, some of these suppliers would already have been producing products for these alternative uses. At least nine small domestic companies and twelve small importers are likely to be significantly impacted because products in scope of this rule represent most or a substantial portion of their product line. Hundreds of home-based manufacturers based in the U.S. supply baby nests, baby pods, in-bed sleepers, hammocks, and crib hammocks are likely to be significantly impacted, although some may be able to relabel their items as not for sleep or for older children. If the products

DRAFT

cannot be remarketed, many of these home-based manufacturers may eliminate infant sleep products from their product lines; it also possible that a significant proportion may go out of business.

In summary, taking all of these factors into account, the final rule is likely to have a significant economic impact on a substantial number of small entities.

G. Other Potential Impacts of the Final Rule

The final rule would make it illegal to sell, offer for sale, manufacture for sale, distribute in commerce, or import into the United States products not compliant with the rule 12 months after the publication of the rule in the *Federal Register*. This means that parents and other caregivers would not be able to purchase these items. The large volume of these products sold or home-made reflect that these products all address a demand for a compact sleep space for babies, so it is reasonable to assume that demand will continue for new or redesigned products that meet one of CPSC's sleep standards. As discussed earlier, products that are compliant with the current CPSC sleep standards are already widely available, provide compact sleep spaces, and are in the same general price range as the items covered by this rule.

Several public commenters suggested that this rule would cause caregivers to resort to less safe sleep solutions, such as putting infants to sleep in car seats, or using pillows to position infants on adult beds. Caregivers may already make home-made sleep places or mis-use other types of products, and CPSC is unaware of data to support the assertion that this rule would further encourage such practices. Directions for making home-made baby nests were widely available on the Internet before CPSC published the 2017 NPR. The DNPES, which was done in 2014, found that a majority of parents were using products for sleep that are not marketed for

DRAFT

sleep, such as swings, bouncer seats, and hand-held carriers at least once a week.⁴⁶ In addition, many inclined products have already been removed from the market or relabeled as not for sleep since publication of the 2017 NPR. While some of the inclined products may be remarketed as not for infant sleep, the final rule will provide parents and other caregivers clearer information as to the manufacturer's intended safe use.

The effective date is a "sold by" date. This means that retailers will need to sell or otherwise dispose of their stock by that date. Given that this rule has been in progress for several years through a notice and comment rulemaking, and that many of the inclined products have already been withdrawn from the market, this should not have a significant impact on small retailers.

This rule would require all infant sleep products not in the scope of other CPSC sleep standards to comply with this rule. This means that new products would have to comply with this rule, or one of the other sleep standards. Suppliers may introduce new products that comply with any of those standards, such as an innovative bassinet design that meets all the requirements of the bassinet standard. They may also work with ASTM to revise one of the ASTM sleep standards to cover their new product, and then CPSC could consider such revision as part of CPSC's procedures for accepting revisions to voluntary standards that are the basis for CPSC mandatory standards. Suppliers of innovative products may also work with ASTM to develop a separate, new sleep standard, then seek to have CPSC codify the new ASTM standard as a mandatory infant sleep standard under section 104 of the CPSIA.

⁴⁶ The DNPES reported that in households with children under 6, children slept in bouncer seats at least once a week in 70% of households that owned a bouncer seat, slept in swings at least once a week in 91% of households with a swing, and slept in hand-held carriers at least once a week in 87% of households with hand-held carriers.

DRAFT

H. Efforts to Minimize the Impact on Small Entities (Alternatives)

CPSC has attempted to minimize the impact of the final rule on small entities by defining the scope of this rule to only include infant sleep products that are:

- not within the scope of another standard;
- marketed or intended for infant sleep, including napping; and
- marketed or intended for use by children up to 5 months old.

These requirements provide small businesses the opportunity to remove their products from the scope of this standard by marketing them as not intended for sleep, or only intended for use by older children, or for pets. Companies can also redesign their products to meet the requirements of another standard, such as infant bouncer seats or hand-held carriers. In some cases where there is another use for the product, the only change required to make a product subject to one of these other standards is to relabel or remarket the product, removing any references to its use for sleeping.

CPSC also published an SNPR in 2019, which means firms have been aware of this rulemaking effort and have had several years to prepare for implementation of the final rule. Many companies that had inclined products that were in the scope of the 2017 NPR have removed those products from the market since 2019, or remarketed them as loungers, bouncer seats, or other products not for sleep.

While the Commission has exempted small batch manufacturers from the testing requirements proposed under other rules, under Section 14(d)(4)(C)(ii) of the CPSA, the Commission cannot “provide any alternative requirements or exemption” from third party testing for “durable infant or toddler products,” as defined in section 104(f) of the CPSIA. Consequently, staff cannot recommend a small batch exemption for small baby nest and hammock home-based manufacturers absent a statutory change.

DRAFT

The ASTM F3118 committee considered wording that would allow manufacturers to choose whether to comply with F3118 *or* another ASTM sleep standard, to allow innovative products to enter the market more easily. This final rule requires suppliers to comply with this rule or one of CPSC mandatory standards for full-size cribs, non-full-size cribs, bassinets and cradles, play yards, or bedside sleepers. The approach considered by ASTM to allow suppliers to choose other ASTM sleep product standards would allow suppliers to sell products that did not meet an existing CPSC sleep standard, such as a drop side crib, so long as that product had a sleep surface incline of less than 10 degrees and otherwise complied with ASTM F3118. Staff did not recommend this approach, which would effectively allow potentially unsafe, non-compliant sleep products to re-enter the market.

Finally, the IRFA discussed allowing a later effective date. A later effective date would reduce the economic impact on firms in two ways. Firms would be less likely to experience a lapse in production/importation, which could result if they are unable to comply and third-party test within the required timeframe. Also, firms could spread costs over a longer time period, thereby reducing their annual costs, as well as the present value of their total costs. CPSC received comments both supporting and opposing a later effective date. Given that many of the products have already been removed from the market or otherwise remarketed to be out of scope of this rule, reducing the impact on domestic small businesses, and that companies already had notice that this final rule was in progress since November 2019, the Commission will maintain a 12-month effective date, as proposed in the 2019 SNPR.

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

DRAFT

environment,” and therefore, they 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 final rule for infant sleep products falls within the categorical exemption.

XV. Paperwork Reduction Act

The final rule contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA; 44 U.S.C. 3501–3521). Under 44 U.S.C. 3507(a)(1)(D), an agency must publish the following information:

- 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.

The preamble to the 2019 SNPR (84 FR 60959-61) discussed the information collection burden of the supplemental proposed rule and specifically requested comments on the accuracy of our estimates. The OMB assigned control number 3041-0177 for this information collection. We did not receive any comment regarding the information collection burden of the proposal in the 2019 SNPR. For the final rule, CPSC adjusts the number of small home-based manufacturers from 6 to 1200, and the number of other suppliers from 13 to 125. In accordance with PRA requirements, the Commission provides the following information:

DRAFT

Title: Safety Standard for Infant Sleep Products

Description: The final rule defines an “infant sleep product” as a product marketed or intended to provide a sleeping accommodation for an infant up to 5 months of age, and that is not already subject to one of the mandatory CPSC sleep standards: full-size cribs, non-full-size cribs, play yards, bassinets, cradles, or bed-side sleepers. The infant sleep products covered by this rule include inclined and flat sleep products, such as inclined sleepers, play yard infant sleep accessories, baby nests and pods, in-bed sleepers, baby hammocks, compact or travel bassinets without a stand or legs, and baby tents. This final rule for infant sleep products incorporates by reference the voluntary standard for infant inclined sleep products issued by ASTM International, ASTM F3118-17a, *Standard Consumer Safety Specification for Infant Inclined Sleep Products*, with modifications to further reduce the risk of injury associated with infant sleep products. The final rule sets a safety floor for all infant sleep products sold in the United States, by requiring infant sleep products to have a seat back/sleep surface angle of 10 degrees or less from horizontal, and to meet the requirements of 16 CFR part 1218, Safety Standard for Bassinets and Cradles, including conforming to the definition of a bassinet/cradle. Part 1218 incorporates by reference the performance and labeling requirements of ASTM F2194-16e1. Sections 8 and 9 of ASTM F2194-16e1 contain requirements for marking, labeling, and instructional literature. These requirements fall within the definition of “collection of information,” as defined in 44 U.S.C. 3502(3).

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

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

DRAFT

Table 6 – 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	1200	1	1200	7	8400
	Other Suppliers	125	2	250	1	250
Labeling Total						8,650
Instructional literature	Home-based manufacturers	1200	1	1200	50	60,000
TOTAL BURDEN						68,650

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 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 1200 entities x 1 models per entity = 8400 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 necessarily labels that are compliant with the requirements of ASTM F2194, as

DRAFT

specified in 16 CFR part 1218, 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 2 models of infant sleep products; therefore, the estimated burden associated with labels for this second group is 1 hours per model x 125 entities x 2 models per entity = 250 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 (8400 burden hours) + non-home-based manufacturers and importers (250 burden hours) = 8,650 burden hours. We estimate the hourly compensation for the time required to create and update labels is \$33.71 (U.S. Bureau of Labor Statistics, “Employer Costs for Employee Compensation,” December 2020, Supplementary table 1, total compensation for all sales and office workers in goods-producing private industries: <https://www.bls.gov/web/ecec/ecsuptc.pdf>). Therefore, the estimated annual cost to industry associated with the labeling requirements is \$291,591.50 (\$33.71 per hour x 8,650 hours = \$291,591.50). No operating, maintenance, or capital costs are associated with the collection.

ASTM F2194 (section 9) requires instructions to be supplied with the product. As already noted, the proposed Safety Standard for Infant Sleep Products requires infant 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.”

DRAFT

We are unaware of infant sleep products that generally require use instructions but lack such instructions. However, it is possible that the 1200 home-based manufacturers of infant hammocks, baby nests, and in-bed sleepers 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, baby nests, or in-bed sleepers might require 50 hours to develop an instruction manual to accompany their products. These firms typically supply only one infant sleep product model. Therefore, the costs of designing an instruction manual for these firms could be as high as \$2,022,600 (50 hours per model x 1 model per entity x 1200 entities = \$2,022,600). However, this cost estimate may overestimate the annual cost to industry because many home-based firms might not pay average U.S. domestic wage rates. 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 instruction manuals 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 final rule for infant sleep products would impose a burden to industry of 68,650 hours at a cost of \$2,314,191.50 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 final rule to the OMB.

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

DRAFT

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 deems rules issued under that provision “consumer product safety standards.” Therefore, once this final rule for infant sleep products issued under section 104 of the CPSIA takes effect, the rule will preempt in accordance with section 26(a) of the CPSA.

XVII. Congressional Review Act

The Congressional Review Act (CRA; 5 U.S.C. §§ 801-808) states that, before a rule may take effect, the agency issuing the rule must submit the rule, and certain related information, to each House of Congress and the Comptroller General. 5 U.S.C. § 801(a)(1). The submission must indicate whether the rule is a “major rule.” The CRA states that the Office of Information and Regulatory Affairs (“OIRA”) determines whether a rule qualifies as a “major rule.” Pursuant to the CRA, OIRA designated this rule as not a “major rule,” as defined in 5 U.S.C. § 804(2). A “major rule” is one that the Administrator of OIRA finds has resulted in, or is likely to result in: (A) an annual effect on the economy of \$100,000,000 or more; (B) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (C) a significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. 5 U.S.C. § 804(2). To comply with the CRA, CPSC will submit the required information to each House of Congress and the Comptroller General.

DRAFT

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 amends Title 16 of the Code of Federal Regulations as follows:

PART 1112—REQUIREMENTS PERTAINING TO THIRD PARTY CONFORMITY ASSESSMENT BODIES

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

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

2. Amend § 1112.15 by adding paragraph (b)(46) to read as follows:

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

* * * * *

(b) * * *

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

* * * * *

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

DRAFT

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

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

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

§ 1130.2 Definitions.

* * * * *

(a) * * *

(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 inclined and flat sleep surfaces, that applies to all products marketed or intended to provide a sleeping accommodation for an infant up to 5 months of age, and that are not already subject to any of the following standards:

- 16 CFR part 1218 Safety Standard for Bassinets and Cradles
- 16 CFR part 1219 Safety Standard for Full-Size Baby Cribs
- 16 CFR part 1220 Safety Standard for Non-Full-Size Baby Cribs

DRAFT

- 16 CFR part 1221 Safety Standard for Play Yards
- 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 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 Barr Harbor Drive, PO Box C700, West Conshohocken, PA 19428-2959; phone: (610) 832-9585; www.astm.org. A read-only copy of the standard is available for viewing on the ASTM website at <https://www.astm.org/READINGLIBRARY/>. You may inspect a copy at the Division of the Secretariat, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone (301) 504-7479, email: cpsc-os@cpsc.gov, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email fedreg.legal@nara.gov, or go to: www.archives.gov/federal-register/cfr/ibr-locations.html.

(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

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

In response to incident data compiled by CPSC, this consumer safety specification attempts to minimize the following: (1) fall hazards, (2) asphyxiation and suffocation, and (3)

DRAFT

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 reduce deaths associated with known infant sleep hazards, including, but not limited to, a seat back or sleep surface angle that is greater than 10 degrees from the horizontal.

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 infant sleep products, including inclined and flat sleep surfaces, marketed or intended to provide a sleeping accommodation for an infant up to 5 months old, and that are not already subject to any of the following standards:

(A) 16 CFR part 1218 - Safety Standard for Bassinets and Cradles, incorporating by reference ASTM F2194, Standard Consumer Safety Specification for Bassinets and Cradles;

(B) 16 CFR part 1219 - Safety Standard for Full-Size Baby Cribs, incorporating by reference ASTM F1169, Standard Consumer Safety Specification for Full-Size Baby Cribs;

(C) 16 CFR part 1220 - Safety Standard for Non-Full-Size Baby Cribs, incorporating by

DRAFT

reference applicable requirements in ASTM F406, Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards;

(D) 16 CFR part 1221 - Safety Standard for Play Yards, incorporating by reference applicable requirements in ASTM F406, Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards;

(E) 16 CFR part 1222 - Safety Standard for Bedside Sleepers, incorporating by reference ASTM F2906, Standard Consumer Safety Specification for Bedside Sleepers.

(ii) 1.3.1 If the infant sleep product can be converted into a product for which a CPSC regulation exists, the product shall meet the applicable requirements of the CPSC regulation, when in that use mode. If the infant sleep product can be converted into a product for which no CPSC regulation exists, but another ASTM consumer safety specification exists, the product shall meet the applicable requirements of the ASTM consumer safety specification, when in that use mode.

(iii) 1.3.2 Crib mattresses that meet the requirements of ASTM F2933 are not covered by the specifications of this standard.

(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.⁴⁷

- F406 Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards

⁴⁷ For referenced ASTM standard, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For Annual Book of ASTM Standards volume information, refer to the standard’s Document Summary page on the ASTM website.

DRAFT

- F1169 Standard Consumer Safety Specification for Full-Size Baby Cribs
- F2194 Standard Consumer Safety Specification for Bassinets and Cradles
- F2906 Standard Consumer Safety Specification for Bedside Sleepers
- F2933 Standard Consumer Safety Specification for Crib Mattresses

(iii) 2.2 Federal Standards.⁴⁸

- 16 CFR 1218 - Safety Standard for Bassinets and Cradles
- 16 CFR 1219 - Safety Standard for Full-Size Baby Cribs
- 16 CFR 1220 - Safety Standard for Non-Full-Size Baby Cribs
- 16 CFR 1221 - Safety Standard for Play Yards
- 16 CFR 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) Do not comply with sections 3.1.1 through 3.1.6 of ASTM F3118-17a.

(9) 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 product marketed or intended to provide a sleeping accommodation for an infant up to 5 months of age, and that is not subject to any of the following:

- 16 CFR part 1218 – Safety Standard for Bassinets and Cradles
- 16 CFR part 1219 – Safety Standard for Full-Size Baby Cribs
- 16 CFR part 1220 – Safety Standard for Non-Full-Size Baby Cribs
- 16 CFR part 1221– Safety Standard for Play Yards

⁴⁸ 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>.

DRAFT

- 16 CFR part 1222 – Safety Standard for Bedside Sleepers

(ii) [Reserved]

(10) Do not comply with sections 3.1.7.1 through 3.1.13 of ASTM F3118-17a.

(11) Do not comply with section 3.1.15 through 3.1.16 of ASTM F3118-17a.

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

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

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

following:

(i) *6.9 Maximum Seat Back/Sleep Surface Angle:*

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

(iii) Do not comply with 6.9.2.

(iv) *6.9.3 Infant Sleep Products*—shall meet, 16 CFR part 1218, Safety Standard for Bassinets and Cradles, including conforming to the definition of a “bassinet/cradle.”

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

(16) Do not comply with section 7.11.1.3 of ASTM F3118-17a.

(17) In section 7.11.2 of ASTM F3118-17a, replace “*Infant Inclined Sleep Product and Infant Inclined Sleep Product Accessory*” with “*Infant Sleep Products.*”

(18) Instead of complying with section 7.11.2.1 and 7.11.2.2 of ASTM F3118-17a, comply with the following:

(i) 7.11.2.1 If applicable, place the product in the manufacturer’s recommended highest seat back/sleep surface angle position intended for sleep.

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(ii) 7.11.2.2 Place the hinged weight gage–infant in the product and position the gage with the hinge centered over the seat bight line and the upper plate of the gage on the seat back/sleep surface. Place a digital protractor on the upper torso/head area lengthwise.

(19) Do not comply with sections 7.11.3 through 9, or the Appendix, of ASTM F3118-17a.

(20) Add section 10.2 to ASTM F3118-17a:

(i) 10.2 infant sleep product

(ii) Reserved.

Dated: _____

Alberta E. Mills,
Secretary, Consumer Product Safety Commission



Staff Briefing Package

**Draft Final Rule for Infant Sleep Products under the
Danny Keysar Child Product Safety Notification Act**

May 12, 2021

Table of Contents

Briefing Memorandum	3
I. EXECUTIVE SUMMARY	4
II. BACKGROUND	5
III. DISCUSSION.....	16
IV. NOTICE OF REQUIREMENTS.....	24
V. RECOMMENDED EFFECTIVE DATE	25
VI. STAFF RECOMMENDATIONS	25
TAB A: Staff Responses to Comments on 2017 NPR and 2019 SNPR for Infant Sleep Products ..	29
TAB B: Epidemiological Data on Infant Sleep Product-Related Deaths, Injuries, and Potential Injuries	62
TAB C: Directorate for Engineering Sciences’ Assessment of Infant Sleep Products: Standards, Regulations, and Hazards for the Draft Final Rule Under the Danny Keysar Product Safety Notification Act	74
TAB D: Human Factors Assessment of Infant Sleep Products (CPSIA Section 104).....	112
TAB E: Final Regulatory Flexibility Analysis of the Staff-Recommended Draft Final Rule for Infant Sleep Products and the Accreditation Requirements for Conformity Assessment Bodies for Testing Conformance to the Infant Sleep Products Standard and the Product Registration Rule	118
TAB F: Infant Sleep Products: Summary of Recalls–August 2019 through January 2021	142

Briefing Memorandum



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

This document has been electronically
approved and signed.

Memorandum

DATE: May 12, 2021

TO: The Commission
Alberta E. Mills, Secretary

THROUGH: Jennifer Sultan, Acting General Counsel
Mary T. Boyle, Executive Director
DeWane Ray, Deputy Executive Director for Safety Operations

FROM: Duane E. Boniface, Assistant Executive Director
Office of Hazard Identification and Reduction

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

SUBJECT: Draft Final Rule for Infant Sleep Products

I. EXECUTIVE SUMMARY

On April 7, 2017, the Consumer Product Safety Commission (CPSC) published a notice of proposed rulemaking for Infant Inclined Sleep Products (82 *Fed. Reg.* 16,963) (2017 NPR)¹ under section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), Danny Keysar Child Product Safety Notification Act. On November 12, 2019, the Commission issued a supplemental proposed rule (84 *Fed. Reg.* 60,949) (Supplemental NPR or 2019 SNPR) to adopt the current voluntary standard, ASTM F3118-17a, *Standard Consumer Safety Specification for Infant Inclined Sleep Products* (ASTM F3118-17a), with modifications to make the mandatory standard more stringent than the voluntary standard, to further reduce the risk of injury associated with these products. For the mandatory standard, the Supplemental NPR proposed to modify ASTM F3118-17a to: (1) expand the scope of the standard to include all infant sleep products, including inclined and non-inclined (flat) products, that are not already covered by one of five existing CPSC infant sleep standards, (2) modify the title, introduction, scope, and definitions to remove the word “inclined,” (3) remove existing performance and labeling requirements and associated test methods that were specific for inclined products, (4) limit the seat back angle for sleep to 10 degrees or less, and (5) require all infant sleep products to meet the requirements of the bassinet and cradle standard, 16 CFR part 1218, Safety Standard for Bassinets and Cradles, which incorporates

¹ On June 12, 2019, CPSC staff submitted a briefing package to the Commission, recommending that the Commission terminate the 2017 NPR, stating that CPSC staff received reports of 42 additional fatalities that involved rocker-like inclined sleep products, and detailing Commission safety alerts and recalls. To date, the Commission has not voted on the package.

by reference ASTM F2194-13, Standard Consumer Safety Specification for Bassinets and Cradles, with modifications.

This briefing package reviews the relevant incident data, including updated data, reviews and responds to comments, and examines and assesses the effectiveness of ASTM F3118-17a (*infant inclined sleep products*) and ASTM F2194-16ε1 (*bassinets/cradles*).² In addition, the briefing package discusses the potential impact the draft final rule may have on small businesses, reviews recent recalls associated with infant sleep products, and provides the basis for staff's recommendations to the Commission. Based on the staff's review of inclined and flat sleep product incident data, and consideration of the comments on the 2017 NPR and the 2019 SNPR, staff recommends finalizing the requirements as proposed in the 2019 SNPR, with the following clarifications in the:

1. scope of the mandatory standard in 16 CFR § 1236.1, to avoid confusion about the scope of the rule, which includes inclined and flat products, the final rule removes the examples of infant inclined sleep products, and aligns the scope of the rule to be consistent with the definition of "infant sleep product";
2. introduction of the standard, to explain better that both inclined and flat sleep products fall within the definition of an "infant sleep product," and that the purpose of the rule is to reduce deaths associated with known infant sleep hazards, including, but not limited to, seat back or sleep surface angles that are greater than 10 degrees from the horizontal;
3. scope of the voluntary standard, to explain better that products subject to the rule are infant sleep products that do not already meet one of CPSC's sleep standards;
4. scope of the standard, to exempt crib mattresses that meet the voluntary standard for crib mattresses, ASTM F2933, because a crib mattress is not used by itself, and instead, is used as the sleep surface in a crib, a product that already must conform to a CPSC sleep standard;
5. referenced documents in the standard, to add the voluntary standard for crib mattresses, ASTM F2933;
6. definition of "infant sleep product" in the standard, to remove the phrases "freestanding" and "generally supported by a stationary or rocker base" from the definition, to not inadvertently exclude certain infant sleep products from the scope of the rule, such as those that may not initially have a base, or may be sold as an attachment to another product, and to clarify that the definition includes products that are marketed or intended to provide sleeping accommodations for an infant up to 5 months old;
7. definitions section of the standard, to remove the definitions for "accessory inclined sleep product," "compact inclined sleep product," and "newborn inclined sleep product," to simplify the regulation text, because these definitions are unnecessary based on the other modifications made to ASTM F3118-17a in the 2019 SNPR and the final rule, and because these products are subsumed within the definition of an "infant sleep product," and the final rule does not contain any unique requirements for these products;

² As explained in this briefing package, the most recent voluntary standard for bassinets, ASTM F2194-16ε1, is substantially similar to the mandatory standard for bassinets and cradles, part 1218, and staff analyzes ASTM F2194-16ε1 to simplify the analysis.

8. requirement for the “Maximum Seat Back Angle” in the standard, to state that the seat back angle also refers to a “sleep surface angle,” to reduce confusion, because flat sleep surfaces do not have a seat back; and
9. requirement to satisfy 16 CFR part 1218, Safety Standard for Bassinets and Cradles, including conforming to the definition of a bassinet/cradle, to reduce confusion and to clarify that infant sleep products must have a stand to meet the performance and labeling requirements in part 1218.

CPSC staff recommends that the Commission issue a mandatory standard for infant sleep products that includes all products marketed or intended to provide sleeping accommodations for an infant up to 5 months old and that are not within the scope of another CPSC sleep standard (bassinets/ cradles, cribs (full-size and non-full size), play yards, or bedside sleepers). Staff also recommends that the draft final rule incorporate by reference the voluntary standard, ASTM F3118-17a, *Standard Consumer Safety Specification for Infant Inclined Sleep Products*, with substantial modifications to the introduction, scope, performance, and testing requirements. The modifications would require that infant sleep products that do not already meet the requirements of a CPSC sleep standard, must be (1) tested, by measuring the seat back/sleep surface angle, to confirm that the seat back/sleep surface angles is 10 degrees or less from horizontal, and (2) meet the requirements of 16 CFR part 1218, Safety Standard for Bassinets and Cradles. The draft final rule would require all infant sleep products (including inclined and flat) that do not meet a CPSC sleep safety standard to meet the requirements of this standard.

Staff also recommends amending part 1112 to include infant sleep products in the list of children’s product safety rules for which the CPSC has issued Notice of Requirements (NORs). Moreover, because infant sleep products were not specifically mentioned as a durable infant or toddler product in CPSIA section 104(f)(2), staff also recommends amending 16 CFR part 1130 to identify infant sleep products specifically as a subcategory of bassinets and cradles.

II. BACKGROUND

A. 2019 SNPR

In the 2019 SNPR, the Commission proposed to issue a standard for infant sleep products, meaning products that (1) provide sleeping accommodations for infants, and (2) are not currently covered by one of the five CPSC mandatory standards for infant sleep: bassinets/cradles, cribs (full-size and non-full-size), play yards, and bedside sleepers (collectively CPSC sleep standards). Specifically, the 2019 SNPR proposed to incorporate by reference ASTM F 3118-17a, with modifications that include requiring that: (1) the seat back angle intended for sleep must be equal to or less than 10 degrees, 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 proposed to amend the consumer registration rule to identify “infant sleep products” as a category of durable infant or toddler products under section 104(f) of the CPSIA. Finally, the Commission proposed to amend its regulation at 16 CFR part 1112 to add infant sleep products to the list of products that require third party testing.

While developing the mandatory standard for bassinets/cradles, cribs (full-size and non-full-size), play yards, and bedside sleepers, staff and ASTM subcommittee members and participants,

reviewed numerous fatal and nonfatal incidents to identify the hazards associated with infant sleep and established performance and labeling requirements to address the hazards. Currently, inclined and smaller, portable, flat, infant sleep products do not meet any of the mandatory CPSC sleep standards, nor do the portable, flat, infant sleep products fall within any voluntary standard. Thus, these products may not provide the safety features established for regulated infant sleep products. Therefore, to address the risk of injury to infants from these, as-of-yet unregulated infant sleep products, consistent with the 2019 SNPR, the draft final rule requires that all infant sleep products marketed or intended for infants up to 5 months old that do not already meet a CPSC sleep standard are measured to confirm the seat back/sleep surface angle is 10 degrees or less from the horizontal, and, at a minimum, meet the requirements of the bassinet standard.³ The draft final rule assures consumers that the infant sleep products they purchase are subject to the minimum safe sleep requirements of the bassinet standard, and have been tested to this mandatory safety standard.

B. Response to 2019 SNPR Comments

In this briefing package, staff's responses to comments address comments received for the 2017 NPR and the 2019 SNPR. As discussed above, the 2017 NPR proposed to incorporate by reference the then-current voluntary standard for infant inclined sleep products, ASTM F3118-17, with a modification to the standard's definition of "accessory." Subsequently, staff identified additional fatalities associated with rocker-like inclined sleep products, and the Commission issued safety alerts and recalls involving infant inclined sleep products. Rather than publish a final rule, on November 12, 2019, the Commission published the 2019 SNPR, incorporating by reference the current voluntary standard for infant inclined sleep products (ASTM F3118-17a), with modifications to make the standard more stringent, to further reduce the risk of injury. Notably, the 2019 SNPR revised the scope of the rule to include all unregulated infant sleep products, including inclined products and non-inclined (flat) products. The 2019 SNPR invited the public to submit written comments during a 75-day comment period, beginning on the 2019 SNPR publication date, and ending on January 27, 2020. In response to a request for an extension of the comment period, the Commission extended the comment period by 30 days, closing on February 26, 2020.

Tab A consolidates staff's responses to comments on the 2017 NPR and the 2019 SNPR. In response to the 2017 NPR, the Commission received seven comments. In response to the 2019 SNPR, the Commission received 56 comments. In addition, on February 2, 2021, JPMA sent a letter to the Acting Chairman and Commissioners following up on a previously submitted comment.

The 2017 NPR and the 2019 SNPR both received comments that expressed support and disagreement with the proposals. Staff grouped the comments and responses into the following categories:

- Safety of Inclined Products

³ Although ASTM F2194 requires a sleep surface of 10 degrees or less, the standard does not contain a test to measure the sleep surface. Accordingly, the draft final rule will finalize the proposal in the 2019 SNPR to include a test to measure the sleep surface to confirm it is 10 degrees or less from the horizontal.

- Definition of Infant Sleep Products
- Comments Superseded by 2019 SNPR
- Scope of the Draft Final Rule
- Incident Data
- Degree of Incline
- Safe Sleep Principles
- Definitions
- Warnings & Instructions
- Economic Analysis
- Effective Date
- Procedural Comments

Generally, commenters expressed concerns about the scope of the final rule and the data supporting including in the final rule unregulated, flat, infant sleep products. Based on staff's review and evaluation of the comments received and staff's responses (see Tabs A-E), and as discussed in sections III.A and III.B of this memorandum, staff recommends for the draft final rule the following clarifications in the:

1. scope of the mandatory standard in 16 CFR § 1236.1, to avoid confusion about the scope of the rule, which includes inclined and flat products, the draft final rule removes the examples of infant inclined sleep products, and aligns the scope of the rule to be consistent with the definition of "infant sleep product";
2. introduction of the standard, to explain better that both inclined and flat sleep products fall within the definition of an "infant sleep product," and that the purpose of the rule is to reduce deaths associated with known infant sleep hazards, including, but not limited to, seat back or sleep surface angles that are greater than 10 degrees from the horizontal;
3. scope of the standard, to explain better that products subject to the rule are infant sleep products that do not already meet one of CPSC's sleep standards;
4. scope of the standard, to exempt crib mattresses that meet the voluntary standard for crib mattresses, ASTM F2933, because a crib mattress is not used by itself, and instead, is used as the sleep surface in a crib, a product that already must conform to a CPSC sleep standard;
5. referenced documents in the standard, to add the voluntary standard for crib mattresses, ASTM F2933;
6. definition of "infant sleep product" in the standard, to remove the phrases "freestanding" and "generally supported by a stationary or rocker base" from the definition, to not inadvertently exclude certain infant sleep products from the scope of the rule, such as those that may not initially have a base, or may be sold as an attachment to another product, and to clarify that the definition includes products that are marketed or intended to provide sleeping accommodations for an infant up to 5 months old;
7. definitions section of the standard, to remove the definitions for "accessory inclined sleep product," "compact inclined sleep product," and "newborn inclined sleep product," to simplify the regulation text, because these definitions are unnecessary based on the other modifications made to ASTM F3118-17a in the 2019 SNPR and the draft final rule, and because these products are subsumed within the definition of an "infant sleep product," and the draft final rule does not contain any unique requirements for these products;

8. requirement for the “Maximum Sleep Back Angle” in the standard, to state that the seat back angle also refers to a “sleep surface angle,” to reduce confusion, because flat sleep surfaces do not have a seat back; and
9. requirement to satisfy 16 CFR part 1218, Safety Standard for Bassinets and Cradles, including conforming to the definition of a bassinet/cradle, to reduce confusion and to clarify that infant sleep products must have a stand to meet the performance and labeling requirements in part 1218.

As set forth in section V of this memorandum, staff recommends maintaining the proposed 12-month effective date for the draft final rule.

C. Requirements for CPSIA Section 104 Rules

Section 104 of the CPSIA requires CPSC to: (1) consult with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts to examine and assess voluntary safety standards for durable infant or toddler products, and (2) promulgate mandatory consumer product safety standards that are substantially the same as the voluntary standards or more stringent than the voluntary standards, if the Commission determines that more stringent standards would further reduce the risk of injury associated with these products. Section 104(f) of the CPSIA defines a “durable infant or toddler product” as “a durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years”

To meet the consultation requirement, CPSC staff participates regularly in the juvenile products subcommittee meetings of ASTM International (ASTM). Staff’s participation in the voluntary standards process includes providing incident data, participating in meetings to assess the ability of a voluntary standard to address the incident data, and working through the ASTM process to develop performance and labeling requirements to address identified hazards. Staff also comments or votes on certain ASTM ballots to revise voluntary standards. ASTM subcommittees consist of members who represent producers, users, consumers, government, and academia.⁴

The consultation process for the inclined sleep product rulemaking commenced in approximately 2012, when ASTM began developing a new voluntary standard to address hammocks and inclined sleep products. Staff has been actively participating in the development of a new standard for inclined products since then. In addition, staff began working with ASTM on bassinets before 2011, and continues, to this day, to participate in task group and subcommittee meetings, including meetings and ASTM ballots involving the unregulated flat infant sleep products within the scope of the draft final rule. Staff also provided data to ASTM regarding in-bed sleepers in 2017, and has been part of the task group working to develop a new voluntary standard for in-bed sleepers since June 2019.

D. ASTM Voluntary Standard Overview

⁴ ASTM International website: www.astm.org, About ASTM International.

ASTM F3118, *Standard Consumer Safety Specification for Infant Inclined Sleep Products*, is the voluntary standard developed to address the identified hazard patterns associated with the use of infant inclined sleep products. The current standard, ASTM F3118-17a, was approved on September 1, 2017, and published in October 2017. This is the fourth revision since ASTM first published the standard in May 2015. ASTM F3118-17a describes “infant inclined sleep products as:

3.1.3 *infant inclined sleep product, n*—a freestanding product, intended to provide a sleeping accommodations for an infant up to approximately 5 months of age, that is generally supported by a stationary or rocker base with one or more inclined sleep surface positions for the seat back that are greater than 10° and do not exceed 30° from the horizontal.

CPSC issued an NPR in 2017, proposing to incorporate by reference the then-current voluntary standard, ASTM F3118-17, with a modification to the definition of an “accessory inclined sleep product.” Subsequently, based on emerging reports of infant deaths in inclined sleep products, 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 staff’s 2019 SNPR briefing package contains Dr. Mannen’s study, *Biomechanical Analysis of Inclined Sleep* (Mannen Study). CPSC issued the 2019 SNPR, based in part on the Mannen Study findings, proposing to incorporate by reference ASTM F3118-17a, with modifications to the title, introduction, scope, and requirements in the standard to remove hazardous inclines from infant sleep products, and to ensure that all products sold for infant sleep for infants up to 5 months old would be subject to minimum safe sleep requirements by meeting the mandatory requirements in a CPSC sleep standard. At the request of CPSC staff, based on the Mannen Study on infants’ behaviors in inclined sleep products, and in response to the 2019 SNPR, the ASTM F15.18 subcommittee for infant inclined sleep products agreed to reevaluate the standard. The subcommittee established task groups to determine the title, introduction, scope, and performance requirements to address best-practice features for infant sleep products in ASTM F3118.

The ASTM subcommittee for infant inclined sleep has tried to revise the voluntary standard to be more consistent with the modifications proposed in the 2019 SNPR, the Commission proposed to remove the term “inclined” to expand the term “infant sleep products,” and to require that all sleep products that are not subject to a CPSC sleep standard, irrespective of the degree of incline in such products, to meet the safe sleep requirements in the new mandatory standard for infant sleep products. For example, in December 2020, the subcommittee balloted⁵ the name change to remove the word “inclined” from the title and to change the scope to include all infant sleep products (and not just inclined infant sleep products) not currently covered by another infant sleep standard. ASTM’s ballot received negative comments regarding the scope part of the balloted item, so the ballot did not pass.

The ASTM subcommittee has not yet approved or published a new version of F3118. Therefore, staff recommends that the draft final rule incorporate by reference ASTM F3118-17a, with substantial modifications as proposed in the 2019 SNPR to make the standard more

⁵ ASTM Ballot F15.18 (20-01) issued 12/15/2020, closed 01/15/2021.

stringent, to further reduce the risk of injury associated with products intended for infant sleep that do not already meet a mandatory CPSC sleep standards:

- 16 CFR part 1218 - Safety Standard for Bassinets and Cradles
- 16 CFR part 1219 - Safety Standard for Full-Size Baby Cribs
- 16 CFR part 1220 - Safety Standard for Non-Full-Size Baby Cribs
- 16 CFR part 1221 - Safety Standard for Play Yards, or
- 16 CFR part 1222 - Safety Standard for Bedside Sleepers.

E. Definition of “infant sleep product”

The scope of the draft final rule includes all infant sleep products. An “infant sleep product,” as defined in ASTM F3118-17a and this draft final rule, has three key components:

- The product is intended for infants up to 5 months old.
- The product must be marketed or intended to provide infant sleeping accommodations. CPSC staff considers any items marketed for “napping,” “snoozing,” “dreaming,” or any other word that implies sleeping, or that are called a “bed,” and items marketed with a picture of a sleeping infant, to be an infant sleep product.
- The product is not within the scope of any other CPSC infant sleep standard. Additionally, a “crib mattress” alone, as defined in ASTM F2933-19, is not an infant sleep product.

Infant sleep products that fall within the scope of an existing CPSC sleep standard would not be required to meet the draft final rule; those products must follow the CPSC infant sleep standard that is applicable to that product. If a product meets the definition of an “infant sleep product” in the draft final rule, by definition, it would not be covered by another CPSC sleep standard. Consistent with the 2019 SNPR, the draft final rule requires that all infant sleep products’ sleep surface, in all positions, must be 10 degrees or less from horizontal. The infant sleep products within the scope of the draft final rule include a variety of inclined sleep products that do not fall within the scope of an existing CPSC sleep standard, such as: frame-type sleep products, inclined accessories to play yards, compact foam inclined “nappers,” and hammocks. Additionally, consistent with the 2019 SNPR, the draft final rule also covers several types of flat sleep surface products that do not have inclined sleep surfaces and are also not covered by an existing CPSC sleep product standard, including: baby boxes, in-bed sleepers, baby nests and pods, rigid-sided and rigid-framed compact bassinets without a stand or legs, various designs of “travel bassinets” with soft padded or mesh sides, and baby tents.

Throughout this briefing package, the term “infant inclined sleep products” describes the current voluntary standard and current products on the market that are associated with the voluntary standard. Staff uses the term “infant sleep products” to describe products within the scope of the draft final rule, because the draft final rule limits sleep product seat back/sleep surface angles to 10 degrees or less from horizontal, thus eliminating the need for the word “inclined” to describe the products. In addition, the draft final rule includes currently unregulated infant sleep products that have a sleep surface angle of 10 degrees or less. Tab C

of this briefing package contains a description of the types of products that fall within the scope of the draft final rule.

F. Juvenile Products Manufacturers Association Certification⁶

The Juvenile Products Manufacturers Association (JPMA) has a certification program for various juvenile products, including infant inclined sleep products. To obtain JPMA certification, manufacturers submit their products to an independent test laboratory for conformance testing to the most current ASTM voluntary standard. Currently, two manufacturers supply JPMA-certified infant inclined sleep products. CPSC staff notes that a lack of participation in the JPMA certification program does not mean that the products are not compliant with, or tested to, the ASTM standard. ASTM F3118-17a is currently in effect for testing purposes under the JPMA certification program. Typically, a 6-month period exists between the time an ASTM standard is published and the time JPMA adopts the standard for use in manufacturer testing to receive JPMA certification. The unregulated flat infant sleep products subject to the draft final rule have not yet been added to the voluntary standard for bassinets and cradles, ASTM F2194. Moreover, because of recalls of inclined sleep products (see Tab F), most of these products should no longer be available on the market as infant sleep products.

G. Incident Data

The memorandum from the Directorate for Epidemiology staff (Tab B) discusses two sets of data collections conducted for the draft final rule. The first set involves 71 new incident reports associated with inclined sleep products since the 2019 SNPR. In the 2019 SNPR, staff identified 451 incidents, of which 59 were fatal and 392 were nonfatal. Of the 71 new reported incidents, 10 are fatalities; among the remaining 61 nonfatal incidents, 17 reported an injury. In response to comments requesting supporting data for including unregulated flat infant sleep products in the draft final rule, staff provides and evaluates a second data set. The second data set involves 183 incident reports related to unregulated flat products marketed as an infant sleep product that are currently not within the scope of any CPSC sleep standard, including incidents associated with in-bed sleepers, baskets (that can function as hand-held carriers as well), baby boxes, compact bassinets most of which are portable for travel, and baby tents (collectively referred to as unregulated flat infant sleep products).

The following discusses the fatalities, nonfatalities, and hazard patterns for each data set.

⁶ Certification JPMA. Juvenile Product Manufacturers Association. (n.d.). Retrieved on April 29, 2016, from: <http://jpma.org/content/certification/overview>.

Inclined Sleep Products

1. Fatalities

Since the 2019 SNPR, 10 fatalities associated with the use of an inclined sleep product reportedly occurred during the period from January 1, 2019 through December 31, 2020; this only includes data reported since the 2019 SNPR.

- Three of the 10 fatal reports describe infants placed supine (on their back) in a rocker-like sleeper product, but who ended up rolling over, fully or partially, resulting in suffocations or positional asphyxiations. Staff does not know whether a restraint was used in any of these cases. All three decedents were 3- or 4-month-old infants.
- One report describes a fatality involving a foam-type reclined infant seat. The seat was placed on an adult bed where the parents were also asleep. The seat was found tipped over on the floor with the 4-month-old decedent underneath the seat.
- One incident reports a fatality of a 3-month-old infant, found supine in an infant rocker-like product (in the same position as originally placed) with a blanket covering the infant's face.
- Five remaining fatality 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. Of the known ages, the decedents ranged in age from 1 to 6 months.

2. Nonfatal Incidents

Since the 2019 SNPR, CPSC staff has received reports of 61 nonfatal incidents associated with the use of an infant inclined sleep product that occurred between January 1, 2019 and December 31, 2020. Among them, 17 reports involved an injury. The severity of the 17 injuries is described below:

- Four infants required hospital admission. Three of the hospitalizations were for respiratory problems due to mold on the sleep product, and one was for treatment of injuries from a fall when an accessory-type product collapsed.
- Three infants were treated and released from emergency departments. Those infants were treated for respiratory problems from exposure to mold or for fall injuries.
- Ten infants required other medical care, mostly for *plagiocephaly* (flat head syndrome), *torticollis* (twisted neck syndrome), or both conditions, which were associated with prolonged use of inclined sleep products; two of the 10 infants suffered minor bumps/bruises due to falls or near falls.

The remaining 44 incidents reported no injuries or provided no information about any injury. However, many of the descriptions indicated the potential for a serious injury, or even death. Thirty-four percent of the incidents involved infants 0 to 5 months of age, and 9 percent involved infants 6 months to 12 months of age. The age was unknown in 58 percent of the incidents.

Unregulated Flat Sleep Products

1. Fatalities

Staff identified 11 fatalities, associated with the use of unregulated flat sleep products, meaning those flat products marketed for infant sleep that are not currently within the scope of an existing CPSC sleep standard or a voluntary standard, reported to have occurred during the time period from January 1, 2019 through December 31, 2020.

- Seven of the 11 fatality reports describe a suffocation death:
 - A 1-month-old was found partially rolled over onto their side in a soft-sided compact bassinet/travel bed.
 - A 2-month-old infant was found completely rolled over the edge of an in-bed sleeper.
 - A 2-month-old was placed in an in-bed sleeper, in a prone position, stomach down, with his face turned to one side; he was discovered with part of his body outside the sleeper, face down on a blanket.
 - A 2-month-old infant was placed in a compact bassinet/travel bed placed on top of an adult bed, with one side of the compact bassinet/travel bed leaning against the wall. According to the official report, the combination of the travel bed's non-reinforced flexible bottom, along with the soft surface of the adult bed, allowed the infant to sink; he was found trapped between the bed and the wall.
 - A 3-month-old, in a hand-held basket that was placed on an adult bed, was found completely rolled over from her original supine position.
 - A 4-month-old was placed on his back in an in-bed sleeper that was placed inside a standard bassinet; the infant was discovered in a prone position.
 - A 7-month-old was wrapped in a blanket and placed supine in an in-bed sleeper. The infant was found rolled over in a prone position.
- A 1-month-old was placed in an in-bed sleeper inside a play yard. The official reports describe the decedent to have either suffocated on the puffy sides of the sleeper or to have been entrapped somehow and suffered positional asphyxia.
- A 7-month-old was placed in an in-bed sleeper for a nap; according to official reports, at some point, the infant got to the edge of the adult bed and became entrapped between the footboard and the mattress of the adult bed and died of positional asphyxia.
- Official reports deemed the cause and manner of death for two additional fatalities as undetermined. Both decedents were 1-month-olds, one placed in a basket, while the other was in an in-bed sleeper.

2. Nonfatalities

From among the 172 nonfatal reports, CPSC staff identified 16 injury reports associated with the use of unregulated flat infant sleep products that occurred between January 1, 2019 and December 31, 2020. The severity of the injury type among the 16 injuries is detailed below:

- Two infants required hospital admissions. An 8-day-old infant suffered unspecified breathing difficulties; another 2-month-old infant fell out of an in-bed sleeper and

suffered head injuries when a sibling jumped onto the couch where the in-bed sleeper was situated.

- Ten infants, ranging in age from 1 month to 9 months, required emergency department (ED) visits after falling out of the sleeper product. For most cases, the sequence of events leading to each fall was unreported; in two cases, the infant fell while being transported in the sleeper; and in another case, the sleeper itself slipped off the adult bed on which it was placed. The injuries included various head injuries, such as a skull fracture, closed head injury, and head contusion, or other injuries, such as face abrasion and knee contusion.
- Four other injury incidents reported an allergic reaction; a mold-related breathing difficulty episode; laceration of the nose on the rough mesh wall surface on the sleeper; and a fall when a sibling pulled the sleeper, which caused it to flip over. One of these infants needed repeated visits to a medical professional, but the levels of care received by the other infants is unspecified.

The remaining 156 incidents reported no injuries or provided no information about any injury. However, many of the descriptions were similar to incidents in which a serious injury or death occurred. Therefore, staff indicated the potential for a serious injury or even death. Forty-nine percent of the incidents involved infants 0 to 5 months of age, and 4 percent involved infants 6 to 12 months of age. The age was unknown in 37 percent of the incidents.

H. Hazard Pattern Characterization Based on Incident Data

This section summarizes the hazard pattern characterizations based on the incident data. The discussion is presented in two sections following the incident data sets discussed above.

Infant Inclined Sleep Products

In the 2019 SNPR, CPSC staff identified eight hazard patterns among 451 reported incidents. The staff-identified hazard categories were: *Design Issues, Electrical Issues, Consumer Comments, Undetermined Issues (due to confounding information), Structural Integrity Issues, Other Product-Related Issues, Infant Placement Issues, and Insufficient Information*. Although the data distribution in this update varies somewhat from the 2019 SNPR, staff finds that the broader hazard categories are very similar to the hazard categories identified in the 2019 SNPR.

Below staff presents the hazard patterns identified among the 71 new reported incidents (10 fatal and 61 nonfatal) associated with the use of infant inclined sleep products since the 2019 SNPR. Staff presents hazard categories in descending order of frequency:

1. **Consumer comments:** Thirty-one of the 71 reported incidents (44 percent) fall in this category. The reports consist of consumer comments/observations of perceived safety hazards, complaints about the sale of recalled infant inclined sleep products, or inquiries regarding the April 2019 safety recall of inclined sleep products. Although one complaint describes a minor injury incident, none of the remaining reports indicate that an incident actually occurred.

2. **Design** of the infant inclined sleep product: Twenty-four of the 71 reported incidents (34 percent) fall in this category:
 - a. Ten incidents report that infants rolled over—fully or partially—from their original supine position. Although a few of the infants were strapped into the product, the use of restraint is unreported for others. Reports describe infants as young as 1 month of age rolling over. Parents/caregivers, who witnessed and reported some of the nonfatal incidents were able to rescue distressed infants quickly; other infants died due to suffocation or asphyxiation.
 - b. One infant stopped breathing temporarily due to difficulty in positioning his head correctly.
 - c. Eight incidents reported that infants developed physical deformations, such as *plagiocephaly* (flat head syndrome) and/or *torticollis* (twisted neck syndrome), from extended product use.
 - d. Five incidents reported that infants developed respiratory ailments due to the growth of mold on the product.

The design category includes three deaths, three hospitalizations, one ED visit, and eight non-hospitalized/non-ED injuries.

3. **Other product-related** issues: Four of the 71 incidents (6 percent) report other product-related issues, such as instability (posed by products that have completely or nearly flipped over) or a lock/latch problem (*i.e.*, the sleep surface failed to remain in position during use). One of the three instability incidents was a fatality that occurred when a foam-type reclined seat tipped over and fell from the adult bed to the floor, trapping the decedent underneath. No injury is reported in this category.
4. Lack of **structural integrity**: Three of the 71 incidents (4 percent) report components breaking, such as the rail, hardware, or other unspecified part. This category includes one hospitalization and one non-ED-treated injury due to a fall.
5. **Electrical** issue: One of the 71 incidents (1 percent) reports describes an odor emanated after a short period of use indicative of overheating; further investigation revealed molten plastic inside. No injury is reported.
6. **Non-product-related** issues: One of the 71 incidents (1 percent) reports a fatality in an unsafe sleep environment. A 3-month-old infant was placed supine in an infant rocker-like product with a blanket covering the face; the infant was found in the same position, with the blanket still covering the infant's face.
7. **Insufficient information**: Seven of the 71 incident reports (10 percent) contain insufficient information for staff to categorize them accurately. Staff has no information on the circumstances of the five deaths in this category. Reports for two injuries in this category describe unspecified falls treated in hospital EDs, with no information on restraint usage.

Unregulated Flat Infant Sleep Products

Similar to the infant inclined sleep products, the hazard patterns reported for unregulated flat infant sleep products varied according to the type and usage pattern of the product. Below staff presents the hazard patterns identified among the 183 reported incidents (11 fatal and 172 nonfatal) associated with the use of these sleep products in descending order of frequency:

- A. ***Lock/Latch*** problems: 115 of the 183 reports (63 percent) fall in this category. All but one of these reports pertain to different models of a particular stand-alone compact bassinet. The locking/latching mechanism that controls the opening/closing of the cover on the product failed. Some reports describe that the inability of the cover to open completely results in the product not lying flat. The single report about a different product describes a foldable sleeper not remaining flat; the unit reportedly folds up while the baby is in it. None of the reports mentions any injuries.
- B. ***Comments/Concerns***: 29 of the 183 reports (16 percent) expressed consumers' or safety advocates' concerns about the perceived safety hazard of a product, noncompliance with the relevant standard(s) that a product is being labeled as, and/or misleading marketing statements about a product. None of the reports indicate that an incident actually occurred.
- C. ***Falls/Containment*** issues: 12 of the 183 incidents (7 percent) report an infant falling out of the product or an infant not being kept contained within the product. Examples include infants rolling out of a sleeper onto an adult bed and then onto floor; an infant falling out of a sleeper when sibling jumped onto the couch containing the sleeper; an infant crawling/rolling (unwitnessed) out of a sleeper and getting entrapped between an adult bed frame and mattress. This category includes one death, one hospital admission, and nine ED visits.
- D. ***Instability*** issues: 12 of the 183 reported incidents (7 percent) describe problems with the product not remaining stable. The incident reports describe some products with legs lifting up higher or leaning on one side; other products have slipped off or flipped over from the adult beds/couches they were resting on. Two injuries are reported in this category, one involved an ED visit.
- E. ***Asphyxiation/Suffocation hazard***: Nine of the 183 incidents (5 percent) fall into this category. The products were compact bassinets/travel beds, baskets, and in-bed sleepers, one of which was being used inside a standard bassinet and another, inside a play yard. All but one of the infants had rolled over from their initial position—either fully or partially; positional information is not available for one infant. Eight of the incidents were fatalities due to suffocation or positional asphyxia; one was a near-suffocation episode, with a parent nearby to rescue the infant.

- F. *Miscellaneous product-related* issues: Three of the 183 incident reports (2 percent) are about mold or quality of the product material. Two of the three products were in-bed sleepers, while the third was a compact bassinet/travel bed. All three reported an injury.
- G. *Undetermined* issues: In three of the 183 incident reports (2 percent), staff could not definitively identify the issue involved. Two of the incidents were fatalities; in both cases, the CPSC Field investigation reports indicated that the cause of death is undetermined. The third incident resulted in a hospitalization due to unspecified breathing difficulties suffered by the infant.

III. DISCUSSION

Infant sleep products are part of a multi-million-dollar industry. These products are marketed to new parents with claims of helping infants and parents sleep, including products that may not meet a mandatory CPSC sleep standard or an industry voluntary standard. Products marketed for “napping,” “snoozing,” or marketed with a picture of a sleeping infant may not meet or fall within the scope of an existing voluntary or mandatory standard that specifically addresses infant sleep hazards. For example, Moses baskets are JPMA-certified to the hand-held infant carrier standard. However, they are not certified to the bassinet standard. Therefore, consumers may not be aware whether the products they use meet an infant sleep voluntary or mandatory standard.

A. *Products Covered by the Draft Final Rule*

The draft final rule, as proposed in the 2019 SNPR, covers two categories of infant sleep products that are not covered by any of the five CPSC sleep standards. The first category is infant inclined sleep products that have seat back/sleep surface angles greater than 10 degrees from horizontal. The Mannen Study recommends that infant sleep products have a sleep surface of 10 degrees or less from horizontal. Numerous commenters to the 2019 SNPR, such as the American Academy of Pediatrics (AAP), consumer groups, and individual parents, agree with this recommendation and indicate support for the 2019 SNPR, and in turn, the draft final rule, because the products covered in the draft rule will support the AAP safe sleep guidelines. Thus, in the draft final rule, by recommending removal of the word “inclined” from the title, scope, and introduction of the mandatory standard, staff is ensuring that infant sleep products are flat, meaning they have a seat back/sleep surface angle of 10 degrees or less from horizontal.

Additionally, consistent with the 2019 SNPR, staff recommends that the scope of the draft final rule include all products (inclined and flat) marketed or intended for infant sleep for infants up to 5 months old that are not currently covered by a CPSC sleep standard. Unregulated flat infant sleep products that would fall within the scope of the rule include products such as: in-bed sleepers, infant nests/pods, baby boxes, compact/travel bassinets, and baby tents. Tab C, Directorate for Engineering Sciences, Division of Mechanical and Combustion (ESMC), describes the current CPSC sleep standards for cribs (full-size and non-full-size), bassinets/cradles, bedside sleepers, and play yards, evaluates international standards

for infant sleep, and provides explanation and analysis of the requirements necessary to reduce the risk of injury associated with infant sleep products.

Staff also evaluates the voluntary standards for ASTM F3118 (*infant inclined sleep products*) and ASTM F2194 (*bassinets*) in relation to the infant inclined sleep products and the unregulated flat infant sleep products identified in the incident data and in the Directorate for Economics (EC) market research (Tab D). Staff's detailed evaluation of unregulated infant sleep products demonstrates that small, portable, and compact/travel size products pose known unsafe sleep hazards for a vulnerable population of young infants. Many of the identified hazard patterns for infant sleep products are similar to hazard patterns previously identified and currently addressed by the bassinet standard, part 1218. Staff concludes that the requirements in part 1218, as set forth in ASTM F2194-16e1, are adequate to address the risk of injury associated with infant sleep products within the scope of the rule, and represent minimum safe sleep requirements for infant sleep products. Therefore, staff recommends that for the draft final rule, infant sleep products must meet the bassinet standard.

During some of the ASTM infant inclined sleep products task group and subcommittee meetings, members have raised concern that this rule, as proposed in the 2019 SNPR, will discourage innovation for new products. Staff contends that the intent of this rule is to create a broad standard that assures consumers that a marketed infant sleep product, both current and future, meets established safe sleep criteria. These are performance and labeling requirements that allow for innovation with certain baseline safety requirements. Although staff understands the concerns that innovation beyond the baseline safety requirements may be discouraged, staff points to the development of infant inclined sleep products as a prime example of innovation preceding safety. Infant inclined sleep products were first marketed as an innovative sleep solution for parents. However, no safety standard existed for these products. Commenters to the 2010 NPR and 2012 SNPR for the bassinet standard indicated that hammocks and inclined sleep products should have their own standard because they could not meet the requirements for bassinets, and parents were likely to create their own "unsafe" alternative, if a regulated product is not available. Accordingly, CPSC and ASTM agreed that inclined sleep products should have their own voluntary standard. The ASTM standard development process for inclined products took many years before the standard was first published in 2015 and during that time manufacturers were designing and selling innovative inclined products. However, as time went on, the hazards posed by these products became apparent. To avoid a repeat of this process involving the most vulnerable infants, those up to 5 months old, staff remains committed to developing an infant sleep standard that contains key elements of safe sleep, so that product innovation does not compromise the safety of the most vulnerable infants.

CPSC regulations set a safety floor for product development. In the case of infant sleep products, staff is relying on the performance and labeling requirements in the bassinets standard to protect the safety of vulnerable infants. The bassinet standard provides product designers with a set of parameters to address known hazards such as falls/containment issues, instability, asphyxiation/suffocation. The product can be designed in any way, provided the end product meets the performance and labeling requirements outlined in the standard. This allows for innovative products while ensuring products meet baseline safety requirements.

***B. Adequacy of the ASTM F3118 Requirements and ASTM F2194 Requirements
(See Tab C)***

Infant Inclined Sleep Product Hazard Patterns

Sleep surface angle (Design and Infant Placement)

The current voluntary standard for infant inclined sleep products, ASTM F3118-17a, states that an inclined sleep product has a seatback angle greater than 10 degrees and not exceeding 30 degrees. Based on the Mannen Study,⁷ staff concluded in the 2019 SNPR that ASTM F3118-17a does not adequately address the risk of injury related to a sleep surface incline greater than 10 degrees because it does not limit the sleep surface to a safe incline angle. In this briefing package, staff compares the inclined sleep surface in ASTM F3118 with the sleep surface requirements in the voluntary standard for bassinets, ASTM F2194-16e1.⁸ The bassinet standard defines a sleep surface as being less than or equal to 10 degrees, and includes performance requirements for mattress flatness that limits measured angles to 10 degrees or less. Thus, the sleep surface requirements in the bassinet standard are consistent with the findings in the Mannen Study, which states that a sleep surface of 10 degrees or less is safest for infant sleep. Therefore, with respect to sleep surfaces, staff concludes that all infant sleep products that do not already comply with an existing CPSC sleep standard, including infant inclined sleep products, should meet the more stringent sleep surface angle requirement of the voluntary standard for bassinets, ASTM F2194-16e1, to further reduce the risk of death from suffocation.

Tip Over and Containment

Deaths and injuries associated with unregulated infant sleep products relate to the stability of the product and how easy it is to tip over the product into a hazardous situation. The current voluntary standard for infant inclined sleep products, ASTM F3118-17a, includes two stability performance requirements that apply to compact inclined sleep products and infant or newborn inclined sleep products. For compact inclined sleep products, the product must remain upright when placed on a 20-degree inclined test platform. For the infant or newborn inclined sleep products, a 23-pound vertical force and 5-pound horizontal force, respectively, are applied to the product's side (occupied with a newborn CAMI dummy) to simulate an older sibling pulling on the side to view the infant in the bassinet, and the product must remain upright containing the CAMI dummy. The compact inclined sleep products are exempt from the 23-pound and 5-pound force requirements, because the compact products are intended to sit on a floor and are unlikely to have an older sibling attempt to pull up to see the infant inside.

⁷ Read the full report from Dr. Mannen beginning on page 91 of CPSC staff's Commission Briefing Package https://cpsc.gov/s3fs-public/SupplementalNoticeofProposedRulemakingforInfantSleepProducts_10_16_2019.pdf

⁸ CPSC's mandatory regulation for bassinets and cradles, 16 CFR part 1218, incorporates by reference ASTM F2194-13, with modifications. ASTM F2194-16e1 is the most recent ASTM standard for bassinets and cradles.

The current voluntary standard for bassinets, ASTM F2194-16 ϵ 1⁹ includes an identical stability requirement that applies a 23-pound vertical force and a 5-pound horizontal force to the product with a newborn CAMI dummy occupant and this requirement applies to all products; it does not provide exemptions for compact inclined sleep products to meet only the less stringent 20-degree inclined test platform test. The rationale in ASTM F2194 states that the dual application of forces simulates a 2-year-old male pulling on the side of the product. Staff concurs that sibling interaction is a reasonable scenario in which a product may tip over. Due to the portability of some of the unregulated compact sleep products, incident data confirm that the products are used on raised surfaces, from which infants and the product may fall. Therefore, with respect to the product's stability, staff concludes that all infant sleep products should meet the more stringent stability requirement in the voluntary standard for bassinets, ASTM F2194-16 ϵ 1, to further reduce the risk of injury from tip over of the product.

Structural Integrity

To address hazards associated with structural integrity, both the bassinet standard and the infant inclined sleep standard include a static load requirement. The static load requirement in the bassinet voluntary standard, ASTM F2194-16 ϵ 1, is 54 lbs., which is a more stringent load compared to the static load of 50 lbs. specified in the infant inclined sleep voluntary standard, ASTM F3118-17a. Therefore, to further reduce the risk of injury associated with structural defects, staff concludes that the static load test in ASTM F2194 is adequate to assess structural integrity of infant sleep products, and is more stringent than the static load test in ASTM F3118-17a. Therefore, for the draft final rule, staff recommends that all infant sleep products, including infant inclined sleep products, meet the more stringent structural integrity requirement of the voluntary standard for bassinets, ASTM F2194-16 ϵ 1.

Electrical

As noted in the 2019 SNPR, the infant inclined sleep products standard, ASTM F3118-17a, does not include any performance requirements for electrical components. In addition, the voluntary standard for bassinets, ASTM F2194-16 ϵ 1, does not address electrical hazards. However, staff raised this issue with ASTM, and the ASTM Ad Hoc Task Group is developing performance requirements to address electrical hazards across juvenile products. As these requirements are added during the ASTM voluntary standard updates, CPSC can review the updated voluntary standard pursuant to the update provision in Pub. L. No. 112-28 and determine whether to revise the mandatory standard based on a revised voluntary standard.

Unregulated Flat Infant Sleep Products Hazard Patterns

Lock/Latch

The purpose of the lock/latch requirement is to ensure that bassinets that can be removed from their stand are securely latched to the stand when in use. The Commission incorporated the

⁹ This version of the voluntary standard is substantially the same as part 1218. CPSC will update the reference in part 1218 as soon as feasible.

requirements of ASTM F2194-13 *Standard Consumer Safety Specification for Bassinets and Cradles*, with specific modifications to address unintentional detachment of bassinets that were designed to be removed from their stand (78 FR 63019). ASTM F2194-16ε1 has since incorporated these removable bassinet bed requirements. Therefore, staff concludes the ASTM F2194-16ε1 (bassinet) standard's requirement adequately simulates the action of a bassinet unintentionally unlatching from its stand. Staff also concludes the ASTM F2194-16ε1 (bassinet) standard's requirement is more stringent compared to the ASTM F3118-17a (infant inclined sleep products) standard, which lacks a requirement for products that can be removed from a stand. Therefore, for the draft final rule, staff recommends that all unregulated inclined and flat infant sleep products meet the ASTM F2194-16ε1 (bassinet) standard's "unintentional folding requirement" and the "Removable Bassinet Bed Attachment to Base/Stand requirement," if applicable, to address the risk of injury associated with locks and latching features on these products.

Falls/containment

ASTM F3118-17a requires a minimum side height of 3 inches for infant inclined sleep products and 2 inches for newborn products and allows the use of restraints to help contain the infant in the product. Typically, bassinets and other infant sleep products do not rely on restraints because restraints can create an entrapment and strangulation hazard. Restraints are unnecessary in flat sleep products with sufficient sidewall height. Accordingly, the ASTM F2194-16ε1 (bassinets) standard does not allow the use of restraints, and instead addresses hazards posed by a product failing to contain the occupant with a side height requirement, a passive safety feature. The requirement specifies that the product's interior side height with an uncompressed mattress shall be at least 7.5 inches. Tab C contains staff's evaluation of side height requirements for ASTM voluntary standards for infant sleep, as well as international standards for infant sleep. Based on the incident data, unregulated flat sleep products with no side height requirements pose a potential fall hazard. Based on the foregoing, staff concludes that ASTM F2194-16ε1 (*bassinet*) standard's 7.5-inch side height requirement is appropriate and would adequately address the falls/containment hazard in unregulated infant sleep products for infants up to 5 months old or who cannot sit up unassisted. Therefore, for the draft final rule, staff recommends that all unregulated, flat infant sleep products meet the side height requirement of the ASTM F2194-16ε1 (bassinet) standard to address fall/containment hazards.

Stability

ASTM F2194-16ε1 (*bassinets*) addresses hazards posed by the product's instability with a stability requirement. The requirement specifies that the product (with newborn CAMI dummy occupant) withstand a 23-pound vertical force and 5-pound horizontal force along its side, without tipping. The rationale in ASTM F2194 states that the dual application of forces simulates a 2-year-old male pulling on the side of the product. Staff concurs that a sibling pulling on the product is a reasonable scenario in which the product may tip over. Incident data also demonstrate that these compact infant sleep products are used on elevated surfaces, such as beds and couches, from which the infant and product fell. Therefore, for the draft final rule, with respect to the product's stability, staff recommends that all infant sleep products meet the stability requirement of the voluntary standard for bassinets, ASTM F2194-16ε1, to further

reduce the risk of injury from tip-over of the product.

Asphyxiation/Suffocation

The voluntary standard for bassinets, ASTM F2194-16 ϵ 1, addresses the asphyxiation/suffocation hazard with the following general/performance requirements:

- 5.10 Corner Posts,
- 6.1 Spacing of Rigid Sided Bassinet/Cradle Components,
- 6.2 Openings for Mesh/fabric Sided Bassinets/Cradle,
- 6.5.3 Pad Dimensions,
- 6.7 Bassinets with Segmented Mattress: Flatness Test,
- 6.8 Fabric Sided Enclosed Openings, and
- 6.9 Rock/Swing Angle.

In total, these requirements address known suffocation hazards with infant sleep and create a minimally safe sleep environment. Therefore, with respect to the asphyxiation/suffocation hazard, for the draft final rule, staff recommends that all infant sleep products meet general and performance requirements of the voluntary standard for bassinets, ASTM F2194-16 ϵ 1, to reduce the risk of death from suffocation.

Mold (Product-related issue)

None of the voluntary standards currently addresses conditions like mold, which manifests due to the conditions under which a product is used. A moisture-resistant requirement has been discussed in the ASTM task group for baby boxes (which is under the bassinet subcommittee), but the task group has not reached a consensus on appropriate performance requirements to address mold and moisture resistance. CPSC staff will continue to work with this task group.

Summary of Draft Final Rule changes from 2019 SNPR

The 2019 SNPR proposed the following modifications to ASTM F3118-17a:

1. expand the scope of the standard to include all infant sleep products, including inclined and non-inclined (flat) products that are not already covered by a CPSC infant sleep standards;
2. modify the title, introduction, scope, and definitions to remove the word “inclined”;
3. remove existing performance and labeling requirements and associated tests that were specific for inclined products;
4. limit the seat back angle for sleep to 10 degrees or less from horizontal; and
5. require all infant sleep products to meet the requirements of the bassinet and cradle standard, 16 CFR part 1218, Safety Standard for Bassinets and Cradles.

As a result of staff's reevaluation of the F3118 and F2194 standards, and in response to comments received on the 2019 SNPR, staff recommends finalizing the mandatory rule similar to the 2019 SNPR, with the following clarifications to the:

1. scope of the mandatory standard in 16 CFR § 1236.1, to avoid confusion about the scope of the rule, which includes inclined and flat products, the draft final rule removes the examples of infant inclined sleep products, and aligns the scope of the rule to be consistent with the definition of "infant sleep product";
2. introduction of the standard, to explain better that both inclined and flat sleep products fall within the definition of an "infant sleep product," and that the purpose of the rule is to reduce deaths associated with known infant sleep hazards, including, but not limited to, seat back or sleep surface angles that are greater than 10 degrees from the horizontal;
3. scope of the voluntary standard, to explain better that products subject to the rule are infant sleep products that do not already meet one of CPSC's sleep standards;
4. scope of the standard, to exempt crib mattresses that meet the voluntary standard for crib mattresses, ASTM F2933, because a crib mattress is not used by itself, and instead, is used as the sleep surface in a crib, a product that already must conform to a CPSC sleep standard;
5. referenced documents in the standard, to add the voluntary standard for crib mattresses, ASTM F2933;
6. definition of "infant sleep product" in the standard, to remove the phrases "freestanding" and "generally supported by a stationary or rocker base" from the definition, to not inadvertently exclude certain infant sleep products from the scope of the rule, such as those that may not initially have a base, or may be sold as an attachment to another product, and to clarify that the definition includes products that are marketed or intended to provide sleeping accommodations for an infant up to 5 months old;
7. definitions section of the standard, to remove the definitions for "accessory inclined sleep product," "compact inclined sleep product," and "newborn inclined sleep product," to simplify the regulation text, because these definitions are unnecessary based on the other modifications made to ASTM F3118-17a in the 2019 SNPR and the draft final rule, and because these products are subsumed within the definition of an "infant sleep product," and the draft final rule does not contain any unique requirements for these products;
8. requirement for the "Maximum Sleep Back Angle" in the standard, to state that the seat back angle also refers to a "sleep surface angle," to reduce confusion, because flat sleep surfaces do not have a seat back; and
9. requirement to satisfy 16 CFR part 1218, Safety Standard for Bassinets and Cradles, including conforming to the definition of a bassinet/cradle, to reduce confusion and to clarify that infant sleep products must have a stand to meet the performance and labeling requirements in part 1218.

C. Product Registration Rule Amendment

As proposed in the 2019 SNPR, staff recommends that the Commission amend the definition of "durable infant or toddler product" in the consumer registration rule to reduce any uncertainty about whether infant sleep products fall within the term "durable infant or toddler product," as used in the product registration card rule and section 104 of the CPSIA. Staff's

recommendation to require infant sleep products to meet the bassinets standard, but also keep infant sleep products as a separate standard, clarifies that products intended for infant sleep for infants under the age of 5 months must meet a CPSC sleep standard and comply with product registration card requirements. Specifically, staff recommends amending 16 CFR section 1130.2(a)(12) to read:

Bassinets and cradles, including bedside sleepers, and infant sleep products.

D. Potential Small Business Impact

At least 60 small, U.S.-based manufacturers and importers supply infant sleep products in this market. In addition, five large domestic companies, and dozens of foreign companies, some of which ship these items directly to customers in the United States via online marketplaces also supply these products. More than a thousand home-based manufacturers, of which hundreds are based in the United States, sell soft-sided baby nests, in-bed sleepers, and infant hammocks directly to consumers via online marketplaces and as third-party sellers via the websites of major retailers.

The majority of the suppliers to which this rule would apply are small by U.S. Small Business Administration (SBA) size standards. Some firms sell these items under multiple brand names and models, including small manufacturers that make “store brands” for larger companies. The number of suppliers selling infant sleep products is approximate because the proliferation of online retail makes it possible for importers to quickly change their product offerings based on demand for particular products. The large number of companies in the infant sleep products market covered by this rule reflects both a strong market demand for these products and a competitive market with relatively low margins. We estimate total sales in this market at more than \$125 million per year, to at least one-third of U.S. households with newborns. These products compete with infant sleep products that are compliant with one of the existing CPSC sleep standards and with other small, portable products that are not marketed for sleep.

Staff anticipates a significant economic impact for 12 small importers and nine small domestic manufacturers that supply infant sleep products to the U.S. market, as well as for hundreds of home-based small businesses. If the Commission approves and publishes this draft final rule, and the rule becomes effective, suppliers of infant sleep products covered by this rule must redesign existing products to comply with the standard and conduct third-party testing to demonstrate compliance, remarket the products as not intended for infant sleep, remarket the products for infants older than 5 months, or stop selling these products. The impact of these options will depend upon how much redesign the product requires, the amount of third party testing that will be required, and what portion of the company’s sales are infant sleep products. The impact of remarketing a product for a different use, such as for an older child, a pet, or not for sleep, may be possible in some cases, but this will depend on the extent to which consumers perceive the product to be suitable for the different use. For items whose physical design demonstrates intended use for sleep, particularly hammocks, compact bassinets, and in-bed sleepers, remarketing options are likely to be limited to use by older children, which in turn, will depend on whether the size is appropriate for that use.

Suppliers that choose to stay in the market for infant sleep products will need to comply with the standard and certify compliance through third party testing. For suppliers that choose to redesign their product to meet the standard, the cost of redesigning the product could be significant, as even a simple redesign could cost hundreds of thousands of dollars per model and require new third party testing. In addition, all of the product marketing and packaging may have to be revised. Compact bassinets and other hard-sided, flat sleep surface products without legs or a stand will require redesign to meet the stability, side height, and occupant containment requirements of this rule. Inclined sleep products will need to meet those requirements, and also be redesigned to reduce the incline to 10 degrees or less. Based on costs for compliance with other ASTM and CPSC standards for durable nursery products, the expected cost to comply with third party testing will be about \$1,500 per model tested, per testing cycle, including the cost of the samples to be tested. This is for compliance with the standard specifically for infant sleep products only; the costs for complying with general requirements for children's products should not be new costs for any suppliers. Some of the companies that are small by SBA standards have multiple models of products impacted by this rule. Some have up to a dozen models of infant sleep products, which could result in \$18,000 in testing costs, even if only one sample per model had to be tested. However, some of the former suppliers of inclined products have already remarketed their items as not for sleep, or redesigned them to meet other standards, particularly the standard for infant bouncer seats.

Suppliers of flat soft-sided products and hammocks likely will be impacted significantly by the draft final rule, if these products make up most of their product line, or if they sell multiple products covered by this rule. Significant impact could occur because compliance with any of the sleep product standards, particularly the stability, side height, and occupant containment requirements, would be difficult to meet for a product with low, soft sides, or a product that is a hammock. Suppliers of products that cannot be redesigned to meet the standard will need to decide whether to exit the market or to conspicuously relabel their products as not intended for infant sleep. The options to remarket these items as not intended for infant sleep are limited by the physical form of a product that is not well-suited to other non-sleep uses, but the items could be remarketed for older children or pets to sleep.

Suppliers of baby tents will need to remarket and relabel products as not intended for infant sleep, or remove them from the market, because it would be difficult to redesign a tent to meet the requirements of this standard. The impact should be minor for most suppliers, because sun shade, insect screen, and play, rather than sleep, are the main intended purposes of these items, and most suppliers are importers with a broad product line. A few small importers that have these items as their main or only product could be significantly impacted if they cannot find a supplier with packaging that conspicuously labels the item as not for infant sleep.

Like other suppliers, home-based manufacturers will have the choice to comply with the standard, remarket their products as not for infant sleep, remarket the products for infants older than 5 months, or stop selling the products. The cost of redesigning the product, and conducting the third party testing to comply with the standard, would be a significant portion of revenue, and redesign may not be possible for products commonly sold by home-based manufacturers, which are baby hammocks and flat sleep surface products with low, soft sides. The products could be remarketed for older children, or for pets, although the market demand for those uses is

unknown. The impact on these businesses could be significant if they choose to stop selling the products, depending on whether these products are most of their product line.

As described above, staff anticipates that the rule could have a significant economic impact on twelve small importers and nine small domestic manufacturers that supply infant sleep products to the U.S. market. Additionally, the rule is likely to have a significant economic impact on the many small home-based manufacturers. Many of these home-based manufacturers are likely to respond to the rule by eliminating infant sleep products from their product lines; it also is possible that a significant proportion may go out of business.

In summary, taking all of these factors into account, the draft final rule is likely to have a significant economic impact on a substantial number of small entities.

E. Compliance Recall Information

CPSC did not conduct any recalls for unregulated flat products from August 2019 through January 2021. Compliance staff reviewed recalls of infant inclined sleep products since the 2019 SNPR, and reports six additional consumer-level recalls. The recalls were conducted in response to potential suffocation hazards involving infant inclined sleep products that had an incline angle greater than 10 degrees. The recalls affected approximately 268,300 units.

IV. NOTICE OF REQUIREMENTS

Section 14(a) of the CPSA requires that any children's product subject to a consumer product safety rule under the CPSA must be certified as complying with all applicable CPSC-enforced requirements. The children's product certification must be based on testing conducted by a CPSC-accepted third party conformity assessment body (test laboratory). The CPSA requires the Commission to publish a notice of requirements (NOR) for the accreditation of third-party test laboratories to determine compliance with a children's product safety rule to which a children's product is subject. As discussed in the 2019 SNPR, the infant sleep products draft final rule is a children's product safety rule that requires issuing an NOR.

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

V. RECOMMENDED EFFECTIVE DATE

At the time of the 2019 SNPR, staff recommended an effective date of 12 months after publication of a final rule for products manufactured or imported on or after that date, to allow time for infant

sleep product manufacturers to bring their products into compliance with the final rule. Staff is recommending incorporating by reference ASTM F3118-17a, with substantial modifications to make the standard more stringent, to further reduce the risk of injury associated with infant sleep products.

In response to several comments and because of the gravity of the hazards associated with infant sleep products, the fact that many products have already been removed from the market, or otherwise remarketed to be out of scope of this rule, and because companies have already had more than one year notice of this rule (since November 2019), a 6-month effective date for the draft final rule would be reasonable.

However, the Final Regulatory Flexibility Analysis indicates that this draft final rule will have a significant economic impact on a substantial number of small entities. Therefore, those manufacturers will need more time to determine if they can remarket, redesign, or leave the market. Therefore, staff recommends staying with the 2019 SNPR recommendation of a 12-month effective date for the draft final rule.

VI. STAFF RECOMMENDATIONS

CPSC staff recommends that the Commission finalize a mandatory standard for infant sleep products that includes all products marketed or intended as a sleeping accommodation for infants up to 5 months old that are not within the scope of another CPSC sleep standard (bassinets and cradles, cribs (full-size and non-full size), play yards, or bedside sleepers). Staff recommends that the draft final rule incorporate by reference the voluntary standard, ASTM F3118-17a, *Standard Consumer Safety Specification for Infant Inclined Sleep Products*, with substantial modifications to the introduction, scope, performance, and testing requirements. The modifications would require that infant sleep products that do not already meet the requirements of a CPSC sleep standard, must be (1) tested, by measuring the seat back/sleep surface angle, to confirm that the seat back/sleep surface angles is 10 degrees or less from horizontal, and (2) meet the requirements of 16 CFR part 1218, Safety Standard for Bassinets and Cradles. The draft final rule would require all infant sleep products (including inclined and flat) that do not meet a CPSC sleep safety standard to meet the requirements of this standard.

Staff also recommends amending part 1112 to include infant sleep products in the list of children's product safety rules for which the CPSC has issued NORs. Moreover, because infant sleep products were not specifically mentioned as a durable infant or toddler product in section 104(f)(2), staff also recommends amending 16 CFR part 1130 to identify specifically infant sleep products as a subcategory of bassinets and cradles.

TAB A: Staff Responses to Comments on 2017 NPR and 2019 SNPR for Infant Sleep Products

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

Memorandum

Date: April 19, 2021

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

THROUGH: Mark E. Kumagai
Associate Executive Director
Directorate for Engineering Sciences

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

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

Robert L. Franklin
Senior Staff Coordinator
Directorate for Economic Analysis

FROM : Zachary S. Foster, Industrial Engineer,
Division of Human Factors,
Directorate for Engineering Sciences

Susannah S. Proper, Economist,
Directorate for Economic Analysis

Kevin K. Lee, Mechanical Engineer,
Division of Mechanical and Combustion Engineering,
Directorate for Engineering Sciences

SUBJECT : Staff Responses to Comments on 2017 NPR and 2019 SNPR for Infant Sleep Products Standard

In 2017, the Consumer Product Safety Commission (CPSC or Commission) published a notice of proposed rulemaking (2017 NPR) for infant inclined sleep products in the *Federal*

Register (82 *Fed. Reg.* 16,964, April 7, 2017). The 2017 NPR proposed to incorporate by reference the then-current voluntary standard for infant inclined sleep products, ASTM F3118-17, with a modification to the standard’s definition of “accessory.” Subsequent to the 2017 NPR, staff identified additional fatalities associated with rocker-like inclined sleep products, and the Commission issued safety alerts and recalls involving infant inclined sleep products. Rather than publish a final rule, on November 12, 2019, the Commission published a supplemental notice of proposed rulemaking (2019 SNPR) for infant sleep products in the *Federal Register* (84 *Fed. Reg.* 60,949). The 2019 SNPR incorporated by reference the current voluntary standard for infant inclined sleep products (ASTM F3118-17a), with modifications to make the standard more stringent, to further reduce the risk of injury. Notably, the 2019 SNPR revised the scope of the rule to include all unregulated infant sleep products, including inclined products and flat products. The 2019 SNPR invited the public to submit written comments during a 75-day comment period, beginning on the 2019 SNPR publication date, and ending on January 27, 2020. In response to a request for an extension of the comment period, the Commission extended the comment period by 30 days, closing February 26, 2020.

Below we consolidate staff’s response to comments on the 2017 NPR and the 2019 SNPR. In response to the 2017 NPR, the Commission received seven comments. In response to the 2019 SNPR, the Commission received 56 comments within the comment period. Numerous commenters on the 2019 SNPR, such as the American Academy of Pediatrics (AAP), consumer groups, and individual parents, supported the SNPR, because the products covered in the final rule will be required to follow the AAP safe sleep guidelines. In addition, staff also considered two late-filed documents, one received on February 2, 2021¹, and one received on April 30, 2021².

Below are staff’s responses to the comments. Staff organized the comments by rulemaking notice (2017 NPR or 2019 SNPR), and then by topic.

I. Comments on the 2017 Notice of Proposed Rulemaking

A. Safety of Inclined Products

Comment 1: Three commenters disagreed with the 2017 NPR, stating that infant sleep products with a 30-degree seat back angle are not safe and contradict the AAP’s safe sleep recommendations. One commenter also indicated that staff should:

- conduct more research on the 30-degree seat back angle;
- conduct more research on developmental implications when an infant is restrained while sleeping;
- provide performance requirements to address product misassembly;

¹ JPMA letter to the Acting Chairman and Commissioners following up on a previously submitted comment.

² On April 30, 2021, in an email to ASTM members and CPSC staff, AAP and consumer advocacy groups reiterated their position that in the development of ASTM voluntary standards, ASTM should ensure that all standards are consistent with the AAP’s evidence-based safe sleep recommendations. The email stated: “[o]ur organizations have observed that several subcommittees have continued to work on performance requirements and other provisions for standards that are inconsistent with expert safe sleep recommendations. If finalized, these standards could all too foreseeably contribute to increased risks of injury and death among infants.”

- make the side height requirement match the 7.5 side height requirement in the bassinets and cradles standard;
- develop performance or design changes for compact units so they cannot be placed on a raised surface, in crib, or on soft surface;
- add seat back height requirement for infant products like newborn products;
- add requirements for hammocks to increase stability;
- add requirements for flat sleep products, so an infant cannot move into an unsafe chin to chest position;
- add pictograms to warnings like slings and hand-held carriers;
- include “marking” on products to show compliance with new regulations;
- conduct market surveillance after a regulation becomes effective; and
- have a 6-month effective date for the final rule.

Staff Response 1: Staff agrees, based on the Mannen Study, that infant sleep products, as defined in the draft final rule, should not have a seat back/sleep surface angle greater than 10 degrees. Many of the other recommendations noted above were raised in the 2019 SNPR. The draft final rule addresses these comments by requiring unregulated inclined and flat sleep products marketed or intended for sleeping accommodations for infants up to 5 months old to meet the bassinet standard. Due to the significant economic impact on some manufacturers, staff continues to recommend the 12-month effective date.

B. Definition of “Infant Sleep Product”

Comment 2: A commenter stated that the language, “primarily intended and marketed to provide sleeping accommodations,” is not needed, and also stated that “incorporating a manufacturer’s marketing intentions into a definition of a product which impacts the safety standard of that product opens the door to potential conflicts of interests.” The commenter reasoned that a child’s age and the product incline are objective factors, while a manufacturer’s intent is more subjective, and could allow manufacturers to market the product in a way to avoid meeting the requirements of the rule.

Staff Response 2: Although the definition the commenter refers to in the standard no longer includes the term “inclined,” we respond here to the concept of including the phrase “marketed or intended” in the definition of “infant sleep product” in the draft final rule. A manufacturer’s intended use of the product and marketing guide informs caregivers about the product’s safe use. Manufacturers of products that are not designed or marketed for use as an infant sleep product should provide caregivers with instructions and warnings regarding safe use of the product. Including a manufacturer’s marketing and intent in the definition also assists the Commission to enforce the regulation, because it provides objective criteria for CPSC staff to apply to a product’s name, packaging, warnings, labeling, and marketing materials about whether the product falls within the scope of the rule. CPSC staff has experience using marketing materials to enforce CPSC’s regulations, and it is required to use such materials in some cases. For example, section 3 of the CPSA provides factors for determining whether a product is a “children’s product,” and includes several factors that require reviewing labeling, promotion, and advertising, to determine whether a product is “designed or intended primarily for children 12 years of age or younger.” 15 USC 2052(a)(2). Products that have no use other than infant sleep,

based on the product’s design, cannot be labelled as not intended for infant sleep to avoid meeting the requirements of the final rule.

C. Comments Superseded by the 2019 SNPR

Comment 3: Two commenters agreed with the modification of the “accessory” definition in the 2017 NPR, and with the 12-month effective date. One commenter had a specific comment related to restraint requirements in the NPR.

Staff Response 3: The 2019 SNPR supersedes the 2017 NPR. The proposed modification to the definition of “accessory” is no longer at issue in the draft final rule, because this definition has been removed, along with other requirements related to inclined infant sleep. Staff continues to support the 12-month effective date for the draft final rule. Finally, a restraint requirement in an infant sleep product was unique to inclined sleep products. Restraints can create hazards, and are therefore, not recommended in a flat sleep environment, as required in the draft final rule.

II. Comments on the 2019 Supplemental Notice of Proposed Rulemaking

A. Scope of the Draft Final Rule

1. All products marketed, promoted, or otherwise indicated for sleep

Comment 4: A commenter suggested: “[t]he new standard should apply not just to those infant products intended by the manufacturer for sleep or certified as being for sleep, but also any product that is marketed, promoted, or otherwise indicated—or may be reasonably interpreted as indicating—as being for any kind of sleep, including products described using substitute language for sleep, such as ‘nap’ or ‘snooze.’”

Several other commenters expressed concern that various terms used in the 2019 SNPR were vague and recommended that more precise definitions be provided for “sleep” and “sleeping accommodations.” In addition, clarification was requested regarding which products are included in the definitions.

Staff Response 4: Staff agrees with the commenters that the draft final rule should clarify what products are covered by the draft final rule, and various terminology should be defined more precisely. To clarify the scope of the rule, the draft final rule specifically identifies inclined and flat sleep products, and broadens the definition of an “infant sleep product” to include the term “marketed”: “a product *marketed* or intended to provide sleeping accommodations for an infant up to 5 months old that is not subject to any of the following standards . . .” (emphasis added). The definition then lists CPSC’s five infant sleep standards, to ensure that all infant products marketed or intended for infant sleep meet the requirements of a CPSC sleep standard, so that all products meet minimum safe sleep requirements. Staff modified the introduction, scope, and definitions in the draft final rule to clarify the applicability of the rule to any infant sleep product not covered by another CPSC sleep standard.

While newborns can and do fall asleep in many products, because young infants sleep for extended hours throughout the day, certain products are designed, marketed, and intended for infant sleep. Therefore, “sleep” and “sleeping accommodations” refer to products that are marketed or intended for both extended, unattended sleep, and also napping, snoozing, and other types of sleep in which a parent may or may not be present, awake, and attentive. Additionally, if a product name implies the product is for use as an infant sleep product, such as use of the terms “bed,” “bassinet,” or “crib,” but does not already comply with the bassinet or crib regulation, the product falls within the scope of the draft final rule. If a product, through marketing, pictures, and written description, indicates that the product is being sold as an infant sleep product for infants up to 5 months old, that product will be covered by this regulation if it is not already subject to a CPSC sleep standard.

The 2019 SNPR proposed four definitions, “infant sleep products,” “newborn sleep products,” “compact sleep products,” and “accessory sleep products.” However, this distinction is not necessary and creates confusion when identifying infant sleep products, because there are no unique requirements in this rule based on these definitions. Accordingly, in the draft final rule staff recommends removing the separate definitions of “newborn,” “compact,” and “accessory” sleep products, and rely solely on the definition of an “infant sleep product”:

3.1.7 infant sleep product, n – a product marketed or intended to provide sleeping accommodations for an infant up to 5 months old that is not subject to any of the following standards:

- 16 CFR part 1219 – Safety Standard for Full-Size Baby Cribs
- 16 CFR part 1220 – Safety Standard for Non-Full-Size Baby Cribs
- 16 CFR part 1221 – Safety Standard for Play Yards
- 16 CFR part 1222 – Safety Standard for Bedside Sleepers
- 16 CFR part 1218 – Safety Standard for Bassinets and Cradles

2. Distinguishing non-sleep products

Comment 5: A commenter stated that infant car seats, swings, and rockers typically have seatback angles greater than 30 degrees, adding that these products have use patterns very similar to products that fall within the scope of ASTM F3118. The commenter requested clarification of the distinguishing features or characteristics that differentiate these two types of products with very similar usage patterns.

Staff Response 5: The purpose of the draft final rule is to regulate all products marketed or intended for infant sleep for infants up to 5 months old. Accordingly, the products within the scope of the draft final rule are all marketed and intended for sleep, and do not include car seats, swings, or rockers, unless a product is marketed or intended for sleep. Newborns can and do fall asleep in many products because young infants typically sleep 16 to 17 hours a day, 1 to 2 hours at a time. By 3 months, infants can sleep 4 to 5 hours during the day and 9 to 10 hours during

the night.³ Products such as car seats, swings, and rockers typically are not marketed for use as an infant sleep product; these products are intended for use while the child is awake. Moreover, regarding car seats, CPSC has jurisdiction only for use outside of an automobile, when the product is being used as an infant carrier; while the National Highway Traffic Safety Administration (NHTSA) has jurisdiction over car seats being used in an automobile, including the car seats' angle and design for safe use in an automobile.

Comment 6: Several commenters stated that the scope of the 2019 SNPR was too broad, and expressed concerns that non-sleep products would be included. Some of the comments requested specific exclusions or inclusions to the scope of the final rule.

Staff Response 6: The draft final rule does not apply to products that are not marketed or intended for infant sleep, such as bouncer seats, swings, infant chairs, or other similar durable infant or toddler products that are for use when a child is awake. In addition, staff recommends specifically excluding crib mattresses that fall within the scope of the voluntary standard for crib mattresses, ASTM F2933, from the scope of the draft final rule. A crib mattress, alone, does not meet the definition of an infant sleep product, and is always used in conjunction with a sleep product, such as a crib or play yard, that is within one of the five existing CPSC sleep standards. The Commission issued a notice of proposed rulemaking for crib mattresses in 2020, and it intends to finalize a separate rule on crib mattresses this fiscal year.

The purpose of the rule is to set minimum safe sleep requirements for products that are marketed or intended for infant sleep up to 5 months old. CPSC staff is aware that infant sleep products share hazard patterns that can be addressed by performance and labeling requirements, but currently a gap exists between regulated and unregulated products. Therefore, staff recommends that the scope of the draft final rule include all infant sleep products not already covered by the mandatory CPSC standards for bassinets, full-sized cribs, non-full-sized cribs, play yards, or bedside sleepers, to be covered by and tested to a mandatory CPSC sleep standard, so that all infant sleep products follow a minimum safety standard, specifically (and minimally) the standard for bassinets and cradles. Based on staff's evaluation, following the requirements of the bassinet and cradle standard would address the hazard patterns found in the incident data for unregulated infant sleep products (see Tab B and C).

Staff is also concerned about new infant sleep products that come on the market and that do not follow any CPSC sleep standard. The concern is that caregivers may view these products as safe because they are on the market, even though these products may not address known infant sleep hazards or may not be tested to an appropriate standard. Accordingly, the draft final rule requires all products marketed or intended for sleep for infants up to 5 months old to follow core safe sleep principles, which staff, in agreement with AAP, states are: place infants alone, on their back, and on a flat, firm surface with no restraints or loose fabric nearby.

Rather than list specific inclusions and exclusions, other than excluding crib mattresses, the scope and definitions in the draft final rule address potential confusion about which infant sleep products are covered. For example, the definition of an "infant sleep product" states:

³ <https://www.stanfordchildrens.org/en/topic/default?id=infant-sleep-90-P02237>.

3.1.7 *infant sleep product, n* – a product marketed or intended to provide sleeping accommodations for an infant up to 5 months old that is not subject to any of the following standards:

- 16 CFR part 1218 – Safety Standard for Bassinets and Cradles
- 16 CFR part 1219 – Safety Standard for Full-Size Baby Cribs
- 16 CFR part 1220 – Safety Standard for Non-Full-Size Baby Cribs
- 16 CFR part 1221 – Safety Standard for Play Yards
- 16 CFR part 1222 – Safety Standard for Bedside Sleepers

Comment 7: Several commenters asked for clarification whether products, similar in design to inclined sleepers but marketed as a “soother,” “rocker,” or “lounger,” are in-scope for the rule, and suggested that such products should be in-scope due to the potential for consumer confusion as to intended uses. Staff also received a comment asking that inclined products for activity and transport, such as a bouncers, strollers, and swings, be excluded from the scope of the rule.

Staff Response 7: Staff considers infant products, inclined or flat, to be out of scope of the draft final rule, as long as they are not intended for sleep, and they are marketed conspicuously as not for sleep by infants up to 5 months old. This means that the product packaging, marketing materials, inserts, and instructions cannot indicate that the product is for sleep, or imply through pictures of sleeping infants that sleeping in the product is acceptable. In addition, if “attended” or “supervised” sleep is indicated, then the product would be considered within the scope of the draft final rule. The product name, description, and instructions also cannot include references to sleep, snooze, dream, or nap. CPSC staff would consider decorations on the product that include pictures of sleeping animals or sleeping cartoon figures to imply the product is intended for sleep. Additionally, the product must not be described as a bed. Some of these products, such as stroller accessories, are already required by the mandatory standard for that product type to meet the bassinet standard when the product is in bassinet mode.

Comment 8: One commenter acknowledged that the scope of the rule does not include sleep positioners and requested “the CPSC to better enforce the ban on sleep positioners.”

Staff Response 8: Neither the CPSC, nor FDA, has a “ban on sleep positioners”; however, both agencies advise consumers not to use them with infants due to the risk of suffocation. Sleep positioners are considered accessories, and not an “infant sleep product” under the definition of the 2019 SNPR. Similar to crib mattresses, sleep positioners are not intended to be used as the sole product for sleep; instead, they are used in conjunction with a sleep product, for example, to hold an infant in a position while inside a crib. Therefore, sleep positioners are not intended to provide a sleeping accommodation for an infant, and staff does not recommend including them at this time.

3. Upper age limit for infants up to 5 months

Comment 9: The 2019 SNPR posed a question regarding whether the Commission should remove the upper age limit from the scope of the mandatory standard, to accommodate a

broad scope of infant sleep products. Several commenters stated that the draft final rule should remain applicable to products intended for infants up to 5 months old. Otherwise, the commenters said new requirements addressing containment, stability, and side height would need to be added to the bassinet standard for products intended for ages 6 to 12 months, noting that the existing bassinet requirements are designed only for infants up to 5 months old.

Staff Response 9: After further consideration, CPSC staff agrees that changing the scope of the draft final rule to remove the upper age limit, or to include products intended for infants up to 12 months old (as suggested at an ASTM task group meeting), would require new performance, labeling, and testing requirements in the bassinet standard. As the commenters noted, the bassinet standard only applies to infants up to 5 months of age. Therefore, a number of requirements in ASTM F2194-16 ϵ 1 (*bassinet*) standard, would need to be changed to address older, larger, and more mobile and active infants, including changes to the scope in section 1.3, the stability requirement in section 6.4, and the side height requirement in section 6.5.4.

Additionally, the draft final rule focuses on hazards to young infants associated with infant sleep products because infants under 5 months old are the most vulnerable due to their limited mobility and young, developing respiratory system. Requiring currently unregulated infant sleep products to meet the bassinet standard sets minimum requirements for safe sleep. Bassinets are designed for children who are not yet mobile, and addresses the hazards seen in this population. Older infants, *i.e.*, 6 to 12 months old, have different needs for sleep, and the existing standards for this older age group are designed to address those needs. By 6 months of age, infants have developed enough mobility that they can perform such actions as rolling back and forth and pulling themselves up. Therefore, staff concludes that it is unsafe for them to be in a confined space, such as a bassinet, for sleeping, as they may roll out of the product, or pull themselves out of the product.

The unregulated products on the market that CPSC staff has concerns about, *e.g.*, in-bed sleepers, baby boxes, and compact bassinets, are intended for this younger, vulnerable population. In addition, CPSC data indicate that 34 percent of the incidents involving inclined sleep products and 49 percent of the incidents involving unregulated, flat, sleep products happened to infants 0 to 5 months of age. Infants 6 to 12 months old were involved in 9 percent of inclined sleep products and 4 percent of unregulated, flat sleep product incidents, respectively. Therefore, consistent with the 2019 SNPR, staff recommends that the draft final rule limit the scope of the standard to infants up to 5 months of age. Staff also concludes that due to the size and design of these unregulated compact/travel products, older infants should not be placed to sleep in these products, and should not be included within the scope of the draft final rule.

4. Product Registration Rule

Comment 10: A commenter expressed no objection to requiring product registration cards for products within the scope of the rule, but suggested that the Commission “remain open to innovation as to the specific methods of achieving optimum product traceability, particularly now that so many products are linked to internet devices.”

Staff Response 10: In the 2009 NPR for the registration rule (74 *Fed. Reg.* 30986, June 29, 2009), the Commission stated that it “intends to encourage innovation in the use of the

Internet for product registration,” and the methods of registration online are encouraged, be it through a website or email. Staff is open to innovation in this area; however, staff notes that the future innovation can only supplement the required product registration card and does not replace the mandatory requirement stated in section 104(d)(1)(A) of the CPSIA that each manufacturer of a durable infant or toddler product must provide consumers with a postage-paid consumer registration form with each such product.

Comment 11: A commenter supported the Commission’s amendment of the consumer registration rule, 16 CFR part 1130, to identify infant sleep products as durable infant or toddler products subject to the product registration requirements, so that free-standing sleep products, without a frame, are included within the scope of part 1130.

Staff Response 11: Staff agrees that to avoid confusion, and to ensure that all infant sleep products fall within the requirements of part 1130, the consumer registration rule should identify expressly “infant sleep products” as a durable infant or toddler product, as a subcategory of bassinets and cradles.

B. Incident Data

1. Inclusion of unregulated flat infant sleep products

Comment 12: Multiple commenters expressed concern about in-bed sleepers, baby boxes, and compact bassinets being subject to the standard. The concerns expressed:

- In-bed sleepers, baby boxes, and compact bassinets not identified in CPSC data;
- Bed-sharing is a common practice in the United States and abroad;
- Potential disparity in safety among in-bed sleepers vs. a potential ban of in-bed sleepers;
- Interest in increased advocacy regarding bed-sharing; and
- Differences among products necessitates different requirements based on demonstrable hazard data.

Commenters objected to including non-inclined infant sleep products in this rulemaking, including replacing the term “inclined infant sleep products,” with the more general “infant sleep products.” Instead, these commenters urged the Commission to focus on inclined products for this rulemaking and to review requirements for non-inclined products in separate rulemaking efforts. A commenter stated that it is inappropriate to require all products not subject to an existing standard to comply with the bassinet standard.

Staff Response 12: Staff recognizes that bed-sharing is a common practice of parents, both in the United States and abroad. However, staff cannot recommend bed-sharing as a safe sleep practice, due to the increased risk of SIDS, overlay, and other hazards. AAP safe sleep recommendations encourage infants to room-share with parents, but to provide infants with their own firm, flat space, near the parents, but not in the same bed. For a more detailed discussion on bed-sharing, please see ESHF’s memorandum (Tab D).

As discussed in Tab B, in response to the comments, the Directorate for Epidemiology staff identified 183 incident reports related to non-inclined, flat products marketed as infant sleep products, such as in-bed sleepers, and compact bassinets. The incident data, reported covering the period from January 1, 2019 through December 31, 2020 identified 11 fatalities and 16 injury reports. Seven of the 11 fatalities described a suffocation death. The other deaths involved the infant rolling over to a prone position or rolling out of the product and becoming entrapped. The draft final rule identifies the flat infant sleep products that fall within the scope of the rule, provides incident data, describes hazard patterns, analyzes the effectiveness of the bassinet standard to address the hazards, and compares the performance requirements in international standards to demonstrate that these products have the similar hazard patterns that can be addressed by the requirements in the bassinet standard.

Comment 13: Several commenters urged the Commission to work with ASTM to develop product-specific safety standards for each of the identified flat products, such as in-bed sleepers, baby boxes, and compact bassinets, and to do so in a separate effort.

Staff Response 13: The ASTM process for developing the voluntary standard for infant inclined sleep products took close to 5 years before the standard was published. The bassinet subcommittee also has been working about 5 years to add “compact bassinets” to the standard, which has not been completed. Staff has participated in these efforts and provided incident data to the ASTM committees and task groups. Throughout all this time, inclined and compact infant sleep products have entered the retail market without meeting any safe sleep testing, voluntary or mandatory. Staff contends that the incident data discussed in Tab B of the briefing package, and the engineering and human factors analysis in Tabs C and D of the briefing package, demonstrate that inclined, compact, and in-bed sleep products pose risks to infants and, therefore, should not be allowed to be sold as infant sleep products without meeting one of the five CPSC regulated sleep products.

Comment 14: A commenter stated that no data indicate that overlay injuries or fatalities exist while using an infant in-bed sleeper.

Staff Response 14: As part of CPSC staff’s participation with ASTM voluntary standards groups, in the fall 2017⁴ and summer of 2019⁵, CPSC staff provided the ASTM in-bed sleeper working group with incident data that identified fatal and non-fatal incidents involving in-bed sleepers. This data demonstrated 11 fatalities and 22 non-fatalities associated with in-bed sleepers. The primary hazard patterns, consistent with the incident data discussed in this draft final rule, involved infants falling out of in-bed sleepers, rolling into the side, bedsharing, and consumer complaints.

An overlay hazard typically occurs during bed-sharing, when a parent lays over their infant, and typically does not realize they have done so because they are asleep. Accordingly, during task group and subcommittee meetings, staff expressed additional concerns with low side height, soft-sided, in-bed sleepers, because use of such products may provide parents with a

⁴ Email dated October 2, 2017, from Hope Nesteruk to Lisa Trofe and Meredith Thomas, JPMA contacts for ASTM meetings.

⁵ Email dated June 4, 2019, from Hope Nesteruk to Meredith Thomas, JPMA contact for ASTM meetings.

potentially false sense of security when bed-sharing. Based on this information, and bed-sharing concerns generally, CPSC has substantial concerns that a low, soft-sided, in-bed sleeper may not prevent a parent from inadvertently laying over an infant and suffocating the baby. CPSC data for in-bed sleepers is anecdotal in nature, and therefore, we may not have received overlay incidents that involve an in-bed sleeper, but the large number of overlay incidents reported to the CPSC generally indicate that bed-sharing can be hazardous.

Comment 15: A commenter states that the 2019 SNPR is well-intentioned, but that it is premature, and that the scope of the rule ultimately may harm consumer safety, because consumers will use soft bedding and other tools to replace an entire category of products that effectively are banned under the 2019 SNPR. The commenter states that the data necessary to support the rule is either missing or incorrect. Another commenter stated that the data on in-bed sleepers, and the existing CPSC sleep standards, do not support the CPSC’s approach in the 2019 SNPR, noting that babies die in all types of infant sleep products despite having an existing standard, citing bassinets, cribs, and play yards. Infants die for reasons not associated with the product, the commenter asserted, adding that CPSC has not presented data to warrant all infant sleep products without a standard to comply with the bassinet standard. This commenter maintained that CPSC staff is using a “back-door method” to remove infant products from the market without the data to support or justify this action. The commenter opined that staff should write safety standards that will ensure safe sleep for each product type, and not funnel various products into one standard, bassinets and cradles, which was not intended for these products.

Staff Response 15: In coordination with a range of stakeholders, CPSC has carefully developed safety regulations for five infant sleep products (cribs: full-size and non-full-size, bassinets, play yards, and bedside sleepers) and staff encourages consumers to use these products for infant sleep. Staff agrees that deaths occur in these products, but as noted, infant deaths are not always associated with the product. Staff particularly urges consumers to follow the AAP safe sleep recommendations when using any product intended for infant sleep. CPSC data, in Tab B, and evaluated in Tabs C and D, show that deaths and injuries occur in untested and unregulated infant sleep products, including inclined and flat sleep products, and sometimes these incidents involve a use contrary to AAP recommendations. However, staff’s evaluation of the incidents demonstrates that requiring currently unregulated infant sleep products to meet the requirements of the bassinet standard will further reduce the risk of death and injury associated with these products (Tab C).

The argument that parents will use soft bedding and other tools to replace products taken off the market is the same argument used in support of creating a separate voluntary and mandatory standard for infant inclined sleep products, and infants died in these products that did not meet AAP safe sleep guidelines. Accordingly, to further reduce the risk of death and injury, the draft final rule requires that all products marketed or intended as a sleeping accommodation for infants up to 5 months old be tested and certified to an existing CPSC sleep standard, and that CPSC, the AAP, and the industry, continue to promote and educate caregivers about safe sleep practices for infants.

2. Question regarding statistically significant data

Comment 16: One commenter questioned whether the data presented in the 2019 SNPR are statistically significant for inclined sleep products, or are the deaths due to SIDS?

Staff Response 16: The analysis presented in the 2019 SNPR package (as well as this draft final rule package) is based on reported incidents, and therefore, it is anecdotal in nature. This means that the data do not constitute a statistical sample representing all incidents related to inclined and flat infant sleep products; nor do the data represent a complete set of incidents that may have occurred involving the products. As such, no statistical inference is possible. However, the data do provide at least a minimum count for the number of incidents related to each type of product reviewed.

Many of the fatality reports contain unclear, conflicting, and/or inconsistent information. For example, for some deaths, medical examiners may have concluded the cause of death to be Sudden Infant Death Syndrome (SIDS) or Sudden Unexpected Infant Death (SUID), but they also may mention co-contributing conditions, such as an unsafe sleep environment (*e.g.*, soft bedding, inclined sleep surface) or other pre-existing medical condition(s). This can confound staff's ability to determine a predominant factor in the fatality. Staff used a consensus decision-making process. If an unsafe sleep environment or a product design was one of the factors, staff classified the death under that category. Otherwise, staff classified the reported incident under the "undetermined" category, when no one factor stood out, or staff classified the incident under the "insufficient information" category, when staff did not have enough information to classify the incident in another category to avoid overestimating the risk.

C. *Degree of Incline*

1. Additional testing for inclines between 10 and 20 degrees

Comment 17: Several commenters stated that the Commission should conduct additional research on the safety of inclines between 10 and 20 degrees for infant sleep products. A commenter stated that CPSC has failed to provide relevant data to support the 2019 SNPR's approach regarding inclined sleep products, to limit the seat back angle to 10 degrees or less, and not to conduct additional study on the 10 to 20 degree angle, or to provide information or incidents to support this decision.

Staff Response 17: During the development of the 2019 SNPR, Commission staff contracted with Dr. Erin Mannen to examine how the degree of a seat back angle affects an infant's ability to move within inclined sleep products, and if the incline angle directly impacts safety or presents a risk factor that could contribute to the suffocation of an infant. The Mannen Study findings showed that infants in products with a seat back angle greater than 20 degrees exhibit increased demand on their abdominal muscles. The Mannen Study concluded that this could lead to increased fatigue and suffocation if an infant is unable to reposition themselves after an accidental roll from supine to prone. The Mannen Study concluded that a sleep surface that is 10 degrees or less is comparable to a crib mattress surface and can be considered a safe sleep surface. The Mannen Study suggested if future work were done on safe sleep angles, one area of study would be additional biomechanical testing to determine "which, if any, angles between 10-and 20-degrees may be safe for infant sleep."

The Mannen Study recommendations do not imply that an incline angle above 10 degrees may be safe; rather, the Mannen Study merely suggests that if higher angles are considered, additional biomechanical testing is required. We are not aware of existing research that suggests that an inclined sleep surface between 10 and 20 degrees is safe, nor is CPSC currently conducting similar research. The Mannen Study also stated that its testing of awake infants was a limitation because “while the muscle use and motion may be similar, it is likely that infants who find themselves in a compromised position in an inclined sleep product during a nap or overnight sleep may not have enough energy or alertness to achieve self-correction and may succumb to suffocation earlier or more easily than infants who are fully awake.” Given the vulnerability of newborn infants and the precedence of fatalities of infants who were most likely asleep in inclined products at the time of incidents, additional research of inclines above 10 degrees is unnecessary for the draft final rule.

Additionally, other research has demonstrated a discernable difference in infant ability between 5, 7, and 10 degrees in a side-to-side tilt, which formed the basis of the 7-degree maximum sleep surface angle in Health Canada’s regulations and the 5-degree limit in the Australian requirement. The 10 degree sleep surface limit in the draft final rule is a slightly higher allowed sleep surface angle than other countries. Based on the Mannen Study and the research that supports sleep surface angles in international standards reviewed by CPSC staff, staff believes that it is unlikely that additional research at angles higher than 10 degrees will demonstrate that an angle greater than 10 degrees is safe for infant sleep. Accordingly, for the draft final rule, infant sleep products must be tested for a seat back or sleep surface angle of 10 degrees or less from horizontal, and they must meet the requirements of the bassinet and cradle standard.

2. Adopt Canadian standard of 7 degrees

Comment 18: One commenter stated that Canada only allows up to 7-degree seat back angle in sleep products, and suggested CPSC should consider adopting the Canadian standard. Another commenter supported staff’s recommendation for infant sleep surfaces to be no more than 10 degrees from horizontal.

Staff Response 18: The Mannen Study concluded that a seatback angle of 10 degrees or less is safe. This seatback angle is consistent with CPSC’s Safety Standard for Bassinets and Cradles, which also requires a 10 degree or less incline. Staff recognizes that Health Canada is using a 7-degree maximum incline; however, that requirement is based on a side-to-side tilt study of infants in rocking cradles published in 1995. The 2019 Mannen Study compared infant muscle and breathing behavior on a flat crib mattress and on a crib mattress, head-to-toe 10 degrees from horizontal, and determined that infant responses were essentially the same on both sleep surfaces. Accordingly, based on the Mannen Study findings, to provide a safe sleep surface, the draft final rule is consistent with the current requirement in the bassinet and cradle standard, requiring that infant sleep products must have a head to toe incline angle of 10 degrees or less.

3. Highest seat back angle clarification

Comment 19: A commenter requested that CPSC replace the phrase: “the manufacturer’s recommended highest seat back angle position intended for sleep,” with “the seat back angle position that is the highest position intended for sleep or that is the highest position that a reasonable consumer would consider as being for infant sleep, whichever is higher.”

Staff Response 19: The commenter’s suggestion for “replacing ‘the manufacturer’s recommended highest seat back angle position intended for sleep,’ with ‘the seat back angle position that is the highest position intended for sleep or that is the highest position that a reasonable consumer would consider as being for infant sleep, whichever is higher’” illustrates a confusion with the focus on “seat back.” The 2019 SNPR applied to infant sleep products, and required all infant sleep products to be 10 degrees or less from horizontal – the same as the sleep surface in bassinets. However, the safe sleep principal requirement from the Mannen Study, and already reflected in the bassinet standard, is that infants should sleep flat on their backs. Accordingly, the 2019 SNPR term “seat back” created confusion, because the term implies that infant sleep products are for “sitting” in a device with a “seat.” Thus, for the draft final rule, CPSC staff recommends replacing the term “seat back” with the term “*Seat Back/Sleep Surface.*”

D. Safe Sleep Principles

1. Request to ban infant inclined sleep products

Comment 20: Approximately 25 commenters requested that CPSC “ban” or “remove” infant inclined sleep products from store shelves. Of those commenters, three indicated that their child died while sleeping in an inclined sleep product.

Staff Response 20: Many products with an incline greater than 10 degrees from horizontal have been removed from the market through CPSC recalls. To address newly manufactured products, the draft final rule does not “ban” all infant sleep products with an angle, but addresses the hazards associated with inclined infant sleep products by requiring that any product marketed or intended for sleep for infants up to 5 months old must not have a sleep surface angle greater than 10 degrees, and that any unregulated infant sleep product meet the bassinet standard, if it is not subject to any CPSC sleep standard. The purpose of these requirements is to ensure that all infant sleep products meet minimum safe-sleep principles, including the sleep surface angle, as addressed through an existing CPSC sleep standard.

2. Aligning with AAP safe sleep practices

Comment 21: One commenter acknowledged that the 2019 SNPR aligns with the AAP’s safe sleep recommendations, and encourages staff to ensure that the proposed rule sends a clear message addressing safe sleep practices.

Staff Response 21: CPSC staff agrees with the importance of addressing safe sleep practices and ensuring that all products marketed, intended, promoted, or otherwise indicated as being for any kind of infant sleep need to be addressed in this rulemaking. Therefore, CPSC staff confirms its recommendation that all currently unregulated infant sleep products be subject

to 16 CFR part 1218 Safety Standard for Bassinets and Cradles, because it includes safe sleep requirements. Additionally, CPSC’s website provides extensive information regarding best practices for safe sleep through its CPSC’s Safe Sleep Campaign and Baby Safety information at: <https://www.cpsc.gov/SafeSleep>.

3. Use of unsafe products by sleep deprived parents

Comment 22: One commenter expressed concern that parents, particularly those who are sleep deprived, cannot reasonably be expected to use a product that is unsafe by design in a safe manner.

Staff Response 22: CPSC staff agrees that lack of sleep may have a detrimental effect on a parent’s judgment when using an infant sleep product. Research demonstrates that fatigue can negatively affect memory, concentration, and decision making.⁶ CPSC staff concludes that proceeding with the rulemaking package is the most effective method of ensuring that infant sleep products for infants up to 5 months of age are safe for use.

E. Definitions

1. Remove “intended” from definitions

Comment 23: A commenter requested that the word “intended” be struck from the definitions of infant and newborn sleep products.

Staff Response 23: Staff disagrees with the request to remove “intended” from the definitions. Manufacturer’s intent, which can be evaluated through stated warning messages, marketing photos, product instructions and other factors, must remain a factor for consideration. As noted by the commenter, some products are marketed for swinging or bouncing. If infant products are not intended for sleep and not marketed in ways that imply they are for sleeping or napping, they should not be subject to the infant sleep standard. However, staff is clarifying that CPSC will evaluate a manufacturer’s intent using all available materials, including marketing, by broadening the definition to include the word “marketed.”

2. Define or clarify “free standing” infant sleep products

Comment 24: One commenter contended that “free standing” is an ambiguous term.

Staff Response 24: A free-standing infant sleep product is a sleep product that can be used by itself without the need of another product, such as a portable play yard. ASTM F3118 – 17a contains a separate definition for “accessory inclined sleep product,” which applies to products that are supported by another product, such as a play yard. The term “free-standing” is used without issue in other ASTM and CPSC standards. For the draft final rule, staff recommends broadening the definition of “infant sleep product” to cover all unregulated products. Accordingly, staff recommends removing the term “free-standing” from the definition in the draft final rule, to reduce confusion about which infant sleep products are subject to the

⁶ <https://www.sleepfoundation.org/sleep-deprivation>.

rule.

F. Warnings and Instructions

1. Provide information about scoliosis and torticollis

Comment 25: One commenter recommended that information about deformities such as scoliosis and torticollis be included on an insert with all infant sleep products.

Staff Response 25: CPSC staff agrees that providing parents with information and resources regarding various infant deformities is beneficial, and manufacturers are not prevented from including if they desire. However, as indicated in the 2019 SNPR, increases in the number of children with plagiocephaly may actually be attributed to the AAP's recommendation to place infants to sleep on their backs to decrease the risk of SIDS. Staff does not recommend any modifications to the voluntary standard to address these issues.

2. Placement of warnings

Comment 26: One commenter recommended that warnings should be placed on the outside and inside of the packaging, as well as on the product. The commenter also recommended that packaging should be labeled, easily visible, and easy to read/understand.

Staff Response 26: Consistent with the 2019 SNPR, the draft final rule requires that infant sleep products not already subject to an existing CPSC sleep standard, be subject to the warning requirements set forth in the bassinet standard, ASTM F2194-16e1, which requires that warning labels be present on the product and its packaging, and that warning information be present in the instructional literature. ASTM F2194-16e1 also requires that the warnings be conspicuous, permanent, and easy to read/understand.

G. Economic Analysis

Comment 27: A commenter suggested that CPSC conduct an exposure study to research the relative risks of these different sleep products. This commenter also suggested that CPSC perform a full cost-benefit analysis of the final rule.

Staff Response 27: CPSC is continuing research related to safe sleep topics, which may potentially involve types of infant sleep products. Although an exposure study is an effective means to estimate exposure, we can estimate exposure by comparing annual sales of products to the number of live births, and staff identifies the hazard patterns from the incident data. The Commission is not required to conduct cost-benefit analyses under section 104 of the CPSIA, and has not done so for any durable infant or toddler rulemaking. Staff is uncertain what the purpose of such an analysis would accomplish for a rule promulgated under section 104 of the CPSIA, where cost/benefit considerations are not germane to the Commission's rulemaking authority.

H. Effective Date

Comment 28: Commenters both supported and opposed the 12-month effective date. Some opposing commenters supported a 6-month effective date instead, because additional time puts infants at risk, while other opposing commenters wanted a longer effective date, or an indefinite delay until ASTM completes additional standards for specific products. The 2019 SNPR proposed that the effective date would apply to products manufactured or imported after the final rule effective date. Staff received multiple comments that the effective date should apply to products sold after the final rule effective date instead of the “sold by date,” to prevent stockpiling and remove the hazards as soon as possible.

Staff Response 28: For the draft final rule, staff recommends the Commission maintain the 2019 SNPR proposed effective date of 12 months after the date of publication in the Federal Register. A 6-month effective date may seem reasonable because suppliers have had ample lead time to prepare for this rule since the 2019 SNPR was published, and many of the products within the scope of the draft final rule have been withdrawn from the market or redesigned, particularly for inclined sleep products. However, for manufacturers of other unregulated flat sleep products that remain in the market, there will likely be a significant economic impact as a result of this draft final rule. While some suppliers can reduce the impact of this rule by relabeling their products as not for infant sleep, not all manufacturers can simply remarket the product if the physical form of the product demonstrates that it is intended for sleep. For some of these products, manufacturers could relabel them as intended for infants older than five months, or, in some cases, for pets. However, the demand for infant sleep products for pet use is probably limited.

The draft final rule is considered a consumer product safety standard issued under the Commission’s authority in section 104 of the CPSIA. Section 104(b)(1)(B). We are unclear regarding what the commenters’ “sold by” date references. The Consumer Product Safety Act (CPSA) sets forth requirements for manufacturers and importers once a rule becomes effective. Section 19(a)(1) of the CPSA states:

- (a) It shall be unlawful for any person to—
 - (1) sell, offer for sale, manufacture for sale, distribute in commerce, or import into the United States any consumer product, or other product or substance that is regulated under this Act or any other Act enforced by the Commission, that is not in conformity with an applicable consumer product safety rule under this Act, or any similar rule, regulation, standard, or ban under any other Act enforced by the Commission;

15 USC 2068(a)(1). Accordingly, the CPSA provides that, as of the effective date of the draft final rule, it is unlawful to “sell, offer for sale, manufacture for sale, distribute in commerce, or import into the United States,” any infant sleep product, as defined in the rule, that is not in conformity with the draft final rule.

I. Procedural Comments

1. Products Subject to the Draft Final Rule

Comment 29: A commenter stated that the proposed rule would apply to domestic products, and not to products made overseas. The commenter stated that the rule should apply to products made overseas and sold in the United States, for “optimal consumer safety.”

Staff Response 29: The commenter appears to misunderstand the scope of products subject to the draft final rule. If finalized, the rule would make it unlawful to sell, offer for sale, manufacture for sale, distribute in commerce, or import into the United States, an infant sleep product that is not in conformity with this rule, regardless of whether the product was manufactured in the United States or overseas.

2. Incorporation by Reference

Comment 30: A commenter states that the Commission should publish the legal standard for infant sleep products, rather than incorporate the standard by reference. The commenter stated:

- Publishing the legal standard “will advance fundamental principles of fair notice and due process by ensuring that the public has open and unimpeded access to the law.”
- The law belongs to the people, regardless of who drafts the law, and thus citizens have a fundamental right to know what the law contains.
- When the public is not informed about relevant legal standards, this has the potential for arbitrary or discriminatory enforcement.
- People cannot comply with a law if they do not know the substance of the law.

Staff Response 30: Section 104 of the CPSIA directs the Commission to issue standards for durable infant or toddler products that are “substantially the same as,” or more stringent than, applicable voluntary standards. Thus, unless the Commission determines that more stringent requirements are necessary to further reduce the risk of injury, the Commission’s rules must be, for the most part, the same as the applicable voluntary standard. In this case, the final rule would incorporate by reference ASTM F3118-17a, with substantial modifications to make the standard more stringent, to further reduce the risk of injury associated with infant sleep products. This draft final rule would set forth in the Code of Federal Regulations (CFR): definitions, one test for the seatback/sleep surface angle of an infant sleep product, and otherwise require infant sleep products that do not already meet a CPSC sleep standard to meet the requirements of the bassinet standard, to further reduce the risk of injury associated with inclined and flat infant sleep products. CPSC’s bassinet standard, 16 CFR part 1218, currently incorporates by reference performance and labeling requirements in ASTM F2194-13, with modifications set forth in the CFR. CPSC’s mandatory standard is substantially similar to ASTM F2194-16ε1.

ASTM’s voluntary standards are protected by copyright, which the Commission (and the federal government generally) must observe. The United States may be held liable for copyright infringement. 28 U.S.C. § 1498. Accordingly, the Commission cannot violate copyright law by publishing ASTM’s voluntary standards in the CFR. The Office of the Federal Register (OFR) has established procedures for incorporation by reference that seek to balance the interests of

copyright protection and public accessibility of material. 1 CFR part 51. OFR's regulations are based on Freedom of Information Act provisions that require materials to be "reasonably available" when incorporated by reference with approval of the Director of the Federal Register. 5 U.S.C. § 552(a)(1). Under the OFR's requirements, an agency may incorporate by reference specific publications, including standards, if they are "reasonably available to and usable by the class of persons affected." 1 CFR § 51.7. To ensure the material is "reasonably available," an agency must summarize the material it will incorporate by reference and discuss how that material is available to interested parties in the Federal Register notice. *Id.* §§ 51.3(a), 51.5(a).

Manufacturers and importers of infant sleep products represent the class of persons affected by the draft final rule. Although any interested person has access to the content of CPSC's regulations through Federal Register notices of proposed and final rules, the CFR, and the content of voluntary standards on ASTM's website, under the statutory scheme set forth in the CPSIA, it is those manufacturers and importers who want to "sell, offer for sale, manufacture for sale, distribute in commerce, or import into the United States," any durable infant or toddler product, that must conduct testing using a third party conformity assessment body (lab) and certify their product as compliant with the applicable consumer product safety rule. 15 U.S.C. § 2063(a)(2).

The Commission complies with the requirement that publications, including standards, are "reasonably available to and usable by the class of persons affected," whenever incorporating material by reference. For example, when the Commission proposes a rule under section 104 of the CPSIA, the Commission describes and summarizes the requirements of the rule, including the voluntary standard, in the preamble of the rule printed in the Federal Register, and explains that ASTM's copyrighted voluntary standards are available to review online for free during the comment period at <https://www.astm.org/CPSC.htm>. Once a rule becomes effective, ASTM provides a read-only copy of the standard for review on the ASTM website at: <https://www.astm.org/READINGLIBRARY/>. As always, a person can purchase a voluntary standard from ASTM, or may schedule a time to review a voluntary standard (for free) at the Commission's headquarters in Bethesda, MD. Accordingly, citizens who are interested in the content of the law have unimpeded access to the regulation, and have several avenues for free access to the text of voluntary standards incorporated by reference into a mandatory CPSC standard for a durable infant or toddler product.

Comment 31: A commenter states that CPSC's practice of incorporating voluntary standards by reference into law forces citizens to either visit the agency in person, or pay for access, to view the proposed law. The commenter contends that CPSC's actions to allow public access to the proposal, including summarizing the proposed requirements in the preamble to the proposed rule, making the voluntary standard available for review at the CPSC's offices, or reading the standard on ASTM's website free of charge, are all problematic, as the regulations are not "reasonably available" to the class or persons affected. The commenter states that ASTM's restrictions on downloading or printing the standard (unless the standard is purchased) are an impediment to accessing the law, and describes the Commission's access to the proposed law as "limited" and insufficient to "ensure robust public access to the law." Specifically, the commenter notes that without the ability to download graphs and charts in the ASTM standard, the graphs are unreadable in portrait view. The commenter states that "reasonably available" is

not defined in the APA, but should be interpreted broadly “to promote fundamental constitutional values....”

Staff Response 31: We disagree with the commenter that CPSC’s efforts to make voluntary standards “reasonably available” are “limited.” For rules issued under section 104 of the CPSIA, stakeholders have several ways to access the content of the voluntary standard proposed to be incorporated by reference, and after the standard is incorporated by reference into a regulation, including reading a summary of the requirements of a voluntary standard in a proposed or final rule (free), reviewing voluntary standards in person at CPSC’s offices (free), reviewing read-only copies of the voluntary standard on ASTM’s website (free), and by purchasing a copy of the standard. The OFR’s regulations do not require free access to the contents of copyrighted materials. In developing a regulation, the OFR considered whether to require free access to materials that are incorporated by reference into regulations, and specifically declined to do so. *79 Fed. Reg.* 66,267 (Nov. 7, 2014). The OFR found that adopting requirements to summarize the content of the material incorporated, and explaining to stakeholders how to obtain the material, was adequate to make the material “reasonably available.” *Id.* at 66,270. Accordingly, CPSC’s efforts to make copyrighted materials reasonably available exceed the OFR’s requirements.

Comment 32: A commenter states that incorporation by reference, without providing free access to the law, undermines due process because it may limit public input and exclude meaningful participation by some stakeholders. The commenter explains, for example, that to participate in ASTM standards development, one must be an ASTM member, which costs \$75 per year. The commenter notes that the regulated community can afford this and participate, while members of the public cannot meaningfully participate.

Staff Response 32: Stakeholders have several options to review the content of a voluntary standard for free, as described in response to comments 30 and 31. We further note that CPSC’s regulation at 16 CFR part 1031 does not allow staff to participate in voluntary standards meetings that are not open to the public. ASTM does not require membership to participate in ASTM meetings where stakeholders discuss standards development for durable infant or toddler products. ASTM requires membership to vote on balloted items to create or revise a voluntary standard. ASTM typically seeks a cross section of stakeholders to participate in standards development. Thus, if a consumer, for example, wanted to participate in an ASTM meeting, they could do so without membership. Staff notes that CPSC staff’s participation in ASTM meetings discussing durable infant or toddler products is posted on CPSC’s calendar (on CPSC’s website) at least a week in advance. The meeting notice provides the date, time, purpose of the meeting, the staff attending, and contact information for staff (to obtain ASTM login information) so that any person who wants to participate in the ASTM meeting may do so. Moreover, CPSC staff creates a written meeting log for each ASTM meeting where staff participates, which summarizes the meeting content. If a consumer wanted to become an ASTM voting member and cannot afford the membership fee, that person can contact ASTM to learn about additional options for membership. For example, students can be ASTM members free of charge. CPSC staff encourages members of the public to meaningfully participate in standards development efforts for durable infant or toddler products through the ASTM process and by commenting on CPSC’s proposed rules.

Comment 33: A commenter describes a recent holding by the Eleventh Circuit finding that annotations to a Georgia statute were “sufficiently law-like” to require free public access. The commenter also describes two district court cases challenging PACER system fees, but notes the cases are in the early stages of litigation, but “the underlying principles of free public access to the law and legal proceedings are directly relevant here.”

Staff Response 33: As described in response to comments 30 and 31, CPSC exceeds the OFR’s regulation to ensure that voluntary standards that are incorporated by reference are reasonably available to all interested parties, and ASTM provides access to review voluntary standards incorporated by reference before and after a rulemaking, free of charge, on ASTM’s website.

3. Alleged notice and comment and section 104 procedural defects

Comment 34: A commenter states that the rulemaking process for including flat products within the scope of the 2019 SNPR, such as in-bed sleepers, is procedurally deficient and does not follow the procedure for rules issued under section 104 of the CPSIA, because the Commission’s 2019 SNPR did not include sufficient data demonstrating the need for a rule to cover non-inclined infant sleep products. The commenter states that the data set for non-inclined products is incomplete and insufficiently reviewed, suggesting that the Commission did not review incident data for non-inclined products with the ASTM committee. The commenter states that the Commission’s failure to publish a revised SNPR to include CPSC staff’s concerns with compact bassinets, baby boxes, and in-bed sleepers, as described in a December 12, 2019 letter from staff to several ASTM subcommittees, which the commenter states did not appear in the 2019 SNPR, and to instead provide a 30 day extension of the comment period, was insufficient notice to all interested parties, and may result in a flawed standard that is unable to withstand judicial scrutiny.

Staff Response 34: The 2019 SNPR provided notice to stakeholders that unregulated non-inclined, flat infant sleep products were included in the proposal, by proposing to remove the term “inclined” from the standard, and to include within the scope of the rule currently unregulated infant sleep products, including inclined and non-inclined products. For example, the 2019 SNPR states:

- “CPSC’s proposed standard would cover products intended for infant sleep that are not already addressed by another standard.” 84 *Fed. Reg.* at 60,949.
- “CPSC proposes to define ‘infant sleep products’ as products that provide sleeping accommodations for infants that are not currently covered by bassinets/cribels, cribs (full-size and non-full size), play yards, and bedside sleepers...” *Id.* at 60,950. Similar statements are also made on pages 60,951 (three times), 60,956, and in the draft regulatory text (proposed 1236.1, 1236.2(b)(4)(D) and 1236.2(b)(11)(i)) at 60,962-963).
- “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 . . .”

- The request for comments on page 60,961 asks for comments on non-inclined products likely to be impacted by the SNPR, including, for example, a request for comment on:
 - “...any additional types of products that commenters believe may be impacted by the Supplemental NPR.”
 - “...products with inclines less than or equal to 10 degrees that do not already comply with the bassinet standard.”
 - removing the upper age limit of 5 months because the SNPR “proposes to address ‘infant sleep products’ not already covered by traditional sleep product [standards].”
- The Staff’s October 16, 2019 SNPR Briefing Package, referenced in the *Federal Register notice*, contains similar statements about the scope of the rule (pages 15, 16, 21, 117, 136), and on page 133 also specifically states (and on page 134, Figure 1 provides a picture of an unregulated flat sleep product):

The draft supplemental proposed rule would also cover products with inclined sleep surfaces greater than 30 degrees and less than 10 degrees, if they are intended or marketed for children under 5 months of age for sleep purposes, and they are not subject to another sleep product standard. For example, the draft supplemental proposed rule would include the hammock-style crib accessory shown in Figure 1. It appears to have an incline of 10 degrees or less, but does not fall under another sleep category.

CPSC’s description of the scope of the rule throughout the 2019 SNPR and the staff’s 2019 SNPR briefing package, and the request for comment on these products, were sufficient to inform stakeholders that these unregulated flat infant sleep products were included within the scope of the rule.

In addition, ASTM members had actual notice of the contents of the 2019 SNPR before and after publication. Sections V.A.3 and V.B.2 of this preamble discuss staff’s work with the ASTM subcommittees and task groups. Staff’s 2019 SNPR Briefing Package was posted on the Commission’s website on October 16, 2019, before ASTM held fall meetings on voluntary standards for juvenile products, and before the Commission voted on the 2019 SNPR, so that ASTM members and other stakeholders could review the package, including the Mannen Study, before the ASTM meetings, and so that staff could discuss the package and the Mannen Study with ASTM members. The ASTM Agenda for the Infant Inclined Sleep Products meeting that occurred on October 21, 2019 included a link to Staff’s 2019 SNPR Briefing Package. CPSC staff discussed the 2019 SNPR Briefing Package at the ASTM meetings in October 2019, including with the ASTM subcommittees for infant inclined sleep products, in-bed sleepers, and bassinets, discussing the Mannen Study findings, as well as addressing the fact that flat sleep products were covered by the 2019 SNPR. Dr. Mannen attended the subcommittee meeting for infant inclined sleep products via telephone, to discuss the Mannen Study and to answer questions.

The 2019 SNPR published in the *Federal Register* on November 12, 2019. In a December 12, 2019 letter to both the ASTM inclined sleep and bassinet subcommittees, CPSC staff again reiterated its concerns with weakening the safe sleep requirements in the voluntary standard for bassinets and cradles to accommodate unregulated products, such as in-bed sleepers, compact bassinets, and baby boxes. Thus, the letter represents an additional effort to ensure that the relevant ASTM subcommittees (and thus subcommittee members) were aware of CPSC staff's concerns with these products, as well as the content of the 2019 SNPR, which proposed that flat sleep products would need to meet the requirements of the bassinet standard. Even though this letter was in addition to, and not instead of, the notice provided in the 2019 SNPR, the Commission extended the comment period for an additional 30 days, to accommodate any confusion among stakeholders. The draft final rule addresses scope and data concerns submitted by commenters on the inclusion of unregulated flat sleep products.

With regard to in-bed sleepers, baby boxes, and compact bassinets specifically, ASTM members, which include manufacturers of these products, have been well aware of CPSC staff's concerns with these products for years, based on activity on the bassinet committee which has been developing requirements for these products to include in the bassinet standard, but has thus far been unsuccessful. With regard to in-bed sleepers, ASTM created a separate standards development effort for this product, which CPSC staff has participated in, and provided incident data on the products, including notice of the injuries and fatalities associated with these products. Indeed, through staff's participation in the ASTM process, including attending meetings, providing incident data, and providing comments and votes on ballot efforts, staff's concerns with unregulated flat products, and the incident data associated with these products, is not unknown to stakeholders and these commenters.

Comment 35: A commenter states that CPSC statutes require the CPSC to defer to voluntary standards under certain conditions, and that CPSC's website states that CPSC follows OMB Circular A-119, but the Commission has done neither in this case. Another commenter states that the 2019 SNPR did not rely on the ASTM consensus-driven process to develop a standard, and that CPSC's data cannot be presented belatedly to ASTM participants, after or at the same time as the 2019 SNPR was provided to the Commission. This commenter states that while CPSC claims the process was a collaborative one, for the 2019 SNPR, the process was not.

Staff Response 35: Rulemaking pursuant to sections 7 and 9 of the CPSA requires the Commission to rely on a voluntary standard, rather than promulgate a rule, if: (1) the voluntary standard adequately addresses the risk of injury associated with a product, and (2) there is likely to be substantial compliance with the voluntary standard. If either of these criteria are not met, the Commission may proceed with rulemaking under sections 7 and 9 of the CPSA, if the Commission can make the other required findings. Those criteria are not relevant under section 104 of the CPSIA, which requires the Commission to consult "with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts, examine and assess the effectiveness of any voluntary consumer product safety standards for durable infant or toddler products," and to promulgate rules that are substantially the same as the voluntary standards, or more stringent than the voluntary standards, if the Commission finds that more stringent standards would further reduce the risk of injury.

Although CPSC staff's standards development work through the ASTM process can colloquially be termed "collaborative," nothing in section 104 of the CPSIA requires "collaboration" on a rule outside of the rulemaking process. Under section 104, the Commission is not required to "defer" to the voluntary standard, rather, the Commission must promulgate rules, and those rules must be substantially the same as the voluntary standard, or more stringent than the voluntary standard, if more stringent requirements would further reduce the risk of injury. Section 104 requires the Commission to consult regarding the effectiveness of a voluntary standard; the Commission is not required to consult on the timing of a proposed rule, the Commission's enforcement work, or on the content of a proposed rule outside of the rulemaking process. In the case of bassinets, unregulated flat sleep products, and inclined infant sleep products, staff has been consulting on the effectiveness of the voluntary standards, or lack thereof, for these products for many years.

Generally, CPSC staff's work through the ASTM process has improved the safety of durable infant or toddler products. However, nothing in section 104 of the CPSIA requires the Commission to delay addressing risks of harm to the most vulnerable infants in sleep products that parents rely upon as a safe place for an infant, until all ASTM members have reached a consensus on whether and how to create or revise a voluntary standard to address the risk. The Commission would be relinquishing the statutory mandate to protect consumers by ceding product safety to the very industry Congress required the agency to regulate. CPSC met the requirement to consult on the effectiveness of the voluntary standards. The lengthy record of staff's participation with the infant inclined sleep committee is available on regulations.gov, as well as through ASTM records. A similarly robust record of staff's participation on the bassinet and cradle committee, outside of the rulemaking process, is available through ASTM and CPSC's Office of the Secretariat.

Finally, the draft final rule addresses scope and data concerns submitted by commenters on the inclusion of unregulated flat infant sleep products. CPSC's description of the scope of the rule throughout the 2019 SNPR and the staff's briefing package, and the request for comment on these products (including a 30 day comment extension), were sufficient to inform stakeholders that these unregulated flat infant sleep products were included within the scope of the rule.

Comment 36: A commenter states that CPSC had been participating collaboratively with the ASTM committee for ASTM F3118 before the summer of 2019, when the commenter states the Commission rescinded its rulemaking to adopt ASTM F3118 as a mandatory standard, and to modify the standard through the 2019 SNPR. The commenter states that the better practice would be to issue an advanced notice of proposed rulemaking (ANPR) while also seeking modifications to ASTM F3118 through the ASTM process, so that stakeholders can "work with urgency" toward addressing CPSC incident data to develop a performance-based standard, versus a design restrictive standard. The commenter also expressed disappointment that CPSC is "subverting" the ASTM process, which has a proven track record for resolving product problems. The commenter requests that CPSC "correct its course" and provide the relevant data to the ASTM committee, so that the committee can address the problems associated with inclined sleep products through the ASTM process. The commenter requests that CPSC hold the 2019 SNPR in abeyance while proceeding as the commenter has suggested, with an ANPR and working through the ASTM process.

Staff Response 36: Although staff submitted an NPR termination package for infant inclined sleep products to the Commission on June 12, 2019, the Commission never voted on the termination package. Instead, the Commission voted (5-0) on October 25, 2019 to issue the 2019 SNPR for infant sleep products.

Generally, CPSC staff's work through the ASTM process to improve the requirements of voluntary standards to address hazards associated with durable infant or toddler products has improved the safety of these products, and CPSC will continue its work through the ASTM process. Accordingly, CPSC did not, and is not, subverting the ASTM process to address the hazards associated with inclined and flat sleep products. CPSC staff has been participating in the infant inclined sleep product standards development process, as well as the bassinet and cradle standards development committee, for many years, both before and after the Commission issued the 2019 SNPR.

ASTM did not hold subcommittee meetings or task group meetings on inclined sleep products or the 2019 SNPR for almost one full year after the October 2019 ASTM meetings, and did not schedule any meetings until after CPSC staff sent a letter to the ASTM subcommittee for infant inclined sleep products on July 16, 2020. After staff's letter, the ASTM F3118 subcommittee established a task group to revise the infant inclined sleep standard's title, introduction, and scope, to be more in line with the proposal in the 2019 SNPR. In December 2020, the ASTM subcommittee introduced ballot F15-18 (20-1) to change the standard's title, introduction, and scope to include all infant sleep products (and not just inclined sleep products). A more detailed description of this ballot is in section V.A.3 of this preamble. However, in January 2021, the ballot did not pass due to six negative votes. The ASTM F3118 subcommittee discussed the ballot results at a meeting on January 27, 2021. During this meeting, ASTM members disagreed on the intent and consequences of changes to the voluntary standard, and the meeting ended without a consensus on a path forward.

Based on the ballot results and the discussions in these ASTM meetings, staff advises that it is unlikely that ASTM will be able to move forward with changes to ASTM F3118 that address safe sleep requirements in the near term.⁷ However, staff notes that a task group to review safe sleep requirements across infant sleep product standards (the comparison task group) has met four times since the January 27, 2021 meeting. CPSC staff has participated in all of these ASTM efforts, including commenting on ASTM's ballot.

The December 2020 ASTM ballot to revise the title, introduction, and scope of ASTM F3118, and the January 2021 meeting to discuss the negatives on the ballot, demonstrate that ASTM members do not have a consensus on moving forward to address the hazards associated with infant sleep products, despite CPSC's 2019 SNPR and staff's continued participation in the

⁷ The ASTM task group approach is different than CPSC's approach in this draft final rule, because ASTM is attempting to put safe sleep requirements in ASTM F3118, rather than relying on the performance and labeling requirements in the bassinets and cradles standard. The Commission determines in this draft final rule that the performance and labeling requirements in the bassinet standard are the minimum safe sleep requirements for infant sleep products, so it remains unclear whether ASTM's approach can be successful. However, if the ASTM committee revises ASTM F3118-17a and notifies the Commission, the staff will evaluate the revised voluntary standard at that time.

process. Although ASTM task groups continue to work on revisions to the voluntary standard, staff reports that the ASTM process is not close to completing their work, and staff was not confident that ASTM would achieve consensus on revisions to the standard in the near term. Staff notes, however, that in a recent task group meeting on revisions to the title, introduction, and scope of the standard (April 22, 2021), task group members discussed balloting the proposed regulatory text in the 2019 SNPR to replace ASTM F3118-17a, to prevent the sale of infant inclined sleep products that purport to certify to ASTM F3118-17a, meaning products with an incline above 10 degrees, while ASTM works to revise the voluntary standard. However, the task group does not plan to ballot the requirement that all infant sleep products meet the bassinet standard, because an ASTM task group is attempting to identify minimum safe sleep requirements that could apply to infant sleep products to include in F3118. Staff is participating in this effort as well, but, based on the assessment in this draft final rule, does not believe that requirements that are different and less stringent than the requirements in the bassinet standard will adequately address the risk of injury associated with infant sleep products.

Section 104 of the CPSIA requires CPSC to consult regarding the effectiveness of the voluntary standard; it does not require CPSC to consult on the timing of rulemaking, the content of a rule outside the rulemaking process, or to delay rulemaking until ASTM members achieve consensus. Moreover, stakeholders have now had sufficient time to consider and comment on the Mannen Study, which has been available on CPSC's website as an attachment to Staff's 2019 SNPR Briefing Package since October 2019, and how to address hazards associated with products within the scope of the 2019 SNPR, through the rulemaking and the ASTM processes. Despite having a year and a half to make progress through the ASTM process, stakeholders have not achieved consensus on how to move forward. When ASTM members do not have, or cannot achieve, consensus on whether or how a voluntary standard can address associated hazards, product safety is not improved.

The Commission's statutory mandate under section 104 of the CPSIA is to ensure that durable infant or toddler product standards provide the highest level of safety for such products that is feasible. Accordingly, CPSC will not delay the draft final rule, and section 104 of the CPSIA does not require CPSC to delay under the circumstances.

Comment 37: A commenter states that the scope of the 2019 SNPR includes many different types of products, with different sizes, age capacities, breathability, firmness, geometry, perceived usage, and different warnings. The 2019 SNPR did not explain CPSC's rationale to include all of these products under ASTM F3118 and to conclude that all of these products are unsafe.

Staff Response 37: The 2019 SNPR stated that the rule applied to all infant sleep products not covered by an existing CPSC sleep standard, including products with an incline less than 10 degrees, as outlined in response to comment 34. CPSC staff has been participating on the ASTM committees for bassinets and inclined infant sleep for many years about the hazards associated with products that would fall within the scope of the draft final rule. The inclined sleep product standard and the developing in-bed sleeper standard both evolved from the bassinet standard, and ASTM is currently trying to create new requirements in the bassinet standard to accommodate designs of certain flat infant sleep products. Accordingly, stakeholders understand

the scope of products addressed in the 2019 SNPR and the draft final rule, ASTM's efforts to modify the bassinet requirements to accommodate these products, and CPSC staff's objection to modification of the safe sleep requirements in the bassinet standard. To address comments on the 2019 SNPR, the draft final rule includes additional incident data and analysis to demonstrate that the performance and labeling requirements of the bassinet standard would address the risk of injury associated with unregulated flat and inclined infant sleep products.

Comment 38: A commenter states that CPSC followed the process set forth in section 104 of the CPSIA when it issued the 2017 NPR to incorporate by reference into a mandatory rule, ASTM F3118. The commenter notes that the NPR was substantially the same as the voluntary standard, and that CPSC staff consulted with representatives from consumer groups, juvenile product manufacturers, and independent child product engineers and experts, to examine and assess the effectiveness of ASTM F3118, as required by section 104 of the CPSIA. The commenter states, however, that the 2019 SNPR for infant sleep products did not meet these two requirements in the CPSIA. Instead of consulting with consumer groups, manufacturers, and product safety experts through the section 104 process, CPSC staff "informed" stakeholders about the Commission's change in direction at the October 2019 ASTM committee meetings, after the 2019 SNPR was already issued. Moreover, although CPSC staff remains engaged in the ASTM F3118 subcommittee, their engagement is in support of the 2019 SNPR. The commenter maintains that the 2019 SNPR was not a collaborative effort, and that the CPSC did not consult with stakeholders before issuing the 2019 SNPR. The commenter states: "The stakeholder community, impacted and potentially impacted manufacturers, are in the very unfortunate position of being subject to a mandatory rule that they had no part in helping to craft, by way of the ASTM development process." The commenter also suggests that CPSC staff has acted in an "ultra vires manner to sanitize from incline sleep products" that are otherwise subject to an existing standard and to the rulemaking. The commenter recommends that the CPSC issue another SNPR to clarify the scope of the rulemaking and evaluate and mitigate any unintended consequences, and to allow time for stakeholders and CPSC staff to work through the ASTM process to examine the impact of the proposed rule. Another commenter similarly urges the Commission to proceed in accordance with section 104 of the CPSIA by working with ASTM to develop a standard with a clearly defined scope, clear definitions, and creation of performance requirements based on specific product types within the infant sleep product category. This approach would require working with ASTM, and then reissuing an SNPR, before proceeding with a final rule.

Staff Response 38: Section 104(b)(1) of the CPSIA requires the Commission to: "(A) in consultation with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts, examine and assess the effectiveness of any voluntary consumer product safety standards for durable infant or toddler products;" and (B) in accordance with the informal notice and comment rulemaking requirements under section 553 of the Administrative Procedures Act (APA), "promulgate consumer product safety standards that – (i) are substantially the same as such voluntary standards; or (ii) are more stringent than such voluntary standards, if the Commission determines that more stringent standards would further reduce the risk of injury associated with such products."

The regulated community participates in the rulemaking process by commenting on a proposed rule. Neither section 104 of the CPSIA nor the APA requires that stakeholders craft a CPSC mandatory rule. CPSC is required to consult regarding the effectiveness of the voluntary standard and to promulgate rules. As set forth in section V.A.3 and V.B.2 of this preamble, CPSC staff has been consulting about the effectiveness of the voluntary standards at issue, infant inclined sleep products and bassinets and cradles, for many years, through participation with the relevant ASTM subcommittees and task groups. For example, since ASTM began development of an infant inclined sleep product standard in or around 2011, CPSC has participated in the development of the standard. Similarly, CPSC staff has participated in the development and revisions to the bassinet and cradle standard since at least 2002. For both standards, CPSC staff has provided incident data, participated in subcommittee and task group meetings, and submitted comments and/or votes on ASTM ballots. For this draft final rule, CPSC has reviewed the incident data, hazard patterns, and the adequacy of the voluntary standards to address the risk of injury associated with products within the scope of the draft final rule, unregulated inclined and flat sleep products, and is promulgating a rule that is more stringent than the voluntary standard, as proposed in the 2019 SNPR, to further reduce the risk of injury associated with infant sleep products.

ASTM members have now had ample time to consider the hazards associated with infant sleep products, to comment on the 2019 SNPR, and to address associated hazards through revised voluntary standards. ASTM is still working on these issues and staff will continue working with ASTM to develop a voluntary standard that addresses the risk of injury associated with infant sleep products. If and when ASTM has revised ASTM F3118-17a, it may send the revised standard to CPSC to evaluate, through the update process set forth in section 104 of the CPSIA.

Comment 39: Commenters allege that the 2019 SNPR represents an unprecedented effort by CPSC to issue a mandatory rule that would create a pre-market testing and approval process for an entire product category. Commenters state that creating an omnibus rule that requires infant sleep products to meet the bassinet standard, instead of creating product specific standards, would have the unintended consequence of stifling innovation.

Staff Response 39: As with all of CPSC's regulations to set performance and labeling requirements, CPSC's mandatory rules for durable infant or toddler products set a floor for safe consumer products. CPSC does not require pre-market approval of consumer products, nor does the agency have the authority to do so. However, CPSC does have the authority to create mandatory performance requirements through rulemaking, and to require that all products offered for sale in the United States meet these requirements to protect consumers from injuries or death. When the Commission is aware of a gap in the regulatory framework for infant sleep products, the Commission can use its authority to address the associated hazards.

Mandating a standard for infant sleep products offered for sale in the United States that are not already within the scope of another CPSC sleep standard is not "unprecedented" and is no different than standards for other durable infant or toddler products that contain different product types within the same standard, such as strollers and high chairs, each of which include a variety of product types. No company can sell a stroller in the United States that does not comply with

the stroller standard, simply based on the type of stroller. Similarly, no company can sell a high chair in the United States unless it complies with the high chair standard. This is not a novel idea. The only difference in these product categories is how the voluntary standards evolved. The scope of the stroller and high chair standards are broad for the purpose of encapsulating all products. Standards for sleep products evolved on a different track. But the Commission is not required to continue a patchwork regulatory scheme that does not serve the interests of consumer safety. In this case, the Commission seeks to broaden the products that fall within the infant sleep product standard to set a floor for safe infant sleep. CPSC's mission is to protect consumers, and staff recommends using the agency's authority to protect the most vulnerable infants, up to 5 months old, and their unsuspecting parents, from sleep surfaces that do not follow known safe sleep principles, as set forth in the existing CPSC sleep standards. Accordingly, the Commission's effort in the 2019 SNPR is consistent with the CPSC's statutory mandate to protect consumers, and specifically, under section 104, to promulgate standards for product categories that the Commission determines to be of the highest priority, and to ensure that such standards provide the highest level of safety for such products that is feasible.

Because CPSC staff has been working with ASTM members on the bassinet and cradle subcommittee for years, on both inclined sleep products, as well as unregulated flat infant sleep products, ASTM members should be well aware of staff's efforts and concerns with both product types. Once CPSC issues an NPR, CPSC's docket on Regulations.gov includes a record of staff's participation through the ASTM process, and ASTM records should reflect this participation as well. CPSC's Office of the Secretariat maintains meeting logs summarizing staff's participation with external parties, such as ASTM, outside of the rulemaking process, and these meeting logs are searchable on CPSC's website.

Finally, performance and labeling requirements for consumer products allow for innovation with certain baseline safety requirements. While staff understands the concerns that innovation beyond the baseline safety requirements may be discouraged, staff notes the development of infant inclined sleep products as a prime example of innovation preceding safety. Infant inclined sleep products were first marketed as an innovative sleep solution for parents; however, no safety standard existed for these products when they were introduced to the market. Commenters to the 2010 NPR and 2012 SNPR for bassinets indicated that hammocks and inclined sleep products should have their own standard because they could not meet the requirements for bassinets, and parents were likely to create their own "unsafe" alternative if a regulated product was not available. The ASTM standards development process for inclined sleep products took many years before the standard was published in 2015, and during that time, manufacturers were designing and selling innovative inclined products. As time went on, the hazards posed by inclined products became apparent in the accumulation of infant deaths and incidents associated with this product category. To avoid a repeat of this process, involving the most vulnerable infants, up to 5 months old, staff remains committed to developing an infant sleep standard that contains key elements of safe sleep, so that product innovation does not compromise safe sleep for infants up to 5 months old.

Comment 40: A commenter states that section 104 of the CPSIA does not permit the application of the bassinet standard to an open-ended and undefined scope of products. The commenter contends that section 104 requires the CPSC to consider specific product types,

characteristics, and hazards. The commenter states that the SNPR approach is “arbitrary” and “is a reversal of the Section 104 process” for existing and new products that are sleep products, but not bassinets or cradles. The commenter states that CPSC must clearly define the scope of the rule and the products that fall within the scope of the rule.

Staff Response 40: The draft final rule identifies product types that fall within the scope of the rule. The purpose of the rule is to regulate any product marketed or intended as a sleeping accommodation for an infant up to five months old that is not already regulated by another CPSC sleep standard. Accordingly, the scope of the rule is not “open-ended.” The draft final rule discusses incident data, hazard patterns, and the effectiveness of the bassinet standard to address identified hazard patterns, to demonstrate that the bassinet standard provides minimum safe sleep characteristics for infant sleep products.

Comment 41: A commenter states that to implement a rule that requires specific products to meet the requirements of the bassinet standard, CPSC must provide a rationale that is supported by “substantial evidence.” The commenter states that the 2019 SNPR did not provide a rationale for the application of the bassinet standard to specific products within the infant sleep product category.

Staff Response 41: As stated in response to comment 37, CPSC and stakeholders have been working through the ASTM process regarding requirements for unregulated flat and inclined sleep products for many years, as part of development of the bassinet standard. Accordingly, based on the 2019 SNPR and this ongoing work with ASTM, staff’s efforts have been to maintain the safe sleep requirements in the bassinet standard and apply them to all sleep products marketed and intended for infants up to 5 months old. In response to comments, the draft final rule more specifically identifies the unregulated flat sleep products that fall within the scope of the rule, provides incident data, identifies hazard patterns, analyzes the effectiveness of the bassinet standard to address the hazards, and compares the performance requirements in international standards to demonstrate that these products have hazard patterns that can be addressed by the requirements in the bassinet standard.

Comment 42: A commenter states that the Commission previously recognized the importance of product specificity in promulgating the product registration card rule, 16 CFR part 1130. Despite this, the commenter states that the 2019 SNPR failed to discuss which product types would be considered “durable infant or toddler products” for product registration card purposes, and “simply concludes in a circular fashion that infant sleep products are durable infant or toddler products.” The commenter believes that a specific rationale is required for each product to “independently qualify” as a durable infant or toddler product. The commenter concludes that under the APA, the CPSC must specifically define products that fall within an “infant sleep product” in another SNPR before it can issue a final rule.

Staff Response 42: The preamble for the draft final rule identifies product types that fall within the scope of the rule. However, the draft final rule purposely does not define product types by name in the regulation text, and instead identifies product types by purpose and age limit, to ensure that all infant sleep products meet minimum safe sleep requirements in the bassinet standard, including existing products and future products. Section 104(f)(1) of the CPSIA does

not require any further product type specificity to identify these products as durable infant or toddler products. The statute defines a durable infant or toddler product as “a durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years” and then provides a list of products that are durable infant or toddler products. The Commission’s implementing rule at 16 CFR § 1130.2(a) states:

DEFINITION OF DURABLE INFANT OR TODDLER PRODUCT means the following products intended for use, or that may be reasonably expected to be used, by children under the age of 5 years. The listed product categories are further defined in the applicable standards that the Commission issues under section 104(b) of the Consumer Product Safety Improvement Act of 2008, and include products that are combinations of the following product categories:

Based on this definition in part 1130, a product marketed or intended as a sleeping accommodation for an infant up to 5 months old is a durable infant or toddler product. Because the products are intended for infants up to 5 months old, the products are “intended for use,” and “reasonably expected to be used,” by children under 5 years old. Products intended for infant sleep are similar to products on the statutory list intended for infant sleep, such as cribs, and bassinets and cradles. And, “infant sleep products” are further defined in the draft final rule. Accordingly, adding “infant sleep products” as a durable infant or toddler product is consistent with the Commission’s approach of adding a durable infant or toddler product category with a mandatory standard to the list of products in part 1130, to clarify that these products must meet the product registration rule, and the testing and certification requirements for durable infant or toddler products.

Comment 43: A commenter contends that the creation of specific types of infant sleep products is not by the Commission’s choice, but required by section 104 of the CPSIA. The commenter states that Congress purposely listed different types of infant sleep products separately in section 104, because “differences between these products warrant individual consideration in any rulemaking proceeding,” and that this principle is true with the remaining infant sleep product types.

Staff Response 43: The commenter offers no legislative history to support the idea that Congress listed sleep products separately because product differences warranted individual rulemaking proceedings. The products listed as durable infant or toddler products are examples of durable infant or toddler products that Congress expected the CPSC to regulate by issuing a mandatory standard. Most of these products had existing voluntary standards in 2008 when Congress passed the CPSIA. Congress gave CPSC the authority to add products to the list of durable infant or toddler products, gave the CPSC the mission to protect consumers, and instructed the CPSC to “periodically review and revise the standards set forth under this subsection to ensure that such standards provide the highest level of safety for such products that is feasible.”

Flat products that are subject to the draft final rule are not currently defined or covered by any existing ASTM standard. If CPSC could not use its authority to expand the scope of a rule to include such products, especially when staff’s analysis demonstrates that the existing bassinet

and cradles standard would address the risk of injury associated with such products, ASTM could dictate when and if durable infant or toddler products are regulated by CPSC. Similarly, when products fall within an ASTM standard, CPSC should not be bound by ASTM's categorization of such products if CPSC can demonstrate that the voluntary standard is inadequate to address the risk of injury associated with the products, but another voluntary standard would be adequate.

Comment 44: A commenter states that the CPSC must not only specifically identify product types that fall within the infant sleep product category, but must also provide the rationale for applying the bassinet and cradle standard requirements to each product type within the category, as well as establishing the product type is a durable infant or toddler product. The commenter contends that this analysis must identify the specific characteristics for each product type and the related hazards, to describe how the bassinet standard would address each hazard pattern. The commenter contends that a requirement that may be applicable to one product type may not be applicable to another product type. The commenter contends that “[n]o broad product category to date has ever been subject to a rule without such specificity.” The commenter states this level of specificity is required to avoid banning existing safe products or chilling future innovation.

Staff Response 44: As set forth in response to comment 34, the 2019 SNPR provided notice that the rulemaking included flat infant sleep products, and multiple other efforts, including those at ASTM, reinforced this. In response to comments, the preamble to this final rule provides further clarity, identifying product types that fall within the scope of the rule, including inclined and flat sleep products, as well as associated incident data and hazard patterns. The final rule also provides an analysis demonstrating that the requirements of the bassinet standard are adequate to address each risk of injury associated with infant sleep products, both flat and inclined product types. As set forth in response to comment 39, staff disagree that a rule under section 104 of the CPSIA cannot have a scope that is broader than one product type. For example, many types of carriages and strollers fall within the Safety Standard for Carriage and Strollers. Strollers offered for sale in the United States must meet the requirements in this regulation, regardless of product type.

The Commission's statutory mandate under section 104 of the CPSIA is to ensure that durable infant or toddler product standards provide the highest level of safety for such products that is feasible. Congress specifically included five products intended for infant sleep in the statutory list of durable infant or toddler products (full-size cribs, non-full-size cribs, play yards, and bassinets and cradles), demonstrating intent for CPSC to regulate such products. Currently, multiple flat and inclined sleep products are not subject to a CPSC regulation, but CPSC has the authority to add “infant sleep products” as a durable infant or toddler product, and to regulate this product category. Accordingly, the draft final rule regulates any product marketed or intended as a sleeping accommodation for an infant up to 5 months old, that is not already regulated by another CPSC sleep standard. In response to comments, the draft final rule expands the justification from the SNPR to demonstrate that the bassinet standard provides the minimum safe sleep characteristics for these infant sleep products. Finally, the scope of the final rule is well-defined, and allows a manufacturer to intentionally design and market a product as an infant sleep product, or to choose not to design and market a product as an infant sleep product.

TAB B: Epidemiological Data on Infant Sleep Product-Related Deaths, Injuries, and Potential Injuries

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

Memorandum

Date: February 24, 2021

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

THROUGH: Stephen J. Hanway
Associate Executive Director
Directorate for Epidemiology

FROM : Risana T. Chowdhury
Division of Hazard Analysis
Directorate for Epidemiology

SUBJECT : Epidemiological Data on Infant Sleep Product-Related Deaths, Injuries, and Potential Injuries¹

This memorandum provides incident data in support of a draft final rule for infant sleep products. The memorandum contains two sections. The first section updates the data presented in the October 2019 Infant Sleep Products supplemental notice of proposed rulemaking (2019 SNPR) briefing package. As done in that earlier package, the data in this section pertains only to infant *inclined* sleep products. In response to comments, the second section of this memorandum presents data that pertains to infant sleep products that do not fall within the scope of any other mandatory CPSC standard for infant sleep products (16 CFR parts 1218, 1219, 1220, 1221, or 1222).

I. Infant Inclined Sleep Products

The 2019 SNPR briefing package covered infant inclined sleep products-related incident data through June 30, 2019. In this memorandum, staff of the Directorate for Epidemiology in U.S. Consumer Product Safety Commission (CPSC) extracted data for incidents reported to have occurred between July 1 and December 31 of 2019 and all of 2020. In addition, staff also

¹ This analysis was prepared by CPSC staff. It has not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.

includes any new reports of incidents from the first half (January – June) of 2019.² Staff's incident characterizations are based on anecdotal incident reports received by CPSC staff. The number of emergency department (ED) treated injuries associated with infant inclined sleep products, for the time frame covered, was insufficient for staff to derive any reportable national estimates.³ Hence, staff does not present injury estimates in this memorandum. However, staff presents the emergency department-treated injuries in the total count of reported incidents.

Incident Data⁴

In the 2019 SNPR, staff had identified 451 incidents of which 59 were fatal, and 392 were nonfatal. Since the 2019 SNPR, CPSC staff received a total of 71 new incident reports related to infant inclined sleep products. Seventy percent of the new incidents are reported to have occurred between July 2019 and December 2020 (*i.e.*, after the timeframe covered in the 2019 SNPR); the remaining 30 percent are newly reported incidents that occurred in the earlier timeframe of January 2019 – June 2019. Manufacturer and retailer reports submitted through CPSC's "Retailer Reporting Program" serve as the *only* source of information for 42 percent (30 out of 71) of the incidents. Of the 71 reported incidents, 10 are fatalities; among the remaining 61 nonfatal incidents, 17 reported an injury. Because reporting is ongoing, staff considers 2019 and 2020 data incomplete. The number of reported fatalities, nonfatal injuries, and non-injury incidents may change in the future. Table 1 provides the breakdown of the incidents by year.

² Not all of these incidents are addressable by an action the CPSC could take. It is not the purpose of this memorandum, however, to evaluate the addressability of the incidents, but rather, to quantify the number of fatalities and injuries reported to CPSC staff and to provide, when feasible, estimates of emergency department-treated injuries.

³ According to the NEISS publication criteria, an estimate must be 1,200 or greater, the sample size must be 20 or greater, and the coefficient of variation must be 33 percent or smaller.

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

Dates of extraction were 12/23/2020 for the 2019 data and 1/14/2021 for the 2020 data. All data coded under product codes 5037 (hammocks), 1537 (bassinets/cradles), 1513 (playpens), 1529 (portable cribs), 1542 (baby mattresses or pads), 1553 (portable baby swings), and 1558 (baby bouncer seats) were extracted, and keyword searches were used to identify the potentially in-scope cases. Upon careful joint review with CPSC's Directorates for Engineering Sciences and Economics, many cases were considered out-of-scope for the purposes of this memorandum. For example, cases with SIDS or other pre-existing medical conditions as official cause of death and no additional circumstantial information was available were excluded from this analysis. However, all incidents where hazardous environments in and around the infant inclined sleep product resulted in fatalities, injuries, or near-injuries were retained. With the exception of incidents occurring on U.S. military bases, all incidents that occurred outside of the U.S. have been excluded. To prevent any double-counting, when multiple reports of the same incident were identified, they were consolidated and counted as one incident.

**Table 1: Infant Inclined Sleep Product-Related Incidents in 2019 - 2020
Reported since 2019 SNPR**

<i>Incident Year</i>	<i>Number of Reported Incidents</i>		
	<i>Total</i>	<i>Injuries (Hospitalizations)</i>	<i>Fatal</i>
2019* – Reported since SNPR	50	10(4)	9
2020*	21	7(0)	1
Total	71	17(4)	10

Source: CPSC epidemiological databases CPSRMS and NEISS.

Note: * indicates data collection is ongoing.

Thirty incident reports provided the victim’s age, of which 18 involved a fatality or injury. Table 2 provides the age breakdown among the 71 incident reports.

**Table 2: Age Distribution in Infant Inclined Sleep Products-Related Incidents in 2019 - 2020
Reported since 2019 SNPR**

<i>Age of Child</i>	<i>All Incidents</i>		<i>Injuries and Fatalities</i>	
	<i>Frequency</i>	<i>Percentage</i>	<i>Frequency</i>	<i>Percentage</i>
Unreported*	41	58	9	33
One – Five Months	24	34	15	56
Six – Eight Months	4	6	3	11
Nine – Twelve Months	2	3	--	--
Total	71	100	27	100

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

* Age may be “unreported” under two circumstances: age was unknown or age was not reported because the incident involved no injury.

Fatalities

Ten fatalities, associated with the use of an infant inclined sleep product, are reported to have occurred during the time period from January 1, 2019 through December 31, 2020; this only includes data reported since the 2019 SNPR.

- Three of the 10 fatality reports describe infants placed supine (on their back) in a rocker-like sleeper product but who ended up rolling over, fully or partially, resulting in suffocations or positional asphyxiations. Staff does not know whether restraints were used in all of these cases. All three decedents were 3- or 4-months old.
- One report describes a fatality involving a foam-type reclined infant seat. The seat was placed on an adult bed where the parents were also asleep. The seat was found tipped over on the floor with the 4-month-old decedent underneath.
- One incident reports a fatality of a 3-month old, found supine in an infant rocker-like product (in the same position as originally placed) with a blanket covering the face.
- Five remaining fatality 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. Of the known ages, the decedents ranged in age from 1- to 6-months.

Nonfatal Incidents

Since the 2019 SNPR, CPSC staff has received reports of 61 nonfatal incidents associated with the use of an infant inclined sleep product that occurred between January 1, 2019 and December 31, 2020. Among them, 17 report an injury. The severity of the 17 injuries are as follows:

- Four infants required hospital admissions. Three of the hospitalizations were for respiratory problems suffered due to mold on the sleep product, and one was for treatment of injuries due to a fall when an accessory-type product collapsed.
- Three infants were treated and released from emergency-departments. These infants were treated for respiratory problems due to exposure to mold or fall injuries.
- Ten infants required other medical care, mostly for *plagiocephaly* (flat head syndrome), *torticollis* (twisted neck syndrome), or both conditions, associated with prolonged use of inclined sleep products; two of the 10 infants suffered minor bumps/bruises due to falls or near-falls.

The remaining 44 incidents reported no injuries or provided no information about any injury. However, many of the descriptions indicated the potential for a serious injury or even death.

Hazard Patterns

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 level floor. Incident reports indicate that these products are not always placed on a level floor. Other inclined products sit on top of larger nursery products as attachments. In the 2019 SNPR, CPSC staff identified eight hazard patterns among 451 reported incidents. The staff-identified hazard categories were: *Design Issues*, *Electrical Issues*, *Consumer Comments*, *Undetermined Issues (due to confounding information)*, *Structural Integrity Issues*, *Other Product-Related Issues*, *Infant Placement Issues*, and *Insufficient Information*. While the distribution of the data in this update varies somewhat, staff finds that the broader hazard categories are very similar to those identified in the 2019 SNPR. Following a CPSC-issued safety recall on infant inclined sleep products in April 2019, staff observed a surge of reports related to the recall; these reports are combined with other consumer comments in the categories below.

Below staff presents the hazard patterns identified among the 71 reported incidents (10 fatal and 61 nonfatal) associated with the use of infant inclined sleep products. As done in the past, the categories are presented in descending order of frequency:

1. **Consumer comments:** Thirty-one of the 71 reported incidents (44 percent) fall in 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 the April 2019 safety recall on inclined sleep products. Although one complaint describes a minor injury incident, none of the remaining reports indicate that an incident actually occurred.

2. **Design** of the infant inclined sleep product: Twenty-four of the 71 reported incidents (34 percent) are in this category.
 - a. Ten incidents report that infants rolled over—fully or partially—from their original supine (on their back) position. Although a few of the infants were strapped into the product, for others, the use of restraint is unreported. Reports describe infants as young as 1-month of age rolling over. Some parents/caregivers, who witnessed and reported some of the nonfatal incidents, were able to rescue distressed infants quickly; some of the other infants died due to suffocation or asphyxiation.
 - b. One infant stopped breathing temporarily due to difficulty in positioning his head correctly.
 - c. Eight incidents report that infants developed physical deformations, such as *plagiocephaly* (flat head syndrome) and/or *torticollis* (twisted neck syndrome), from extended product use.
 - d. According to five reported incidents, infants developed respiratory ailments due to the growth of mold on the product.

The design category includes three deaths, three hospitalizations, one ED visit, and eight non-hospitalized, non-ED injuries.

3. **Other product-related** issues: Four of the 71 incidents (6 percent) report other product-related issues, such as instability (posed by products that have completely or nearly flipped over) or lock/latch problem (*i.e.*, the sleep surface failed to remain in position during use). One of the three instability incidents was a fatality that occurred when a foam-type reclined seat tipped over and fell from the adult bed to the floor, trapping the decedent underneath. No injury is reported in this category.
4. Lack of **structural integrity**: Three of the 71 incidents (4 percent) report components breaking, such as the rail, hardware, or other unspecified part. This category includes one hospitalization and one non-ED-treated injury due to a fall.
5. **Electrical** issue: One of the 71 incidents (1 percent) reports describes an odor emanating from the product after a short period of use indicative of overheating; further investigation revealed molten plastic inside. No injury is reported.
6. **Non-product-related** issues: One of the 71 incidents (1 percent) reports a fatality in an unsafe sleep environment. A 3-month old was placed supine (on their back) in an infant rocker-like product with a blanket covering the face; the decedent was found in the same position, with the blanket still covering the face.
7. **Insufficient information**: Seven of the 71 incident reports (10 percent) contain insufficient information for staff to categorize them accurately. For five deaths, staff has no information on the circumstances of the deaths. Reports for two injuries in this category describe unspecified falls treated in hospital EDs, with no information on restraint usage.

Table 3 presents the distribution of the 71 reported incidents by the hazard patterns and severity of incidents.

**Table 3: Hazard Patterns and Incident Severity Associated with Infant Inclined Products
2019 – 2020 Incidents (Reported since 2019 SNPR)**

<i>Issues</i>	<i>Total Incidents</i>		<i>Deaths</i>		<i>Injuries</i>	
	<i>Count</i>	<i>Percentage</i>	<i>Count</i>	<i>Percentage</i>	<i>Count</i>	<i>Percentage</i>
Product-Related	63	89	4	40	15	88
<i>Comments/Concerns</i>	31	44	--	--	1	6
<i>Design</i>	24	34	3	30	12	71
<i>Other Product-Related</i>	4	6	1	10		
<i>Structural Integrity</i>	3	4	--	--	2	12
<i>Electrical</i>	1	1	--	--	--	--
Non-Product-Related	1	1	1	10	--	--
<i>Unsafe Sleep Environment</i>	1	1	1	10	--	--
Insufficient Information	7	10	5	50	2	12
Total	71	100	10	100	17	100

Source: CPSC epidemiological databases CPSRMS and NEISS. Percentages may not add to sub-totals and totals due to rounding.

II. Unregulated Flat Infant Sleep Products

In response to the 2019 SNPR, CPSC staff received numerous public comments regarding the safety of infant sleep products that do not fall within an existing CPSC sleep standard or a voluntary standard (referred to as “unregulated infant sleep products” in the rest of this memorandum) that are available in the marketplace. Staff completed a review of the CPSC epidemiological databases, CPSRMS and NEISS, in order to respond to these comments and concerns. This section of the memorandum characterizes the number of deaths and injuries and the types of hazards related to unregulated infant sleep products available in the marketplace that are currently not under the purview of any existing CPSC sleep standard, nor any voluntary standard. Staff’s characterizations are based on anecdotal incident reports received by CPSC staff. The number of emergency department (ED)-treated injuries associated with unregulated infant sleep products, for the covered time frame, is insufficient to derive any reportable national estimates.⁵ Hence, staff does not present injury estimates in this memorandum. However, staff includes ED-treated injuries in the total count of reported incidents.

⁵According to the NEISS publication criteria, an estimate must be 1,200 or greater, the sample size must be 20 or greater, and the coefficient of variation must be 33 percent or smaller.

Incident Data⁶

CPSC staff received a total of 183 incident reports related to unregulated infant sleep products available in the marketplace. These incidents reported a date of occurrence between January 1, 2019 and December 31, 2020. Unregulated infant sleep products include: in-bed sleepers, baskets (that can function as hand-held carriers as well), baby boxes, compact bassinets (most of which are portable for travel), and baby tents. Based on the descriptions in the incident reports received, some have soft, puffy sides along the sleep area perimeter; others have semi-rigid sides, with mesh or soft-padded sidewalls held in place by tubular structures along the perimeter. Baby boxes have cardboard walls, while baby tents have flexible wires which provide structural support for fabric/mesh tent walls. All of these unregulated sleep products are flat and come with mattress pads. Some have short legs; many can sit on the floor or can be used on a bed or a couch. The data show that some products were placed inside a standard-sized crib, play yard, or bassinet. In the reports received by CPSC, consumers referred to unregulated infant sleep products as “cribs,” “bassinets,” “cosleepers,” “cribettes,” “nests,” “pads,” or “positioners”. Because of the variety of terms used by consumers to describe these products—often unfamiliar to CPSC staff—the data search for this analysis was challenging and staff believes it possible that some relevant reports may have been missed. Moreover, reporting is ongoing and staff considers 2019 – 2020 data incomplete. The number of reported fatalities, nonfatal injuries, and non-injury incidents in this memorandum may change in the future.

Manufacturer and retailer reports submitted through CPSC’s “Retailer Reporting Program” serve as the *only* source of information for 73 percent (133 out of 183) of the incidents. Of the 183 reported incidents, 11 are fatalities; among the remaining 172 nonfatal incidents, 16 reported an injury. Table 4 provides the breakdown of the incidents over two years.

Table 4: Unregulated Infant Sleep Product-Related Reported Incidents in 2019 - 2020

<i>Incident Year</i>	<i>Number of Reported Incidents</i>		
	<i>Total</i>	<i>Injuries (Hospitalizations)</i>	<i>Fatal</i>
2019*	96	9(0)	6
2020*	87	7(2)	5
<i>Total</i>	<i>183</i>	<i>16(2)</i>	<i>11</i>

⁶ Dates of extraction were 12/23/2020 for the 2019 data and 1/14/2021 for the 2020 data. Both CPSRMS and NEISS databases were searched. Since there is no single product code or a set of product codes dedicated for these flat-surfaced, *other* sleep products, all data coded under product codes 1502 (baby changing tables), 1519 (car seats for infants or children), 1526 (crib mobiles/gyms), 1548 (baby carriers, not specified), 1549 (other bay carriers), 1560 (baby slings and wraps), 1537 (bassinets/crib), 1513 (playpens), 1529 (portable cribs), 1542 (baby mattresses or pads), 1543 (cribs, non-portable), 1545 (cribs, not specified), and 4082 (toddler beds) were extracted. Age was limited to 12 months or under; keyword searches were used to identify and exclude the out-of-scope cases. Upon careful joint review with CPSC’s Directorates for Engineering Sciences and Economics, many cases were considered out-of-scope for the purposes of this analysis. For example, cases with SIDS or other pre-existing medical conditions as official cause of death (and with no other circumstantial information available) or cases where a criminal investigation was ongoing were excluded from this analysis. However, all incidents where hazardous environments in and around the infant sleep product resulted in fatalities, injuries, or near-injuries were retained. With the exception of incidents occurring on U.S. military bases, all incidents that occurred outside of the U.S. have been excluded. To prevent any double-counting, when multiple reports of the same incident were identified, they were consolidated and counted as one incident.

Source: CPSC epidemiological databases CPRMS and NEISS.

Note: * indicates data collection is ongoing.

Staff’s data search was limited to children aged 12 months or under because that is typically the manufacturer-recommended use age for these products. One hundred and fifteen incident reports provided the victim’s age; among them, 24 involved a fatality or injury. Table 5 provides the age breakdown among the 183 incident reports.

Table 5: Age Distribution in Unregulated Infant Sleep Products-Related Incidents in 2019 - 2020

<i>Age of Child</i>	<i>All Incidents</i>		<i>Injuries and Fatalities</i>	
	<i>Frequency</i>	<i>Percentage</i>	<i>Frequency</i>	<i>Percentage</i>
Unreported*	68	37	3	11
One – Five Months	89	49	19	70
Six – Eight Months	18	10	4	15
Nine – Twelve Months	8	4	1	4
Total	183	100	27	100

Source: CPSC epidemiological databases CPRMS and NEISS.

* Age may be “unreported” under two circumstances: age was unknown or age was not reported because the incident involved no injury.

Fatalities

Staff identified 11 fatalities associated with the use of unregulated infant sleep products that are reported to have occurred during the time period from January 1, 2019 through December 31, 2020.

- Seven of the 11 fatality reports describe a suffocation death.
 - A 1-month-old infant was found partially rolled over onto their side in a soft-sided compact bassinet/travel bed.
 - A 2-month-old infant was found completely rolled over the edge of an in-bed sleeper.
 - A 2-month-old was placed in an in-bed sleeper, in a prone position, stomach down, with his face turned to one side; he was discovered with part of his body outside the sleeper, face down on a blanket.
 - A 2-month-old infant was placed in a compact bassinet/travel bed on an adult bed with one of its sides leaning against the wall. According to the official report, the combination of the travel bed’s non-reinforced flexible bottom along with the soft surface of the adult bed allowed the infant to sink and become trapped between the bed and the wall.
 - A 3-month-old infant, in a hand-held basket that was placed on an adult bed, was found completely rolled over, face down, from her original supine position.
 - One 4-month-old infant was placed on his back in an in-bed sleeper which was placed inside a standard bassinet; the infant was discovered in a prone position.
 - A 7-month-old infant was wrapped in a blanket and placed supine in an in-bed sleeper. The infant was found rolled over in a prone position.
- A 1-month-old infant was placed in an in-bed sleeper inside a play yard. The official reports describe the decedent to have either suffocated on the puffy sides of the sleeper or to have been entrapped somehow and suffered positional asphyxia.

- A 7-month-old infant was placed in an in-bed sleeper for a nap; according to official reports, at some point, the infant got to the edge of the adult bed and became entrapped between the footboard and the mattress of the adult bed and died of positional asphyxia.
- Official reports deemed the cause and manner of death for two additional fatalities as undetermined. Both infants were 1-month-olds, one placed in a basket while the other in an in-bed sleeper.

Nonfatal Incidents

From among the 172 nonfatal reports, CPSC staff identified 16 injury reports associated with the use of unregulated infant inclined sleep products that occurred between January 1, 2019 and December 31, 2020. The severity of the injury type among the 16 injuries are as follows:

- Two infants required hospital admissions. One 8-day-old suffered unspecified breathing difficulties; another 2-month-old fell out of the in-bed sleeper and suffered head injuries when a sibling jumped onto the couch where the in-bed sleeper was situated.
- Ten infants, ranging in age from 1-month to 9-months, required ED visits following a fall out of the sleeper product; for most cases, the sequence of events leading to the fall was unreported; in two cases, the infant fell while being transported in the sleeper and in another case, the sleeper itself slipped off the adult bed it was sitting on. The injuries included various head injuries like skull fracture, closed head injury, and head contusion, or other injuries such as face abrasion and knee contusion.
- Four other injury incidents report an allergic reaction; a mold-related breathing difficulty episode; laceration of the nose on the rough mesh wall surface on the sleeper; and a fall when a sibling pulled the sleeper, which caused it to flip over. One of these infants needed repeated visits to a medical professional but the level of care received by the other infants is unspecified.

The remaining 156 incidents reported no injuries or provided no information about any injury. However, many of the descriptions indicated the potential for a serious injury or even death.

Hazard Patterns

Similar to the infant inclined sleep products, the hazard patterns reported for the unregulated infant sleep products varied according to the type and usage pattern of the product. Many of the products are new in the marketplace and consumers and safety advocates expressed concern about their safety. The hazard patterns identified among the 183 reported incidents (11 fatal and 172 nonfatal) associated with the use of these sleep products are presented below in descending order of frequency of the incident reports.

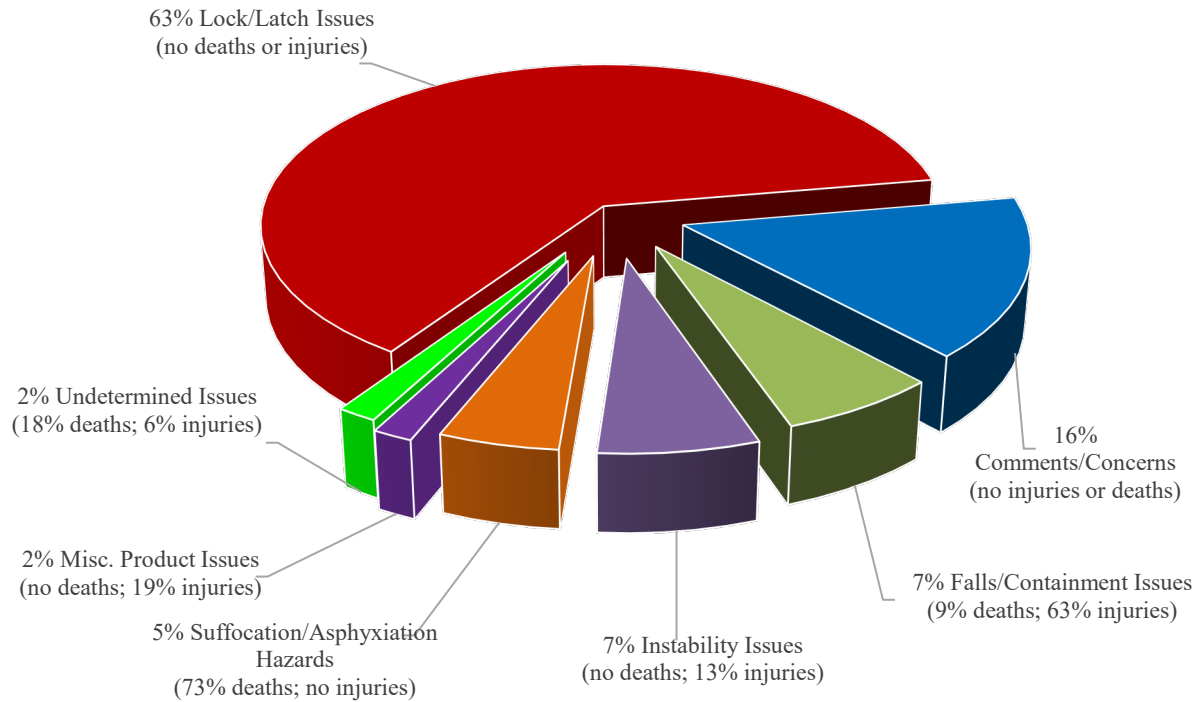
1. **Lock/Latch** problems: One hundred and fifteen of the 183 reports (63 percent) fall in this category. All but one of these reports pertain to different models of a particular stand-alone compact bassinet. The locking/latching mechanism that controls the opening/closing of the cover on the product failed. Some reports describe that the inability for the cover to open completely results in the product not lying flat. The single report about a different product describes a foldable sleeper not remaining flat; the unit

reportedly folds up while the baby is in the product. None of the reports mention any injuries.

2. **Comments/Concerns:** Twenty-nine of the 183 reports (16 percent) expressed consumers' or safety advocates' concerns about the perceived safety hazard of a product, non-compliance with the relevant standard(s) for which a product is being labeled, and/or misleading marketing statements about a product. None of the reports indicate that an incident actually occurred.
3. **Falls/Containment** issues: Twelve of the 183 incidents (7 percent) report an infant falling out of the product or an infant not being kept contained within the product. Examples include infants rolling out of a sleeper onto an adult bed and then onto floor; infant falling out of a sleeper when sibling jumped onto the couch containing the sleeper; infant crawling/rolling (unwitnessed) out of a sleeper and getting entrapped between an adult bed frame and mattress. This category includes one death, one hospital admission, and nine ED visits.
4. **Instability** issues: Twelve of the 183 reported incident (7 percent) describe problems with the product not remaining stable. The incident reports describe some products with legs lifting up higher or leaning on one side; other products have slipped off or flipped over from the adult beds/couches they were resting on. This category includes two reported injuries, one of which involved an ED visit.
5. **Asphyxiation/Suffocation hazard:** Nine of the 183 incidents (5 percent) fall into this category. The products were compact bassinets/travel beds, baskets, as well as in-bed sleepers, one of which was being used inside a standard bassinet and another, inside a play yard. All but one of the infants had rolled over from their initial position—either fully or partially; positional information is not available for one infant. Eight of the incidents were fatalities due to suffocation or positional asphyxia; one was a near-suffocation episode, with a parent nearby to rescue the infant.
6. **Miscellaneous product-related** issues: Three of the 183 incident reports (2 percent) are about mold or quality of the product material. Two of the three products were in-bed sleepers, while the third was a compact bassinet/travel bed. All three report an injury.
7. **Undetermined** issues: In three of the 183 incident reports (2 percent), staff could not definitively identify the issue involved. Two of the incidents were fatalities; in both cases, the CPSC Field investigation reports indicate that the cause of death is undetermined. The third incident resulted in a hospitalization due to unspecified breathing difficulties suffered by the infant.

Figure 1 presents the distribution of the 183 reported incidents by the hazard patterns and severity of incidents.

Figure 1: Distribution of Incident Reports Associated with Unregulated Infant Sleep Products by Hazard Pattern Characterizations January 1, 2019 – December 31, 2020



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

TAB C: Directorate for Engineering Sciences' Assessment of Infant Sleep Products: Standards, Regulations, and Hazards for the Draft Final Rule under the Danny Keysar Product Safety Notification Act

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C**



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

Memorandum

Date: April 19, 2021

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

Through: Caroleene N. Paul, Division Director
Division of Mechanical and Combustion Engineering
Directorate for Engineering Sciences

From: Kevin K. Lee, Mechanical Engineer
Division of Mechanical and Combustion Engineering
Directorate for Engineering Sciences

Subject: Directorate for Engineering Sciences' Assessment of Infant Sleep Products:
Standards, Regulations, and Hazards for the Draft Final Rule under the Danny
Keysar Product Safety Notification Act

I. INTRODUCTION

This memorandum supports the draft final rule for infant sleep products as proposed by the supplemental proposal rule (Supplemental NPR or 2019 SNPR) published in the *Federal Register* on November 12, 2019 (84 *Fed. Reg.* 60,949). The 2019 SNPR proposed to adopt the current voluntary standard, ASTM F3118-17a, *Standard Consumer Safety Specification for Infant Inclined Sleep Products*, with modifications that will make the mandatory standard more stringent than the voluntary standard. In support of the draft final rule, this memorandum provides a description of infant sleep products, an explanation of regulated and unregulated sleep products, a review of incident data and hazards, an assessment of the applicable voluntary standards, and a staff recommendation for the draft final rule.

II. BACKGROUND

A. Regulatory Action

On April 7, 2017, the Consumer Product Safety Commission (CPSC or Commission) published a notice of proposed rulemaking (NPR) for infant inclined sleep products in the *Federal Register*

(FR) (82 *Fed. Reg.* 16,963). The proposed rule incorporated by reference the then-current voluntary ASTM standard for infant inclined sleep products (ASTM F3118-17), with a modification to the definition of an “accessory inclined sleep product.” Based on subsequent information and events, the Commission issued a 2019 SNPR on November 12, 2019, proposing to adopt the current ASTM standard for infant inclined sleep products (ASTM F3118-17a), with substantial modifications that would make the mandatory standard more stringent than the voluntary standard. The proposed changes included expanding the scope of products to include all infant sleep products not already covered by another CPSC infant sleep product standard, limiting the seatback angle for sleep to 10 degrees or less, and requiring that all infant sleep products not already subject to one of five CPSC mandatory infant sleep product standards¹ comply with the bassinet standard specified in 16 CFR part 1218 *Safety Standard for Bassinets and Cradles*.

B. Recalls

From May 10, 2000, to August 20, 2019, CPSC conducted 13 consumer-level recalls involving infant inclined sleep products in response to hazards involving strangulation, suffocation, fall, structural reliability, entrapment, exposure to mold, and death. Since issuing the 2019 SNPR, CPSC conducted six additional recalls involving inclined infant sleep products in response to suffocation hazards.

C. Mannen Study

During the development of the Supplemental NPR, staff received 450 new incidents, 59 of which were deaths that occurred while in infant inclined sleep products. 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. Dr. Mannen’s study, *Biomechanical Analysis of Inclined Sleep* (Mannen Study), attached as Tab B of the 2019 SNPR, examined how the degree of a seatback angle affects an infant’s ability to move within the products and if those designs directly impact safety or present a risk factor that could contribute to the suffocation of an infant. The testing compared infants’ muscle movement and oxygen saturation on a flat crib mattress at 0 degrees, 10 degrees, and 20 degrees versus seven different inclined sleep products. The Mannen Study concluded that none of the inclined sleep products tested were safe.

The Mannen Study concluded that muscle activity for infants who rolled over in inclined sleep products with a 20-degree incline sleep surface was significantly different than in products with a 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 rolling from

¹ The five existing mandatory CPSC standards for infant sleep (collectively CPSC sleep standards) are:

- 16 CFR part 1218 - Safety Standard for Bassinets and Cradles,
- 16 CFR part 1219 - Safety Standard for Full-Size Baby Cribs,
- 16 CFR part 1220 - Safety Standard for Non-Full-Size Baby Cribs,
- 16 CFR part 1221 - Safety Standard for Play Yards, or
- 16 CFR part 1222 - Safety Standard for Bedside Sleepers.

a supine to prone position. The Mannen Study also concluded that inclined sleep products with a 10-degree incline sleep surface do not significantly impact infant motion or muscle activity. Based on the Mannen Study, staff concluded that 10 degrees is the maximum sleep surface angle that should be allowed for any product intended for infant sleep, similar to the requirements found in the EN 1130:2019 *Children's cribs*, EN 1466:2014 *carry cots*, and the AS/NZS 4385:96 *infant rocking cradles* international standards.

D. 2019 Supplemental NPR - Safety Standard for Infant Sleep Products

The 2019 SNPR proposed to incorporate by reference ASTM F3118-17a, *Standard Consumer Safety Specification for Infant Inclined Sleep Products*, with substantial modifications to address hazards in all infant sleep products. In the 2019 SNPR briefing package, based on the Mannen Study, staff concluded that 10 degrees is the maximum sleep surface angle that should be allowed for any product intended for infant sleep. Therefore, staff concluded that the voluntary standard for inclined sleep products (ASTM F3118-17a) did not adequately address hazards associated with infant inclined sleep products because the standard allows for products with seatback angle greater than 10 degrees. Accordingly, staff recommended the following substantial modifications of the standard to address associated hazards, including:

1. Modify the title, introduction, and scope of the standard to state that the purpose of the standard is to address infant sleep products not already covered by traditional sleep product standards.
2. Modify the definitions of “accessory,” “compact,” “infant inclined sleep products,” and “newborn inclined sleep products” to remove the term “inclined.”
3. Modify seatback angle so that the maximum allowable seatback angle intended for sleep must be equal to or less than 10 degrees in all positions recommended for sleep.
4. Add new requirement – accessory, compact, infant and newborn sleep products must meet 16 CFR 1218 – Safety Standard for Bassinets and Cradles.
5. Remove all the performance requirements, except for the above new or modified requirements.
6. Remove all test methods, except for maximum seatback angle.

For a full discussion of these recommendations, please see Tab C in the 2019 SNPR briefing package.

E. Activity on ASTM F3118-17a, *Standard Consumer Safety Specification for Infant Inclined Sleep Products*

Since the 2019 SNPR was published, ASTM has not updated ASTM F3118-17a to address hazards associated with inclined products, and despite proposed changes to the standard that ASTM balloted in December 2020, staff has no assurance that ASTM will be able to reach consensus on revising the standard in the near future. After the SNPR published in November 2019, the ASTM subcommittee for ASTM F3118 did not meet to address issues raised in the 2019 SNPR until August 26, 2020, following a July 16, 2020 letter² from CPSC staff. After

² <https://cpsc.gov/s3fs-public/IIISPLettertoASTM-07162020.pdf?6ntZUkyau.r2mlrQnM31s0B3g1EkUg.9>

staff's letter, the ASTM F3118 subcommittee established a task group to revise the standard's title, introduction, and scope.

In December 2020, the ASTM subcommittee introduced ballot F15-18 (20-1) to change the standard's title, introduction, and scope to include all infant sleep products (and not just inclined sleep products). The ballot sought to:

- Remove the word “inclined” throughout the standard.
- Include in the scope, products intended for infants up to 12 months old.
- Include in the scope, products marketed or intended to provide sleeping accommodations.
- Change the scope to include all infant sleep products that do not fall within the scope of an existing infant sleep product standard:
 - Full-Sized Cribs (F1169),
 - Bassinets (F2194),
 - Bedside Sleepers (F2906), and
 - Non-Full-Size Cribs/Play Yards (F406).
- Exempt crib mattresses from the scope of the standard.
- Limit the sleep surface in all positions to be 10 degrees or less.

However, in January 2021, the ballot did not pass due to six negative votes. The negative votes objected to a variety of different aspects of the ballot, including four broad categories:

1. That the proposal would discourage innovation and be too broad,
2. That the ballot appeared to allow products that fall under other sleep standards to opt to meet ASTM F3118 instead,
3. That the voter could not support changing the title, introduction, and scope without seeing the underlying requirements, and
4. Editorial comments.

The ASTM F3118 subcommittee discussed the ballot results at a meeting on January 27, 2021. During this meeting, ASTM members disagreed on the intent and consequences of changes to the voluntary standard, and the meeting ended without a consensus on a path forward. However, a task group to review safe sleep requirements across infant sleep product standards (the comparison task group) has met four times since the January 27, 2021 meeting. Based on the ballot results and the discussions in these ASTM meetings, staff advises that it is unlikely that ASTM will be able to move forward with changes to ASTM F3118 that address safe sleep requirements in the near term.³

Recently, on April 22, 2021, at an ASTM task group meeting on the title, introduction, and scope of the voluntary standard, task group members discussed balloting the proposed regulatory text

³ The ASTM task group approach is different than CPSC's approach in this draft final rule, because ASTM is attempting to put safe sleep requirements in ASTM F3118, rather than relying on the performance and labeling requirements in the bassinets and cradles standard. The Commission determines in this draft final rule that the performance and labeling requirements in the bassinet standard are the minimum safe sleep requirements for infant sleep products, so it remains unclear whether ASTM's approach can be successful. However, if the ASTM committee revises ASTM F3118-17a and notifies the Commission, the staff will evaluate the revised voluntary standard at that time.

in the 2019 SNPR for the voluntary standard, to prevent the sale of infant inclined sleep products that purport to certify to ASTM F3118-17a, meaning products with an incline above 10 degrees, while ASTM works to revise the voluntary standard to be more in line with the 2019 SNPR. However, the task group does not plan to ballot the 2019 SNPR requirement that infant sleep products meet the requirements of the bassinet standard, because ASTM is working to create minimum safe sleep requirements in a revised ASTM F3118 standard. Staff is participating in this effort as well, but, based on the assessment in this draft final rule, does not believe that requirements that are different and less stringent than the requirements in the bassinet standard will adequately address the risk of injury associated with infant sleep products.

III. PRODUCT DESCRIPTION

CPSC staff considers any product that is marketed or intended for infant sleep to be an infant sleep product. A variety of infant sleep products exist in the marketplace, and some are currently regulated by five CPSC mandatory standards for infant sleep products (together CPSC sleep standards):

- 16 CFR part 1218 – *Safety Standard for Bassinets and Cradles*,
- 16 CFR part 1219 – *Safety Standard for Full-Size Baby Cribs*,
- 16 CFR part 1220 – *Safety Standards for Non-Full-Size Baby Cribs*,
- 16 CFR part 1221 – *Safety Standards for Play Yards*, and
- 16 CFR part 1222 – *Safety Standard for Bedside Sleepers*.

However, some products, such as inclined sleep products and in-bed sleepers, are not regulated by an existing CPSC sleep standard. Moreover, in recent years, new products have entered the marketplace that are marketed for infant sleep, but are not within the scope of current CPSC sleep standards. Infant sleep products not covered by a CPSC sleep standard are currently unregulated products. These unregulated sleep products collectively include inclined sleep products, in-bed sleepers, baby boxes, compact/travel bassinets without handles or handholds, and infant travel tents. Hand-held bassinet/cradles are regulated as part of 16 CFR Part 1225, Safety Standard for Hand-Held Infant Carriers, but the standard does not address hazards associated with infant sleep; therefore, staff also includes these products as unregulated sleep products because many are marketed for infant sleep. The 2019 SNPR proposed to regulate all products marketed for infant sleep with requirements that address known hazards associated with infant sleep products, regardless of the title of the product.

A. Regulated Infant Sleep Products

Bassinets

ASTM F2194-16e1, *Standard Consumer Safety Specification for Bassinets and Cradles*, is the current voluntary standard for bassinets and provides performance and labeling requirements for this product. In October 2013, CPSC promulgated a mandatory standard for bassinets and cradles, codified at 16 CFR part 1218 (effective on April 23, 2014) (78 *Fed. Reg.* 63,019). Part 1218 incorporates by reference the earlier ASTM F2194-13 version standard with the following

modifications to the voluntary standard:

1. Clarify the scope of the standard to include multi-mode products in which a mode meets the definition of a bassinet/cradle (seat incline is 10 degrees or less from horizontal);
2. Modify the stability test procedure to require the use of a newborn CAMI dummy rather than an infant CAMI dummy;
3. Add stability requirements for removable bassinet beds;
4. Add more stringent mattress flatness performance requirements to limit measured angle to 10 degrees (versus 14 degrees allowed in ASTM F2194-13); or
5. Exempt bassinets that are less than 15 inches across from the mattress flatness requirement.

In 2016, ASTM approved and published revision ASTM F2194-16ε1 with new requirements to bring the voluntary ASTM standard in line with the mandatory standard for bassinets in 16 CFR part 1218. In developing ASTM F2194-16 ε1, ASTM harmonized the voluntary standard with all modifications specified in part 1218. In addition to including all modifications contained in part 1218, ASTM added:

1. additional clarification to further clarify that strollers that have a removable bassinet must be tested to the bassinet standard,
2. Minor formatting and editorial changes, and
3. An additional warning statement to be applied to bassinet bed products that are removable from the base/stand without the use of tools and that contains a lock/latch mechanism that secures the bassinet bed to the base/stand.

Staff's assessment of the additional changes, beyond harmonization with 16 CFR part 1218, are either non-substantive or an improvement in safety. For the exemption in item (5), staff assess that this exemption is neutral in safety. Therefore, to reduce confusion, staff will evaluate and discuss ASTM F2194-16ε1 in this memorandum. Staff recommends that CPSC update the reference in part 1218 to ASTM F2194-16ε1 as soon as feasible.

The scope of ASTM F2194-16ε1 includes products that “provide sleeping accommodations for an infant up to approximately 5 months in age or when the child begins to push up on hands and knees, whichever comes first.” The standard defines “bassinet/cradle” as a “small bed designed primarily to provide sleeping accommodations for infants, supported by free-standing legs, a stationary frame/stand, a wheeled base, a rocking base, or which can swing relative to a stationary base.” In addition, products with a sleep surface inclined greater than 10 degrees are not within the bassinet/cradle standard's scope. Bassinet and cradle attachments for non-full-sized cribs or play yards must meet the requirements in the bassinet/cradle standard.

Bedside Sleepers

ASTM F2906-13, *Standard Consumer Safety Specification for Bedside Sleepers*, is the current voluntary standard for bedside sleepers and provides performance and labeling requirements for this product. ASTM F2906-13 requires bedside sleepers to be tested to the voluntary standard for bassinets (ASTM F2194) before and after testing to the provisions in ASTM F2906-13. CPSC promulgated a mandatory standard for bedside sleepers, codified at 16 CFR part 1222 (effective

on July 15, 2014) (79 *Fed. Reg.* 2,581). Part 1222 incorporates by reference the ASTM F2906-13 (bedside sleepers) standard with modification to replace references to ASTM F2194 (voluntary standard for bassinets) with 16 CFR part 1218 (mandatory standard for bassinets).

ASTM F2906-13 defines a “bedside sleeper” as “a rigid frame assembly that may be combined with a fabric or mesh assembly, or both, used to function as sides, ends, or floor or a combination thereof, and that is intended to provide a sleeping environment for infants and is secured to an adult bed.” A “multi-mode product” is “a unit that is designed and intended to be used in more than one mode (for example, a play yard, bassinet, changing table, hand-held carrier, or bedside sleeper).” A bedside sleeper is intended to be secured to an adult bed to permit newborns and infants to sleep close by an adult without being in the adult bed. Bedside sleepers have a sleep surface that is at least 4 inches below the adult bed’s mattress level. The bedside sleeper side adjacent to the adult bed can be adjusted to a lower position, a feature that differentiates bedside sleepers from bassinets, where all four sides of a bassinet are the same height. Bedside sleepers are intended for use with infants up to the developmental stage when they can push up on their hands and knees (about five months). This is the same developmental range for the intended users of bassinets. Some bedside sleepers can be converted to four-sided bassinets when not attached to a bed, and must meet the bassinet standard when in the bassinet mode.

Full-sized cribs and Non-full-sized cribs

ASTM F1169-19, *Standard Consumer Safety Specification for Full-Size Baby Cribs*, is the current voluntary standard for full-size cribs and provides performance and labeling requirements for these products. CPSC promulgated a mandatory standard for cribs in 2010, codified at 16 CFR part 1219 (the current version of the standard became effective on October 28, 2019). ASTM F1169-19 defines “full-sized crib” as “a bed that is designed to provide sleeping accommodations for an infant that is intended for use in the home. A full-size crib has interior dimensions of $28 \pm 5/8$ inches (71 ± 1.6 centimeters) in width by $52 \frac{3}{8} \pm 5/8$ inches (133 ± 1.6 centimeters) in length. ASTM F1169-19 also covers bassinets, changing tables, or similar accessories to a crib that are in the occupant retention area when in the manufacturer’s recommended use position.

ASTM F 406-19, *Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards*, is the current voluntary standard for non-full-sized cribs and provides performance and labeling requirements for these products. CPSC promulgated a mandatory standard for non-full-size cribs in 2010, codified at 16 CFR part 1220 (the most recent version of the standard became effective January 20, 2020). The interior dimensions of the crib distinguish full-size cribs from non-full-size cribs. A non-full-size crib may be either smaller or larger than the dimension of a full-sized-crib or non-rectangular in shape. Non-full-size cribs include oversized, specialty, undersized, and portable cribs but do not include any product with mesh/net/screen siding, non-rigidly constructed cribs, cradles, car beds, baby baskets, or bassinets.

Play Yards

ASTM F406-19, *Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards*, is the current voluntary standard for play yards and provides performance and labeling

requirements for these products. CPSC promulgated a mandatory standard for play yards in 2012, codified at 16 CFR part 1221 (the most recent version of the standard became effective January 20, 2020). ASTM F406-19 (non-full-sized cribs/play yards) defines a “play yard” as a “framed enclosure that includes a floor and has mesh or fabric sided panels primarily intended to provide a play or sleeping environment for children. It may fold for storage or travel.” Play yards are intended for children who are less than 35 inches tall and cannot climb out of the product. Some play yards include accessory items that attach to the product, such as mobiles, toy bars, canopies, bassinets, and changing tables. The accessory item usually connects to the side rails or corner brackets of the play yard.

Table 1 summarizes CPSC sleep standards applicable to regulated infant sleep products.

Table 1: Regulated infant sleep products and applicable standards

Product	Voluntary Standard	Mandatory Standard
Bassinet/Cradle	ASTM F2194-16e1	16 CFR 1218
Bedside Sleeper	ASTM F2906-13	16 CFR 1222
Full-Size Crib	ASTM F1169-19	16 CFR 1219
Non-Full-Size Crib	ASTM F406-19	16 CFR 1220
Play Yard	ASTM F406-19	16 CFR 1221

B. Unregulated Infant Sleep Products

If finalized, the draft final rule would regulate infant sleep products on the market that are currently unregulated, to reduce the risk of injury associated with these products. Below staff describes unregulated infant sleep products.

Infant Inclined Sleep Products

ASTM F3118-17a, *Standard Consumer Safety Specification for Infant Inclined Sleep Products*, is the current voluntary standard for infant inclined sleepers and provides performance and labeling requirements for these products. CPSC issued an NPR in 2017, proposing to adopt the ASTM standard, with a modification to the definition of an “accessory inclined sleep product.” After a number of fatalities and subsequent recalls of infant inclined sleep products and the Mannen Study issued in 2019, CPSC issued an SNPR in 2019, assessing that ASTM F3118-17a is inadequate to address the risk of injury associated with these products, and proposing substantial modifications to the ASTM standard to require a seatback angle incline of 10 degrees or less, and require that all infant sleep products meet an existing CPSC sleep standard, or meet the bassinet standard. After considering the comments received on the 2019 SNPR, staff recommends finalizing the mandatory rule similar to the 2019 SNPR, with the following clarifications to the:

1. introduction to the standard, to better explain that the purpose of the standard is to reduce deaths associated with known hazards associated with infant sleep, including, but not limited to, seat back angle,
2. scope of the standard, to better explain that products subject to the rule are those infant sleep products that do not already meet one of the CPSC sleep standards,

3. scope of the standard, to exempt crib mattresses that meet the voluntary standard for crib mattresses, ASTM F2933, because a crib mattress is not used by itself and instead is used as the sleep surface in a crib, a product that already conforms to a CPSC sleep standard,
4. definition of “infant sleep product,” to state that the definition includes those products that are marketed or intended to provide sleeping accommodations for an infant up to 5 months old,
5. definitions section of the standard, to remove the definitions for “accessory inclined sleep product,” “compact inclined sleep product,” and “newborn inclined sleep product,” because these definitions are unnecessary based on the other modifications made to ASTM F3118-17a in the 2019 SNPR and the draft final rule, because these products are subsumed within the definition of an “infant sleep product,” and the revised standard does not contain any unique requirements for these products,
6. requirement for the “Maximum Seat Back Angle” to state that the seat back angle also refers to a “sleep surface angle,” to reduce confusion, because flat sleep surfaces do not have a seat back, and
7. requirement to meet the requirements of 16 CFR part 1218, Safety Standard for Bassinets and Cradles, including conforming to the definition of a bassinet/cradle, to reduce confusion and to clarify that infant sleep products must have a stand to meet the performance and labeling requirements in part 1218.

Attached in Appendix A is a “redline” version of ASTM F3118-17a with staff’s modifications as noted above.

ASTM F3118-17a currently states that an inclined sleep product has a seatback angle greater than 10 degrees and not exceeding 30 degrees. In addition, inclined sleep products can be categorized as frame-type, hammock, compact, and inclined sleep product accessories. However, few products meeting the current seatback angle description remain in the market after CPSC issued recalls of inclined sleep products in April 2019, based on 35 fatalities associated with infant suffocation.

The ASTM F15.18 subcommittee for inclined sleep products recently balloted modifications to ASTM F3118-17a to be more consistent with the modifications proposed in the 2019 SNPR, including changes to the title, introduction, and scope of the infant inclined sleep product standard to:


- Remove the word “inclined” throughout the standard,
- Include in the scope, products intended for infants up to 12 months old,
- Include in the scope, products marketed or intended to provide sleeping accommodations,
- Change the scope to include all infant sleep products that do not fall within the scope of an existing infant sleep product standard:
 - Full-Sized Cribs (F1169),
 - Bassinets (F2194),
 - Bedside Sleepers (F2906),
 - Non-Full-Size Cribs/Play Yards (F406),

- Exempt crib mattresses from the scope of the standard, and
- Limit the sleep surface in all positions to be 10 degrees or less.

This ballot did not pass, but the ASTM subcommittee has agreed that it will continue working to expand the scope as noted above to create a standard that will address known hazards associated with infant sleep. As stated above, however, staff is not confident that ASTM F3118 will be updated in the near term. Until such time, unregulated products remain on the market. Moreover, newer products that are not subject to any voluntary or mandatory standard could still come onto the market.

Table 2 summarizes the infant inclined sleep products and applicable standards.

Table 2: Infant inclined sleep products and applicable standards

Product	Voluntary Standard	Mandatory Standard	Example
Inclined sleep products	ASTM F3118-17a	None	

Infant Non-inclined (flat), Bassinet-sized Sleep Products

Staff is aware of a group of products with sleep areas that are slightly larger than an infant and with no incline angle to the sleep surface. Staff describes these products as flat bassinet-size sleep products as shown in Table 3. These products may have soft sides (*e.g.*, stuffed padded sides), rigid sides (*e.g.*, hard plastic, cardboard), or a rigid frame covered by fabric or mesh, but they all are marketed for use as an infant sleep product.

Soft-sided flat sleep products

Several types of flat, soft-sided sleep products are sold and often referred to as baby pods, soft-sided travel bassinets, in-bed sleepers, baby nests, or baby tents. The majority of these products are not included in the scope of any existing voluntary standard or mandatory CPSC sleep standard. Although a product intended for infant sleep may use the name “bassinet” in its title, unless the product meets the definition and scope of a bassinet as defined in the voluntary standard for bassinets, ASTM F2194, the product is not required to conform to the bassinet standard; and is therefore an unregulated infant sleep product.






Some hand-held carriers, referred to as Moses baskets (hand-held bassinets/cradles), that are intended to facilitate sleep, are regulated by 16 CFR part 1225 *Safety Standard for Hand-Held Infant Carrier*. However, part 1225 primarily addresses risks associated with these products when used as a carrier, and does not address hazards related to sleep. Therefore, hand-held carriers are unregulated with regard to sleep hazards. Some Moses baskets that attach to a stand are subject to the mandatory standard for bassinets (16 CFR part 1218) in this use mode.

In addition, baskets and carriage accessories that can be converted to a bassinet or cradle by attachment to a separate base/stand are also considered a bassinet/cradle when used with the base/stand and subject to the mandatory standard for bassinets 16 CFR part 1218.

Baby tents are infant-sized tents that can include a mattress pad. These products are not covered by an existing voluntary standard or CPSC sleep standard. Typically, a flexible spring wire is used for the structural supports of the fabric/mesh tent walls. They are marketed for sun protection and baby sleep.

Table 3 summarizes the soft-sided, flat, bassinet-sized products and the applicable standards.

Table 3: Soft-sided, Flat bassinet-sized products and the applicable standards

Product		Voluntary Standard	Mandatory Standard	Examples
<i>Soft -Sided, Flat, bassinet-sized products</i>				
Common Names	In-bed sleeper	none	None	
	Moses Basket (hand-held carrier)	ASTM F2050	16 CFR 1225	
	Moses Basket w/ stand	ASTM F2194	16 CFR 1218	
	Soft-sided travel bassinets w/o carry handle	none	none	
	Travel tent	none	none	




Rigid-sided, rigid-framed, flat, bassinet-sized infant sleep products

Rigid-sided and rigid-framed, flat, bassinet-sized infant sleep products can be free-standing

without legs or with short legs. These products sit on the floor and resemble a bassinet without a stand, but do not meet the ASTM F2194 definition or requirements of a bassinet and therefore are not within the scope of the bassinet standard. They include baby boxes and compact/travel bassinets with rigid sides or frames. A baby box is an open-top cardboard box with a fitted mattress pad.

Table 4 summarizes the rigid-sided and rigid-framed, flat, bassinet-sized products, and the applicable standards.

Table 4: Rigid-sided and rigid-framed, flat, bassinet-sized products and the applicable standards

Product		Voluntary Standard	Mandatory Standard	Examples
<i>Rigid-sided and rigid-framed, Flat, bassinet-sized products</i>				
Common Names	Compact (floor) bassinet	none	none	
	Baby Box	none	None	
	Hand-held carriers	ASTM F2050	16 CFR 1225	

IV. STANDARDS ASSESSMENT

A. Unregulated Infant Inclined Sleep Products

i. Hazard Pattern Categories

In the 2019 SNPR, CPSC staff reviewed 451 reported incidents involving inclined sleep products, which included 59 fatalities and 96 injuries. Staff identified seven hazards that involved deaths and injuries (in this analysis, staff did not consider patterns, such as consumer comments, that did not involve injuries or deaths):

- *Design issues* (31 percent). This hazard involved 19 deaths, 17 of which resulted from infants rolling over into a prone (face down) position. An additional 71 injuries were reported in this category, including five hospitalizations and four emergency

- department visits. Thirty-three percent of the reported incidents involved infants rolling from their original supine (on their back) position.
- *Electrical issues* (28 percent). This hazard involved no deaths and two reports of injuries.
 - *Undetermined* (8 percent). This hazard involved 28 deaths and six injuries. Among the 28 deaths, staff was unable to determine the product's role, but often unsafe sleep environment was cited as a co-contributing condition to sudden infant death syndrome (SIDS).
 - *Structural Integrity* (6 percent). This hazard involved no deaths and two injuries.
 - *Insufficient information* (4 percent). This hazard involved eight deaths and six injuries. The reports did not provide information on the circumstances of deaths and injuries involved unspecified falls.
 - *Other Product-Related Issues* (3 percent). This hazard involved no deaths and nine injuries. The category includes reports of instability (product tipping over) and inadequacy of restraints, and most of the injuries involved falls.
 - *Infant placement issues* (1 percent). This hazard involved four deaths and no injuries. Three of the four deaths involved infants placed in a prone position.

Since the 2019 SNPR, CPSC staff received a total of 71 new incident reports related to infant inclined sleep products. While the distribution of the data in this update varies somewhat, staff finds that the broader hazard categories are very similar. The 71 new reports included ten fatalities and 17 injuries. Of the ten fatalities, three deaths involved an infant who rolled from a supine position, one death involved an overturned sleeper, one death involved infant placement with a blanket, and five deaths did not have reports with information on the circumstances of the death. Of the 17 injuries: 12 involved design issues, two involved structural integrity, and two involved unspecified falls.

ii. Assessment of ASTM Standards in Addressing Hazards

Below, staff summarizes the hazard patterns associated with deaths and injuries from all 522 incident reports related to infant inclined sleep products received and reviewed since the NPR. Staff did not consider patterns, such as consumer comments, that did not involve injuries or deaths. The 522 incidents involve 69 deaths and 113 injuries. Staff assesses the adequacy of the voluntary standard for infant inclined sleep products (ASTM F3118) and the adequacy of the voluntary standard for bassinets (ASTM F2194) in addressing hazards associated with injuries and deaths.

In the 2019 SNPR, staff determined that ASTM F3118-17a (*inclined sleep products*) is not adequate to address the risk of injury associated with the incline of sleep products, because the standard allows for products with a seatback angle greater than 10 degrees. The majority of deaths (in which the circumstances were known) were due to suffocation after the infant rolled over in the product and the same hazard pattern was reported in non-fatal incidents. Staff, therefore, recommended that CPSC's mandatory standard modify ASTM F3118-17a to limit the seatback angle for all infant sleep products to 10 degrees or less, and to replace the performance requirements with the performance requirements in part 1218 (*bassinets*)

(which incorporates by reference ASTM F2194-13 *Standard Consumer Safety Specification for Bassinets and Cradles with modifications*).

Hazard: Design Issues

When combining the data from the 2019 SNPR and the data since the SNPR, the “design issues” hazard is associated with 22 deaths and 83 injuries. At least 20 deaths involved infants rolling into a prone position (face down) and suffocating. Over a third of the incidents also reported that infants rolled over—fully or partially—from their original supine (on their back) position.

In the 2019 SNPR, staff concluded that a flat sleeping surface that does not exceed 10 degrees from horizontal offers infants the safest sleep environment. This conclusion was based on findings from the Mannen Study. The Mannen Study found that muscle activity for infants who rolled over in inclined sleep products with a 20-degree incline sleep surface was significantly different than in products with a 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. The Mannen Study also found that inclined sleep products with a 10-degree incline sleep surface do not significantly impact infant motion or muscle activity. While some comments to the 2019 SNPR stated that more testing should be done to determine if the maximum angle for safe sleep may be between 10 degrees to 20 degrees, the Mannen Study suggested if future work were done on safe sleep angles, one area of study would be additional biomechanical testing to determine “which, if any, angles between 10-and 20-degrees may be safe for infant sleep.”

The Mannen Study recommendations do not imply that an incline angle between 10 and 20 degrees may be safe, merely that if higher angles are considered, additional biomechanical testing is required. The Study also stated that its testing of awake infants was a limitation because “while the muscle use and motion may be similar, it is likely that infants who find themselves in a compromised position in an inclined sleep product during a nap or overnight sleep may not have enough energy or alertness to achieve self-correction and may succumb to suffocation earlier or more easily than infants who are fully awake.” Given the vulnerability of newborn infants and the precedence of fatalities of infants who were most likely asleep at the time of incidents in inclined products, staff concludes additional research of inclines above 10 degrees is unnecessary for the draft final rule. Based on the biomechanical results of the Mannen Study and its conclusion that 10 degrees is likely a safe incline for infant sleep, which supports the 10 degrees stated in the scope of F2194-16e1, staff concludes that 10 degrees is the maximum sleep surface angle that should be allowed for any product intended for infant sleep. In addition, other research⁴ has demonstrated a discernable difference in infant ability between 5, 7, and 10 degrees in a side-to-side tilt, which formed the basis of the 7 degree maximum sleep surface angle in Health Canada’s regulations. ESMC staff believes that it is unlikely additional research at angles higher than 10 degrees will alter staff’s conclusions that 10 degrees is the maximum safe incline.

⁴ Beal SM, Moore L, Collett M, Montgomery B, Sprod C, Beal A. The danger of freely rocking cradles. *J Paediatr Child Health*. 1995 Feb;31(1):38-40. doi: 10.1111/j.1440-1754.1995.tb02910.x. PMID: 7748688.

The current voluntary standard for infant inclined sleep products, ASTM F3118-17a, states that an inclined sleep product has a seatback angle greater than 10 degrees and not exceeding 30 degrees. Based on the Mannen Study, staff concludes that ASTM F3118-17a does not adequately address the risk of injury related to a sleep surface incline greater than 10 degrees because it does not limit the sleep surface to a safe incline angle. In comparison, the voluntary standard for bassinets, ASTM F2194-16ε1, defines a sleep surface as being less than or equal to 10 degrees, and includes performance requirements for mattress flatness that limits measured angles to 10 degrees or less.⁵ Therefore, with respect to sleep surfaces, staff concludes that all infant sleep products, including infant inclined sleep products, should meet the more stringent sleep surface angle requirement of the voluntary standard for bassinets, ASTM F2194-16ε1, to further reduce the risk of death from suffocation.

Hazard: Undetermined Product Issue

This hazard category is associated with 28 deaths and six injuries. Among the 28 deaths and injuries, staff was unable to determine the product's role. Without information on the product role in deaths or injuries, staff is unable to assess whether the voluntary standard for infant inclined sleep, ASTM F3118-17a, or the voluntary standard for bassinets, ASTM F2194-16ε1, would adequately address the hazards in this category.

Hazard: Insufficient Information

This hazard category is associated with 13 deaths and eight injuries. The reports did not provide information on the circumstances of deaths and injury reports involving unspecified falls. Without information on the circumstances of deaths or injuries, staff is unable to assess if the voluntary standard for infant inclined sleep, ASTM F3118-17a, or the voluntary standard for bassinets, ASTM F2194-16ε1, would adequately address the hazards in this category. Falls are discussed in more detail in "Other Product-Related Issues," below.

Hazard: Infant Placement

This hazard category is associated with five deaths and no injuries. Three of the deaths involved infants placed in a prone position and one death involved an infant placed in a supine position with a blanket covering the face. Based on the Mannen study, sleep surfaces with a 20-degree incline significantly increased the demand on abdominal muscles and could lead to increased fatigue and suffocation if an infant is unable to reposition themselves after rolling from a supine to prone position. In three of the deaths in this hazard category, the infant was placed in the prone position and the inclined sleep surface may have contributed to suffocation if the angle of the sleep surface led to fatigue that prevented the infant from rolling to a supine position.

While infants can die in flat products when placed to sleep in the prone position, based on the Mannen Study, an inclined surface could further contribute to deaths in the prone position. A

⁵ In the final rule for bassinets the Commission stated they intended to limit the scope of the bassinet standard to exclude all inclined products "when the incline is more than 10 degrees from horizontal." (78 Fed. Reg. 63,021),

sleep surface limited to a 10 degree or less incline, as required in the bassinet standard (ASTM F2194-16ε1), could reduce the risk of injury associated with the prone position, when compared to an inclined sleep product. Therefore, with respect to sleep surfaces, staff concludes that all infant sleep products, including infant inclined sleep products, should meet the more stringent sleep surface angle requirement of the voluntary standard for bassinets, ASTM F2194-16ε1, to further reduce the risk of death from suffocation.

Hazard: Other Product-Related Issues (instability, restraints, etc.)

This hazard category includes reports of instability (product tipping over) and containment; the category is associated with one death and nine injuries. One death occurred when a foam type reclined product tipped over and fell from the adult bed to the floor, trapping the infant underneath. Most of the injuries involved falls and at least 10 reports (with no injury reported) related to nearly or completely flipped over products.

The death, and most likely the injuries, relate to the stability of the product and how easy it is to tip the product over into a hazardous situation. The current voluntary standard for infant inclined sleep products, ASTM F3118-17a, includes two stability performance requirements that apply to *Compact Inclined Sleep Products* and *Infant or Newborn Inclined Sleep Products*. For the *Compact Inclined Sleep Products*, the product must remain upright when placed on a 20-degree inclined test platform. For the *Infant or Newborn Inclined Sleep Products*, a 23 lb. vertical force and 5 lb. horizontal force are applied to the product's side with a newborn CAMI dummy occupant to simulate an older sibling pulling up on the side to view the infant in the bassinet, and the product must remain upright containing the CAMI dummy. The *Compact Inclined Sleep Products* are exempt from the 23 and 5-pound force requirements, with the rationale that the compact product are intended to sit on a floor and are unlikely to have an older sibling attempt to pull up to see the infant inside.

The current voluntary standard for bassinets, ASTM F2194-16ε1 includes an identical stability requirement that applies a 23 lb. vertical force and a 5 lb. horizontal force to the product with a newborn CAMI dummy occupant, and this requirement applies to all products; it does not provide exemptions for *Compact Inclined Sleep Products* to only meet the less stringent 20-degree inclined test platform test. The rationale in ASTM F2194 states the dual application of forces simulates a 2-year old male pulling on the side of the product; staff concurs that sibling interaction is a reasonable scenario in which the product may tip over. Due to the portability of some of the unregulated compact sleep products, incident data confirms that the products are used on raised surfaces from which infants and product may fall. Therefore, with respect to the product's stability, staff recommends for the draft final rule that all infant sleep products, should meet the more stringent stability requirement of the voluntary standard for bassinets, ASTM F2194-16ε1, to further reduce the risk of injury from tip over of the product.

Hazard: Structural Integrity

This hazard category includes reports of some component failures on the product such as buckles/straps, hardware coming loose, hub/rail/leg coming loose, or other unspecified components breaking. This hazard category involved no deaths and four injuries. All injuries were related to falls, and include one hospitalization and three emergency department visits.

The current voluntary standard for infant inclined sleep products, ASTM F3118-17a, includes performance requirements to assess the integrity of inclined sleep products. The requirements specify a dynamic test in which an 18 lb. load, consisting of a 6 to 8-inch steel shot bag, is dropped 50 times from a height of 1.0 inch onto the seat surface. The requirements also specify a static test in which a 50 lb. load or three times the product's maximum recommended weight, whichever is greater, is gradually applied through a 6-inch square wooden block to the seat surface for 60 seconds. The current voluntary standard for bassinets ASTM F2194-16ε1 has a performance requirement to address structural integrity that specifies a static load test that applies a 54 lb. load or three times the manufacturer's recommended weight, whichever is greater, through a 6-inch aluminum block to the sleep surface for 60 seconds. The rationale in ASTM F2194 states 54 lbs. is three times the weight of the 95th percentile of a 3 to 5-month-old infant

Although the voluntary standard for infant inclined sleep products, ASTM F3118-17a, requires a dynamic test for structural integrity, its effectiveness in evaluating the product's strength is minimal compared to the static test. The load in the dynamic test being one-third of the static load, the low drop height, short test timeframe, and presence of energy-absorbing material (shot bag and flexible product material), combine to minimize the effect of this test on the product's structural integrity. In contrast, the static test applies a much larger load, three times the heaviest infant in the product, with a rigid applicator continuously for 60 seconds. Therefore, staff concludes the static test is the more stringent evaluator of product integrity.

The static load in ASTM F2194-16ε1 is 54 lbs., which is a more stringent load compared to the static load of 50 lbs. in ASTM F3118-17a. Therefore, to further reduce the risk of injury associated with structural defects, staff concludes that the static load test in ASTM F2194 is adequate to assess structural integrity of infant sleep products, and is more stringent than the static load test in ASTM F3118-17a. Therefore, for the draft final rule, staff recommends that all infant sleep products, including infant inclined sleep products, meet the more stringent structural integrity requirement of the voluntary standard for bassinets, ASTM F2194-16ε1.

Hazard: Electrical Issues

This hazard category involved no deaths and two reports of injuries related to electric shock. Non-injury incidents reported overheating/melting of components and issues with batteries. As noted in the 2019 SNPR, the infant inclined sleep products standard, ASTM F3118-17a, does not include any performance requirements for electrical components. In addition, the voluntary standard for bassinets, ASTM F2194-16ε1, does not address electrical hazards.

However, staff raised this issue with ASTM and the ASTM Ad Hoc task group is developing performance requirements to address electrical hazards across juvenile products. As these requirements are added during the ASTM voluntary standard updates, CPSC can review the updated voluntary standard pursuant to the update provision in P.L. 112-28 and determine whether to revise the mandatory standard based on a revised voluntary standard.

iii. Assessment of International Standards

EN1466:2014 Carry cots

The BS EN 1466:2014 *Child use and care articles- Carry cots and stands- Safety requirements and test methods* European standard applies to products intended for carrying a child in a lying position using a handle or stand. This standard applies to children who cannot sit unaided or roll over or push up on their hands and knees and is a maximum weight of 19.84 pounds.

Side height

For cots on a stand, EN 1466:2014 standard requires an internal height of at least 7.87 inches (200 mm) from the top of a mattress, compressed by a 19.84-pound (9kg) steel plate, to the lowest point of the upper edge of the sides. For carry cots, not on a stand, the standard requires an internal height 5.9 inches (150mm) to 7.09 inches (180mm), depending on the length of the cot, using the same test method. This requirement measures the internal side height when an occupant of the maximum weight compressed the mattress. This standard has a similar side height requirement to the ASTM F2194-16ε1 *bassinet* standard, which requires a minimum side height of 7.5" from an uncompressed mattress. For cots on a stand, if the mattress compresses more than 3/8 of an inch, ASTM F2194-16ε1 requires a higher side. For cots not on a stand, ASTM F2194-16ε1 has a higher side height of 7.5 inches from an uncompressed mattress, compared to the EN 1466:2014 requirement, which is 7.09 inches from a compressed mattress.. Additionally, ASTM F2194-16ε1 requires a consistent side height no matter the configuration.

Sleep surface angle

The EN 1466:2014 standard requires a maximum sleep surface angle of 10 degrees. This standard is a similar requirement to the ASTM F2194-16ε1 *bassinet* standard, which requires a maximum sleep surface angle of 10 degrees.

Latching requirements

The EN 1466:2014 standard requires the stand for products with a folding stand mechanism not to collapse after the latch is operated (closed and opened) 300 times, and a 44.96 pound-force (200N) is applied in the area of the stand most likely to cause the product to fold. The EN 1466:2014 standard's latching requirement only simulates the action of unintentionally folding the stand without the carry cot or box assembled on the

stand, while the ASTM F2194-16ε1 *bassinet* standard test both the stand and the bassinet as a fully assembled product.

The ASTM F2194 -16ε1 *bassinet* standard requires products without a latching or locking device not to fold when a 20 pound- force applied to the top edge of the bassinet in the direction most likely to cause it to fold. The ASTM F2194 -16ε1 *bassinet* standard requires a lower force than the EN standard but the force is applied at a higher location (top side of the bassinet) than the EN standard (force applied to the stand). The higher location of the force can create a higher torque at the latch due to the longer lever arm. For bassinets with a locking hinge or latch, the locking mechanism must withstand a 10-pound force in the direction most likely to release it. Determining which latching requirement is more stringent is difficult since the test parameters are not directly comparable. ESMC staff considers testing the product fully assembled, as required by ASTM, a better test because it simulates realistic use of the product.

The ASTM standard also includes a *Removable Bassinet Bed Attachment to Base/Stand* requirement and testing to address latching and locking devices intended to secure removable bassinet beds to the base/stand. These requirements and test are unique because they address known incidents of false latching of a removable bassinet bed. By considering the latching, unintentional folding and bassinet bed attachments to the stand requirements in total, staff concludes the ASTM F2194-16ε1 *bassinet* standard's latching requirements are adequate.

Stability requirements

The EN1466:2014 standard requires products with an occupant test mass of 15.43 pounds not to tip over when placed on a 20-degree surface. EN1466:2014 rationalizes this test by stating "Carry cots shall be designed so that they do not tip over when they are placed on slightly sloping ground or when the child leans against one side of the carry cot." This is different compared to ASTM F2194-16ε1 *bassinet* standard that requires the product (with simulated newborn occupant) to withstand a 23 lb. vertical force and 5 lb. horizontal force along its side without tipping. The rationale in ASTM F2194 states the dual application of forces simulates a 2-year old male pulling on the side of the product; staff concurs that this is a reasonable scenario in which the product may tip over. Determining which stability requirement is more stringent is difficult because both standard's torque arms are dependent upon the product's geometry. Using a 10 inch wide by 10 inch tall sidewall box on a 10 inch stand as a reference product for comparison, staff determined the reference product would fail the ASTM F2194 bassinet standard's test and pass the EN 1466 standard's test. Therefore, staff concludes the ASTM 2194-16ε1 *bassinet* standard's stability requirement is more stringent for this reference product.

EN1466:2014 Summary

The EN 1466:2014 Carry cots standard has similar side height and sleep surface angle requirement to ASTM F2194-16 ε1 *bassinet* standard. The ASTM F2194-16ε1 standard has a potentially more stringent stability requirement.

EN 1130:2019 Children's Cribs and Cradles

The European Standard, EN 1130-1: 2019 "Furniture – Cribs and Cradles for Domestic Use" has several requirements not found in ASTM F2194-16 ϵ 1. Most of these additional requirements address hazards associated with cribs intended for use with older children (in excess of the 5- month recommended maximum age for bassinets), and thus, they are not applicable to bassinets.

Side Height

The EN 1130:2019 standard requires a side height of at least 7.87 inches (200 mm) when a 19.84 pound (9kg) steel plate is placed on the compressed mattress. This measures the crib's internal side height with a 19.84 pound occupant is compressing the mattress. This standard has a similar side height requirement to the ASTM F2194-16 ϵ 1 *bassinet* standard, which requires a minimum side height of 7.5" from an uncompressed mattress. If the mattress compresses more than 3/8 of an inch, ASTM F2194-16 ϵ 1 requires a higher side.

Sleep surface angle

The EN 1130:2019 standard requires a maximum sleep surface angle of 10 degrees. This standard has a similar requirement to the ASTM F2194-16 ϵ 1 *bassinet* standard, which requires a maximum sleep surface angle of 10 degrees.

Latching requirements

The EN 1130:2019 standard requires folding products to contain a dual-action locking mechanism, unlock with a tool, fold only when the crib is lifted, or not to collapse after the latch is operated (closed and opened) 300 times and at least 11.24-pound-force (50N) is required to unlock it. The EN 1130:2019 standard's latching requirement only simulates the action of unintentionally folding the product's folding or adjustable legs, while the ASTM F2194-16 ϵ 1 *bassinet* standard test both the standard and the bassinet as a fully assembled product.

The ASTM F2194 -16 ϵ 1 *bassinet* standard requires products without a locking mechanism to withstand a 20 pound-force applied to the top edge of the bassinet in the direction most likely to cause it to fold. For products with a locking hinge or latch, the locking mechanism must withstand a 10-pound force in the direction most likely to release it. ESMC staff considers testing the product fully assembled, as required by ASTM, a better test because it simulates realistic use of the product.

The ASTM standard also includes a *Removable Bassinet Bed Attachment to Base/Stand* requirement and testing to address latching and locking devices intended to secure removable bassinet beds to the base/stand. These requirements and test are unique because they address known incidents of false latching of a removable bassinet bed. By considering the latching, unintentional folding, and bassinet bed attachments to the stand requirements in total, staff concludes the ASTM F2194-16 ϵ 1 *bassinet* standard's latching requirements are adequate.

Stability requirements

The EN1330:2019 standard requires products not to tip over when a 19.87-pound weight is placed on one side of the crib, while on the opposite side's top rail, a 6.74 pound-force is horizontally applied towards the weight. This test is similar to the ASTM F2194-16ε1 *bassinet* standard with reasonably similar forces. EN1330:2019 rationalizes the test, stating the product "should remain stable when the child moves in the crib or when the crib swings along the amplitude permitted by the suspension device." ASTM F2194-16ε1 is based on U.S. incident data of a 2-year-old sibling pulling over a bassinet, which is a more severe condition than an infant moving within the product; therefore, staff concludes the ASTM F2194-16ε1 bassinet standard's stability requirements are adequate.

EN 1130:2019 Summary

The EN 1130:2019 children's cribs and cradle standard has similar side height, sleep surface angle, and stability requirements compared to the ASTM F2194-16ε1 *bassinet* standard; however, the ASTM F2194-16ε1 standard has a more extensive and stringent latching requirement.

AS/NZS 4385:1996 Infant's rocking cradles

The Australian/New Zealand standard (AS/NZS 4385:1996) contains requirements for rocking and swinging angles used to develop some of the ASTM F2194-12 requirements. The ASTM rock/swing rest angle performance requirement is more stringent because the occupant surrogate, a CAMI dummy, is placed against the sidewall, resulting in higher rest angles.

Side Height

The AS/NZS 4385:1996 standard requires a minimum side height of 11.81 inches (300 mm) between the top of the mattress support to the top edge of the lowest rocking cradle's side. The maximum mattress thickness the AS/NZS standard permits is 2.95 inches (75mm). Therefore, the minimum side height between the top of the mattress and the top edge of the lowest side is 8.85 inches. This is similar to the ASTM F2194-16ε1 *Bassinet* standard which requires a minimum side height of 7.5 inches between the top of the mattress and the top of the lowest sidewall.

Sleep surface angle

The AS/NZS 4385:1996 standard requires the mattress angle on rocking cradles without a self-leveling device to not exceed 5 degrees and 10 degrees on rocking cradles with a self-leveling device. This is similar to the ASTM F2194-16ε1 *Bassinet* standard, which requires a maximum sleep surface angle of 10 degrees.

Latching requirements

The AS/NZS 4385:1996 standard does not contain any latching requirements to address the unintentional folding hazard. The ASTM F2194-16ε1 *bassinet* standard is more stringent by requiring products without a locking mechanism to withstand a 20-pound force without folding or a 10-pound force for hinges with locking mechanisms. The ASTM F2194-16ε1 also addresses the false latching of a removable bassinet bed with requirements including an automatic locking latch or a false latch indicator.

Stability requirements

The AS/NZS 4385:1996 standard requires a product not to tip over when a 19.84-pound (9 kg) weight is on the mattress and a 4.49 pound-force (20N) is horizontally applied to the uppermost rail. This test is similar to the ASTM F2194-16ε1 *bassinet* standard that requires the product (with simulated newborn occupant) to withstand a 23-pound vertical force and 5 lb. horizontal force along its side without tipping. The rationale in ASTM F2194 states the dual application of forces simulates a 2-year old male pulling on the side of the product; staff concurs that this is a reasonable scenario in which the product may tip over.

AS/NZS 4385:1996 Summary

The AS/NZS 4385:1996 infant's rocking cradle standard has a similar side height, sleep surface angle, and stability requirement to the ASTM F2194-16ε1 *bassinet* standard. However, the ASTM F2194-16ε1 *bassinet* standard has a more stringent latching requirement.

Canadian standard (SOR/2016-152) Cribs, cradles, and bassinets

The Canadian standard (SOR/2016-152) includes requirements for cribs, cradles, and bassinets. Staff focused this analysis on the requirements for bassinets, which is defined as providing sleeping accommodations for a child with sides to confine the child, and a sleep surface area less than or equal to 4000 cm² (620 in²).

Side Height

The Canadian standard requires a minimum side height of 230 mm (9.05 inches), measured from the mattress support. Because ASTM F2194 – 16 ε1 allows a bassinet mattress of 1.5 inches, measuring from the upper surface of the mattress support to the upper surface of the side would be 1.5 inches greater than measuring from the upper surface of an uncompressed mattress. Therefore, staff concluded that the 7.5 inch side height, from the upper surface of an uncompressed mattress is functionally equivalent to the 9 inch side height, measured from the upper surface of the mattress support in Canada.

Sleep surface angle

The Canadian standard requires the sleep surface angle not to exceed 7 degrees, which is based on a 1995 study that demonstrated a discernable difference in infant ability

between 5, 7, and 10 degrees in a side-to-side tilt. Staff understands that Health Canada selected 7 degrees and applied it to all sides of the product, regardless of head-to-toe or side-to-side tilt. ASTM F2194-16 ϵ 1 allows for a side-to-side resting angle of 7 degrees for rocking cradles, and limits head-to-toe angle to 10 degrees. As discussed in section IV. A, staff has concluded that a flat sleeping surface that does not exceed 10 degrees from horizontal offers infants the safest sleep environment.

Latching requirements

The Canadian standard requires folding products to contain an auto-locking mechanism that requires a dual simultaneous action to disengage and does not fold when a 52.91 pound (24kg) load is applied on any area most likely to damage the mattress support. While the Canadian standard requires an auto-locking mechanism that requires a dual simultaneous action to disengage, it also tests the latching strength by loading the mattress support. The ASTM F2194-16 ϵ 1 (*bassinet*) standard requires products without a latching or locking device not to fold when a 20-pound force applied to the top edge of the bassinet in the direction most likely to cause it to fold. The ASTM F2194-16 ϵ 1 (*bassinet*) standard requires a lower force than the Canadian standard but the force is applied at a higher location (top side of the bassinet) than the Canadian standard (force applied to the mattress support). The higher location of the force could create a higher torque at the latch due to the longer lever arm. For bassinets with a locking hinge or latch, the locking mechanism must withstand a 10-pound force in the direction most likely to release it. Determining which latching requirement is more stringent is difficult since the test parameters are not directly comparable.

The ASTM standard also includes a *Removable Bassinet Bed Attachment to Base/Stand* requirement and testing to address latching and locking devices intended to secure removable bassinet beds to the base/stand. These requirements and test are unique because they address known incidents of false latching of a removable bassinet bed. By considering the latching, unintentional folding, and bassinet bed attachments to the stand requirements in total, staff concludes the ASTM F2194-16 ϵ 1 *bassinet* standard's latching requirements are adequate.

Stability requirements

The Canadian requirement in Schedule 11, Test for Stability of Cradles, Bassinets and Stands, of their regulation is substantially equivalent to the requirement in ASTM F2194-16 ϵ 1. The requirement specifies that the product (with a simulated newborn occupant) withstand a 10-kg (approximately 22 pounds) withstand a static vertical load over a period of five seconds and a 22 N (approximately 4.9 pounds) horizontal force without tipping. Staff concludes this test evaluates the same stability hazard and is substantially equivalent to ASTM F2194-16 ϵ 1, differing slightly due to conversions to metric.

SOR/2016-152 Summary

The Canadian standard has a similar side height and stability requirement compared to the ASTM F2194-16 ϵ 1 *bassinet* standard. While the Canadian standard has a more

stringent sleep surface angle requirement, the ASTM F2194-16 ϵ 1 *bassinet* standard has a more extensive latching requirement. Staff concludes that the requirements in the ASTM standard are adequate to address the risk of injury as demonstrated in the incident data.

B. Unregulated Non-Inclined (Flat) Infant Sleep Products

i. Hazard Pattern Categories

In response to the 2019 SNPR, CPSC staff received numerous public comments regarding the safety of other currently-unregulated sleep products available in the marketplace. Staff completed a review of the CPSC epidemiological databases, CPSRMS and NEISS, to respond to these comments and concerns. CPSC staff received a total of 183 incident reports from January 1, 2019 through December 30, 2020 related to unregulated flat infant sleep products available in the marketplace that are currently not under the purview of any standard that addresses sleep hazards. These include in-bed sleepers, baskets (that can function as hand-held carriers as well), baby boxes, compact bassinets, most of which are portable for travel, and travel tents. All of these unregulated sleep products are flat (sleep surface has no incline) and come with mattress pads.

Of the 183 reported incidents, 11 are fatalities; among the remaining 172 non-fatal incidents, 16 reported an injury. Seven of the 11 fatalities involved suffocation. Staff identified six hazards related to the risk of injury or death (staff did not consider patterns that did not relate to injuries or deaths, such as consumer comments). The hazard patterns identified among the 183 incidents are: lock/latch problems, falls/containment issues, instability, asphyxiation/suffocation, product-related issues, and undetermined causes.

ESMC staff analyzed whether the voluntary standard for bassinets, ASTM F2194-16 ϵ 1, would address the identified hazards for unregulated, flat infant sleep products (ISPs). The voluntary standard for bassinets, ASTM F2194-16 ϵ 1, is more applicable to these flat products because they have a sleep surface less than 10 degrees, and because, as set forth below, the standard addresses the identified hazards associated with these products. The current voluntary standard for infant inclined sleep products, ASTM F3118-17a, is not applicable to these flat sleep products, and does not address hazards associated with flat sleep surfaces.

In the 2019 SNPR, staff recommended expanding the scope of ASTM F3118-17a for the CPSC rule, to include all infant sleep products (inclined and flat) that are not covered by another CPSC sleep standard, including the bassinets, cribs (full-size and non-full size), play yards, or bedside sleepers standards. Staff also recommended in the 2019 SNPR that all products marketed or intended for infant sleep have a seatback angle of 10 degrees or less, and meet 16 CFR 1218 Safety Standard for Bassinets and Cradles, which is also the performance requirements of ASTM F2194-16 ϵ 1 (*bassinets*). The following are the identified hazards for unregulated flat infant sleep products.

Hazard: Lock/Latch Issue

One hundred fifteen of the 183 incidents, and no deaths, were related to latches that control the

opening/closing of the cover on the product failed. Although these latch incidents did not relate to a product folding or collapsing, they illustrate that these products do have latch failures. From analyses on other products, staff is aware that failure of a product's latch can cause the product to fold or collapse unintentionally and pose a suffocation hazard to the infant. ASTM F2194-16 ϵ 1, *Standard Consumer Safety Specification for Bassinets and Cradles*, addresses hazards posed by a lock/latch failure with an unintentional folding requirement. The requirement specifies that if a folding product does not have a latching or locking device, then it shall not fold when a 20 lb. force is applied in the direction most likely to fold the product (with simulated infant occupant). The requirement also specifies if a folding product does have a single action latch, then it shall not fold when a 10 lb. force is applied in the direction most likely to fold the product. Staff concludes this requirement adequately simulates the action of unintentionally folding the product, and therefore, staff concludes that all currently unregulated infant sleep products with a lock or latch should at least meet the ASTM F2194-16 ϵ 1 (bassinet) standard's unintentional folding requirement.

The ASTM F2194-16 ϵ 1 (*bassinets*) standard also includes a “*Removable Bassinet Bed Attachment to Base/Stand*” performance requirement. A removable bassinet bed attaches to the bassinet stand and is secured with a latch/lock. This requirement states a removable bassinet bed shall either:

- not be supported by the bassinet stand in an unlocked/latched configuration,
- automatically locks to the bassinet stand and can't be placed in an unlocked position on the bassinet stand,
- clearly and obviously be unstable when the product is unlocked/latched by placing the sleeping surface at a 20-degree incline,
- have a false latch/lock visual indicator designed to visually alert caregivers when the bed is not properly locked to the stand, or
- have a lock/latch mechanism that is not needed to pass the stability requirement.

The purpose of this requirement is to ensure that bassinets that can be removed from their stand are securely latched to the stand when in use. Staff concludes the ASTM F2194-16 ϵ 1 (*bassinet*) standard's requirement adequately simulates the action of a bassinet unintentionally unlatching from its stand. Staff also concludes the ASTM F2194-16 ϵ 1 (*bassinet*) standard's requirement is more stringent compared to the ASTM F3118-17a (*infant inclined sleep products*) standard, which lacks a requirement for products that can be removed from a stand. Therefore, for the draft final rule, staff recommends that all unregulated infant sleep products meet the ASTM F2194-16 ϵ 1 (*bassinet*) standard's “unintentional folding requirement” and the “Removable Bassinet Bed Attachment to Base/Stand requirement,” if applicable, to address the risk of injury associated with locks and latching features on these products.

Hazard: Falls/Containment Issue

Twelve of the 183 incidents were related to falls or an infant otherwise not being kept contained within the product. Of the 12 incidents, one resulted in a death, one required hospital admission, and nine required ED visits. The failure to contain occupants in an infant sleep product can lead to infants falling or climbing out of the infant sleep product into a hazardous area.

Typically, regulated sleep products do not allow an active occupant restraint system for occupant containment. Active restraint systems are only effective when the caregiver actively uses them and adjusts them correctly, but in a sleep environment, active restraints can create an entanglement and asphyxiation hazard.

The ASTM F2194-16ε1 (*bassinets*) standard does not allow the use of restraints, and instead addresses hazards posed by a product failing to contain the occupant with a side height requirement, a passive safety feature. The requirement specifies that the product’s interior side height with an uncompressed mattress shall be at least 7.5 inches.

In 2012, the ASTM F2194-12 bassinets standard first required a minimum 7.5-inch side height based on the Canadian standard.⁶ The side height is measured from the upper surface of the uncompressed mattress to the upper surface of the lowest side. This requirement remains in effect in ASTM F2194-16 ε1. Canada requires a side height of 230 mm (9 inches), measured from the mattress support. Because ASTM F2194-16ε1 allows a bassinet mattress of 1.5 inches, measuring from the upper surface of the mattress support to the upper surface of the side would be 1.5 inches greater than measuring from the upper surface of an uncompressed mattress. Therefore, staff concluded that the 7.5 inch side height, from the upper surface of an uncompressed mattress is functionally equivalent to the 9 inch side height, measured from the upper surface of the mattress support in Canada.

Products that the CPSC staff identified as infant non-inclined (flat), bassinet-sized sleep products are not subject to a voluntary or mandatory standard that specifies a minimum side height. Flat products that are considered Hand-held carriers under 16 CFR part 1225 *Safety Standard for Hand-Held Infant Carrier* and ASTM F2050-19 *Standard Consumer Safety Specification for Hand-Held Infant Carrier* can be defined as a *hand-held bassinet/criadle* product intended for sleep, but *hand-held bassinet/criadles* are not subject to a side height requirement in the mandatory or voluntary standard. Products without a minimum side height could fail to contain occupants, which can lead to infants falling or climbing out of the product into a hazardous area.

Table 5 shows the side height requirements for each sleep product standard. Sleep products that have minimum side height requirement range from 2-inches for Inclined Sleep Products to 9-inches for Cribs. Bassinets, bedside sleepers, and inclined sleepers are intended for infants from birth to 5 -months old. Cribs are intended for newborns up to children 35 inches tall which is equivalent to a 95th percentile in stature 21-month-old.

Table 5. Side Height Requirements for Sleep Products

Standard	Side Height Requirement	Age range
16 CFR 1218 – Safety Standard for Bassinets and Cradles ASTM F2194-16ε1, <i>Standard Consumer Safety Specification for Bassinets and Cradles</i>	7.5 inches	0-5 month, or sit up

⁶ 78 *Fed. Reg.* 63,109 (Oct. 23, 2013).

16 CFR 1219 – Safety Standard for Full-Size Baby Cribs ASTM F1169-19, <i>Standard Consumer Safety Specification for Full-Size Baby Cribs</i>	9 inches	0-35 inches tall (95 th percentile 21-month old)
16 CFR 1220 – Safety Standards for Non-Full-Size Baby Cribs 16 CFR 1221 – Safety Standards for Play Yards ASTM F 406-19, <i>Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards</i>	9 inches	0-35 inches tall (95 th percentile 21-month old)
16 CFR 1222 – Safety Standard for Bedside Sleepers ASTM F2906-13, <i>Standard Consumer Safety Specification for Bedside Sleepers</i>	4 inches on side next to adult bed. 7.5 inches for other 3 sides.	0-5 month, or sit up
ASTM F3118-17a, <i>Standard Consumer Safety Specification for Infant Inclined Sleep Products</i> ,	3 inches	0-5 month or sit up
	2 inches	0-3 months
16 CFR part 1225 <i>Safety Standard for Hand-Held Infant Carrier</i> ASTM F2050-19 <i>Standard Consumer Safety Specification for Hand-Held Infant Carrier</i>	No requirements	

Inclined sleep products covered in ASTM F3118-17a, *Standard Consumer Safety Specification for Infant Inclined Sleep Products*, can meet the standard with a minimum side height of 3-inches for products intended for newborns to 5-month of age and a minimum side height of 2-inches for products intended for newborns up to 3-months old.

Upon review of applicable standards, staff determined the ASTM F2194-16e1 (*bassinet*) standard’s side height requirements provided the greatest safety for the intended use for newborns to 5-month of age. Staff considers the minimum side height requirement of 2-inch and 3-inch in ASTM F3118-17a, *Standard Consumer Safety Specification for Infant Inclined Sleep Products* to be inadequate because there are incident of infants failing to be contained in low-sided products and the 3-inch side height is lower than the center of gravity of a 5-month old infant on its side.

Staff determined that most unregulated flat infant sleep products are intended for infants, under 5-months, who cannot sit upright unassisted. Staff considers unregulated flat products with no side height requirements pose a potential fall hazard, as reflected in the incident data.

Based on the foregoing, staff concludes that ASTM F2194-16e1 (*bassinet*) standard’s 7.5-inch side height requirement is appropriate and would adequately address the falls/containment hazard in unregulated infant sleep products for infants up to 5 months old or who cannot sit up unassisted. Therefore, for the draft final rule, staff recommends that all unregulated, inclined and flat infant sleep products meet the side height requirement of the ASTM F2194-16e1 (*bassinet*) standard to address fall/containment hazards, as recommended in the 2019 SNPR.

Hazard: Instability

Twelve of the 183 incidents were related to the instability of the product. An unstable product can lead to tip-overs. Of the 12 incidents, two resulted in injuries, one of which involved an ED

visit.

The data summarized in Tab B of this briefing package includes at least one incident in a small, portable infant sleep product involving a sibling interaction resulting in a fall. Specifically, the NEISS report states: “7WKOF WITH HEAD INJURY, FELL FROM PORTABLE BASSINET THAT WAS ON COUCH, APPROX 1.5FT , YOUNGER BROTHER PULLED THE BASSINET AND IT FLIPPED ONTO THE PLAYMAT, PT LANDED ON RT SIDE OF HEAD.” This sibling interaction-type incident is addressed by the bassinet standard, as discussed below.

Unregulated infant sleep products do not require a stand. Therefore, these products can be placed directly on the floor or potentially hazardous or unstable elevated surfaces such as tables, countertops, soft mattresses, or couches. The ASTM F2194-16ε1 (bassinet) standard addresses this hazard scenario by requiring bassinets to have a stand/base/frame. ASTM F2194-16ε1 defines a bassinet as a small bed “supported by free standing legs, a stationary frame/stand, a wheeled base, a rocking base, or which can swing relative to a stationary base.” This requirement to have a stand, and be raised off the floor, increases the stability of a portable product by discouraging or preventing their use on other, less stable, surfaces, such as elevated surfaces or soft surfaces (couches and adult beds). Therefore, with respect to this hazard scenario, for the draft final rule staff recommends that all infant sleep products meet the ASTM F2194-16ε1 bassinet’s requirements, including requiring sleep products to have a stand, to further reduce the risk of injury from a product placed on a hazardous elevated surface or an unstable surface, such as a couch or adult bed.

ASTM F2194-16ε1 (*bassinets*) addresses hazards posed by the product’s instability with a stability requirement. The requirement specifies that the product (with simulated newborn occupant) withstand a 23 lb. vertical force and 5 lb. horizontal force along its side without tipping. The rationale in ASTM F2194 states the dual application of forces simulates a 2-year old male pulling on the side of the product; staff concurs that this is a reasonable scenario in which the product may tip over. Incident data also demonstrates that these compact products are used on elevated surfaces, such as beds and couches, from which the infant and product fell. Therefore, with respect to the product’s stability, staff recommends that all infant sleep products meet the stability requirement of the voluntary standard for bassinets, ASTM F2194-16ε1, to further reduce the risk of injury from tip-over of the product.

The Canadian requirement in Schedule 11, Test for Stability of Cradles, Bassinets and Stands, of their regulation is substantially equivalent to the requirement in ASTM F2194-16ε1. The requirement specifies that the product (with a simulated newborn occupant) withstand a 10-kg (approximately 22 pounds) withstand a static vertical load over a period of five seconds and a 22 newton (approximately 4.9 pounds) horizontal force without tipping. Staff concludes this test is substantially equivalent, differing slightly due to conversions to metric.

Hazard: Asphyxiation/Suffocation

Nine of the 183 incidents were related to infants that partially or fully rolled over from their initial position in infant sleep products. Of the nine incidents, eight resulted in a death, and one resulted in a near-suffocation prevented by a nearby parent.

The voluntary standard for bassinets, ASTM F2194-16 ϵ 1, addresses the asphyxiation/suffocation hazard with the following general/performance requirements:

- *5.10 Corner Posts:* This requirement addresses corner post extensions which can entangle ribbons, pacifier cords, necklaces, or occupant clothing. Entanglement of any of these items could lead to the asphyxiation of the occupant. This requirement limits the extension of a bassinet's corner post from extending more than .06 inches above the upper edge of an end or side panel. Corner posts that extend at least 16 inches above the top of a side rail are exempt as they are deemed inaccessible to the occupant. These are the same requirements found in the regulated ASTM F406-19 (*non-full-sized cribs*) and F1169-19 (*full-sized cribs*) standards that CPSC staff concluded adequately addressed the corner post entanglement hazard.
- *6.1 Spacing of Rigid Sided Bassinet/Cradle Components.* This requirement limits the distance between slats to less than 2 3/8 inch to mitigate the suffocation hazard from feet-first head entrapment.
- *6.2 Openings for Mesh/fabric Sided Bassinets/Cradle.* This requirement tests openings in the bassinet's mesh for entrapment of fingers, toes, and snaring buttons often used on infant clothing. The snaring of a button entraps the button and could lead to asphyxiation as the infant becomes entangled and entrapped. In this performance requirement, the mesh-sided bassinet's openings cannot allow a 1/4 inch rod to fit through.
- *6.5.3 Pad Dimensions.* This requirement mitigates the hazard of suffocating when entrapped in the space between the edge of the mattress and the bassinet's sidewall by limiting the available space to less than 1 inch.
- *6.7 Bassinets with Segmented Mattress: Flatness Test.* This requirement limits sleep surface variability of a segmented or folding mattress to 10 degrees or less. This angle was determined to reduce the likelihood of an infant's face becoming engulfed by a small "V" shape formed by the creases in a folded mattress, potentially present in a bassinet that uses a folding play yard mattress as the bassinet mattress.
- *6.8 Fabric Sided Enclosed Openings.* This requirement addresses the hazard of a feet first head entrapment through the openings of fabric-sided bassinets. This requirement limits the openings in a fabric-sided bassinet to prevent the 5th percentile 0-2-year-old torso probe from passing through. This requirement prevents a child's torso from fitting through any openings in the fabric sidewalls; therefore, staff concludes this requirement would prevent a feet first head entrapment.
- *6.9 Rock/Swing Angle.* This requirement limits the bassinet's sleeping surface angle to less than 20 degrees when rocked and seven degrees when the bassinet is at rest. In the 2019 SNPR for Infant Sleep Products, staff concluded that a flat sleeping surface that does not exceed 10 degrees offers infants the safest sleep environment. This conclusion was based on the Mannen Study.

In total, these requirements address known suffocation hazards with infant sleep and create a minimally safe sleep environment. Therefore, for the draft final rule, with respect to the

asphyxiation/suffocation hazard, staff recommends that the 2019 SNPR be finalized, requiring all infant sleep products meet general and performance requirements of the voluntary standard for bassinets, ASTM F2194-16ε1, to further reduce the risk of death from suffocation.

Hazard: Product-Related issues

Three of the 183 incidents were related to mold or quality of the product material. Two of the three products were in-bed sleepers, while the third was a compact bassinet/travel bed. All three reported an injury.

None of the voluntary standards currently address conditions, such as mold, that manifest due to the conditions under which a product is used. A moisture resistant requirement has been discussed in the ASTM task group for baby boxes (which is under the bassinet subcommittee), but the task group has not reached a consensus on appropriate performance requirements to address mold and moisture resistance. CPSC staff will continue to work with this task group.

Hazard: Undetermined issues

Three of the 183 incidents did not have enough reported information for staff to determine the issue involved. Two of the incidents were fatalities; in both cases, the CPSC Field investigation reports indicate that the cause of death is undetermined. The third incident resulted in a hospitalization due to unspecified breathing difficulties suffered by the infant.

The reports did not provide sufficient information on the circumstances of deaths and injury reports involved unspecified falls. Without information on the circumstances of deaths or injuries, staff is unable to assess whether the voluntary standard for bassinets, ASTM F2194-16ε1 would adequately address the hazards in this category.

ii. Assessment of International Standards

EN12790:2009 Reclined cradles

The scope of the European Standard, EN 12790-2009 “Child use and care articles – Reclined cradles” includes inclined bassinets/cradles, car seat carriers, hammocks, and bouncers. Some of the general requirements could apply, but because the scope of the products that fall within this standard is not the same as the draft final rule, most of the requirements are not applicable to infant sleep products.

Side height

The EN 12790:2009 standard does not have a side height requirement but includes a three-point restraint to address the containment hazard. The ASTM F2194-16ε1 *bassinet* standard is more stringent by requiring a minimum side height of 7.5 inches. Restraints are an active safety feature that might not always be used, while the side height requirement is a passive safety feature.

Sleep surface angle

The EN 12790:2009 standard requires a seatback angle between 10 degrees and 80 degrees, while the ASTM F2194-16 ϵ 1 *Bassinet* standard is more stringent by requiring a maximum sleep surface angle of 10 degrees. The EN 12790:2009 standard was written for products that may or may not be intended for sleep, such as car seats, a scope that is broader than the scope of the ASTM bassinet standard. The Mannen Study concluded that a seatback angle of 10 degrees or less is safe. Staff continues to recommend that the draft final rule be consistent with the Mannen Study findings.

Latching requirements

The EN 12790:2009 standard requires infant rocking cradles with at least one automatic locking latch mechanism, and that the locking mechanisms:

- Require 50N (11.24 pounds-force) to unlatch after operating the latch 300 times;
- Require a tool to unlatch;
- Require two consecutive actions to unlatch; or
- Require two independent and simultaneous actions to unlatch.

The EN 12790:2009 standard's latching requirement simulates the action of unintentionally folding the product. The ASTM F2194-16 ϵ 1 *bassinet* standard similarly includes requirements that address the unintentional folding hazard and requirements that address the false latching of a removable bassinet bed; therefore, staff concludes the ASTM F2194-16 ϵ 1 bassinet standard's latching requirements are adequate.

Stability requirements

The EN 12790:2009 standard requires products with a test mass not to tip over when placed on a 15-degree surface. The test mass for cradles designed for occupants up to 13.22 pounds is 19.84 pounds. The test mass for cradles designed for occupants up to 19.87 pounds is 33.06 pounds. This standard simulates the stability of an occupied reclined cradle on an uneven surface. This is different compared to the ASTM F2194-16 ϵ 1 *bassinet* standard that requires the product (with simulated newborn occupant) to withstand a 23 lb. vertical force and 5 lb. horizontal force along its side without tipping. The rationale in ASTM F2194 states the dual application of forces simulates a 2-year old male pulling on the side of the product; staff concurs that this is a reasonable scenario in which the product may tip over.

EN 12790:2009 *Summary*

The EN 12790:2009 reclined cradle standard is less stringent than ASTM F2194-16 ϵ 1 *Bassinet* standard by not requiring any minimum side height for containment and permits a more inclined sleep surface angle for products that include reclined cradles and car seats for children up to 19.84 pounds.

C. Applicability of ASTM F2194-16 ϵ 1 to Infant Sleep Product Hazards

Table 6 summarizes the hazards associated with flat unregulated infant sleep products and how each hazard is addressed by the voluntary standard for bassinets ASTM F2194-16 ϵ 1.

Table 6: Infant sleep product hazards identified and how addressed

Product	Applicable Voluntary Standard	Infant Sleep Hazards					
		Latching	Falls/Containment	Instability	Asphyxiation/Suffocation	Miscellaneous product-related	Undetermined
Unregulated products		115 incidents Not currently addressed	12 incidents: 1 death Not currently addressed	12 incidents: 2 injuries Not currently addressed	9 incidents: 8 deaths; not currently addressed	3 mold-related incidents; not currently addressed	3 incidents: two deaths Too little information to determine addressability
Bassinet/Cradle	ASTM F2194-16e1	Unintentional folding requirement	Side height requirement	Stability requirement	Max sleep surface angle defined in definition; Restraints not allowed; Flatness/hazardous Vs identified; Pad dimensions; Corner posts; fabric sided enclosed openings; Spacing; Mesh openings	Not currently addressed; task group work	Too little information to determine addressability

Table 6 and Section B of this memorandum illustrate how the voluntary standard for bassinets ASTM F2194-16e1 addresses the hazards identified by staff with unregulated flat bassinet-sized sleeping products. In addition, Section A of this memorandum explains why ASTM F2194-16e1 addresses the hazards, including suffocation hazard identified with sleep surface inclines greater than 10 degrees, associated with unregulated infant inclined sleep products. Based on staff’s assessment of the hazards associated with unregulated infant inclined sleep products and unregulated infant non-inclined (flat) sleep products, staff recommends for the draft final rule that all infant sleep products not already regulated by a CPSC sleep standard meet the requirements in ASTM F2194-16e1 (*bassinet*) to reduce the risk of injury associated with these products.

V. RECOMMENDATIONS

Based on the foregoing analysis, CPSC staff recommends that the Commission finalize a mandatory standard for infant sleep products, consistent with the 2019 SNPR, that includes all infant sleep products, including inclined and flat products, that are marketed or intended as a sleeping accommodation for infants up to 5 months old that are not within the scope of another CPSC sleep standard (bassinets and cradles, cribs (full-size and non-full size), play yards, or bedside sleepers). Based on the comments received and this analysis, staff recommends several clarifications to the proposal in the 2019 SNPR, as listed in section III.B of this memorandum. Accordingly, for the draft final rule, staff recommends that the Commission incorporate by reference the voluntary standard, ASTM F3118-17a, *Standard Consumer Safety Specification for Infant Inclined Sleep Products*, with substantial modifications to the, introduction, scope, performance, and testing requirements. The modifications would require that infant sleep products

that do not already meet the requirements of a CPSC sleep standard, must be (1) tested, by measuring the seat back/sleep surface angle, to confirm that the seat back/sleep surface angles is 10 degrees or less from horizontal, and (2) meet the requirements of 16 CFR part 1218, Safety Standard for Bassinets and Cradles. Staff recommends compliance with part 1218 for infant sleep products that do not meet another CPSC sleep standard because, as demonstrated in the memorandum, the bassinet standard addresses hazards associated with infant sleep products, including locking and latching issues, falls and containment issues, product stability issues, and asphyxiation and suffocation issues.

APPENDIX

Staff's Recommended Modification to ASTM F3118-17a

The following are staff's recommended modifications to ASTM F3118-17a with the double underlined text being additions, the text with strikethroughs being deletions, and instructions for specific sections:

Modifications throughout the entire standard

Delete the term "inclined sleep products" and change to "infant sleep products."

Modification to Introduction

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

In response to incident data compiled by ~~the~~ CPSC, this consumer safety specification attempts to minimize the following: (1) fall hazards, (2) ~~positional~~ asphyxiation and suffocation, and (3) 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 reduce deaths associated with known infant sleep hazards, including, but not limited to, a seat back or sleep surface angle that is greater than 10 degrees from the horizontal. ~~This consumer safety specification is intended to cover normal use and reasonably foreseeable misuse or abuse of inclined sleep products. This specification does not cover inclined sleep products that are blatantly misused or used in a careless manner that disregards the safety instructions and warnings provided with each inclined sleep product.~~

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.

Modifications to Scope (section 1)

1.3 This consumer safety performance specification covers ~~a free-standing~~ infant sleep products, including with an inclined and flat sleep surfaces, primarily marketed or intended and marketed to provide a sleeping accommodations for an infant up to 5 months old, and that are not already subject to any of the following standards:

- 16 CFR part 1218 - Safety Standard for Bassinets and Cradles, incorporating by reference ASTM F2194, Standard Consumer Safety Specification for Bassinets and Cradles;
- 16 CFR part 1219 - Safety Standard for Full-Size Baby Cribs, incorporating by reference ASTM F1169, Standard Consumer Safety Specification for Full-Size Baby Cribs;
- 16 CFR part 1220 - Safety Standard for Non-Full-Size Baby Cribs, incorporating by reference applicable requirements in ASTM F406, Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards;

- 16 CFR part 1221 - Safety Standard for Play Yards, incorporating by reference applicable requirements in ASTM F406, Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards;
- 16 CFR part 1222 - Safety Standard for Bedside Sleepers, incorporating by reference ASTM F2906, Standard Consumer Safety Specification for Bedside Sleepers.

~~or when the infant begins to roll over or pull up on sides, whichever comes first. It also covers a smaller product intended for newborns up to 3 months old or when newborn begins to wiggle out of position or turn over in the product or weighs more than 15 lb (6.8 kg), whichever comes first. It also covers infant and newborn inclined sleep product accessories, which are attached to, or supported by, another product with the same age or abilities, or both, as the free standing products.~~

1.3.1 If the ~~inclined~~ infant sleep product can be converted into a product for which a CPSC regulation exists, the product shall meet the applicable requirements of the CPSC regulation, when in that use mode. If the infant sleep product can be converted into a product for which no CPSC regulation exists, but another ASTM standard consumer safety specification exists, the product shall meet the applicable requirements of that standard, when in that use mode. For example, an inclined sleep product that can have the recline angle adjusted below 10° shall also comply with the applicable requirements of Consumer Safety Specification F2194.

1.3.2 Crib mattresses that meet the requirements of ASTM F2933 are not covered by the specifications of this standard.

Modifications to Reference Documents (section 2)

Delete all references, FIG. 1, and FIG. 2, except F2194 *Consumer Safety Specification for Bassinets and Cradles* reference.

Add the following references:

2.1 *ASTM Standards:*

F406 Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards
F1169 Standard Consumer Safety Specification for Full-Size Baby Cribs
F2906 Standard Consumer Safety Specification for Bedside Sleepers
F2933 Standard Consumer Safety Specification for Crib Mattresses

2.2 *Federal Standards:*

16 CFR 1218 - Safety Standard for Bassinets and Cradles
16 CFR 1219 - Safety Standard for Full-Size Baby Cribs
16 CFR 1220 - Safety Standard for Non-Full-Size Baby Cribs
16 CFR 1221 - Safety Standard for Play Yards
16 CFR 1222 - Safety Standard for Bedside Sleepers

Modifications to Terminology (section 3)

Delete sections 3.1.1 - 3.1.6-

Modify 3.1.7 to:

3.1.7 *infant ~~inclined~~ sleep product, n*— a ~~freestanding~~ product; marketed or intended to

provide a sleeping accommodations for an infant up to approximately 5 months of age, ~~that is generally supported by a stationary or rocker base with one or more inclined sleep surface positions for the seat back that are greater than 10° and do not exceed 30° from the horizontal.~~ and that is not subject to any of the following:

- 16 CFR part 1218 – Safety Standard for Bassinets and Cradles
- 16 CFR part 1219 – Safety Standard for Full-Size Baby Cribs
- 16 CFR part 1220 – Safety Standard for Non-Full-Size Baby Cribs
- 16 CFR part 1221 – Safety Standard for Play Yards
- 16 CFR part 1222 – Safety Standard for Bedside Sleepers

Delete sections 3.1.7.1 - 3.1.13

Delete sections 3.1.15 - 3.1.16

Modifications to General Requirements (section 5)

Delete this section

Delete FIG. 4.

Modifications to Performance Requirements (section 6)

Delete section 6.1 - 6.8

Modify section 6.9 and 6.9.1 to:

~~6.9 Maximum Seat Back/Sleep Surface Angle-Incline:~~

~~6.9.1 Infant Inclined Sleep Product and Infant Inclined Sleep Product Accessory~~—The angle of the seat back/sleep surface intended for sleep along the occupant's head to toe axis relative to the horizontal shall not exceed ~~30~~10° when tested in accordance with 7.11.2.

Delete section 6.9.2

Delete FIG. 5 – FIG. 6

Add the following new requirement:

6.9.3 *Infant Sleep Products* - shall meet, 16 CFR 1218 Safety Standard for Bassinets and Cradles, including conforming to the definition of bassinet/cradle.

Delete sections 6.10 – 6.11

Modifications to Test Methods (section 7)

Delete section 7.1 - 7.10

Delete FIG. 7 - FIG. 10.

Delete section 7.11.1.3

Modify section 7.11.2 to:

~~7.11.2 *Infant Inclined Sleep Products and Infant Inclined Sleep Product Accessory*:~~

Modify section 7.11.2.1 to:

7.11.2.1 If applicable, place the product in the manufacturer's recommended highest ~~incline seat back/sleep surface angle position~~ intended for sleep.

Modify section 7.11.2.2 to:

7.11.2.2 Place the hinged weight gage—infant in the product and position the gage with the hinge centered over the seat bight line and the upper plate of the gage on the seat back/sleep surface. Place a digital protractor on the upper torso/head area lengthwise.

Delete sections 7.11.3 - 7.15, and associated FIG. 12

Modifications to Marking and Labeling (section 8)

Delete this section and associated FIG. 13 – 15

Modifications to Instructional Literature (section 9)

Delete this section and associated FIG. 16

Modifications to Keywords (section 10)

Add section 10.2:

10.1 infant inclined sleep product

10.2 infant sleep product

Modifications to the APPENDIX

Delete this section.

TAB D: Human Factors Assessment of Infant Sleep Products (CPSIA Section 104)

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

Memorandum

DATE: March 17, 2021

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

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

FROM: Zachary S. Foster, Industrial Engineer,
Division of Human Factors, Directorate for Engineering Sciences

SUBJECT: Human Factors Assessment of Infant Sleep Products (CPSIA Section 104)

BACKGROUND

On November 12, 2019, the Commission issued a supplemental notice of proposed rule (2019 SNPR) for infant sleep products (84 *Fed. Reg.* 60,949), proposing to incorporate by reference, ASTM F3118-17a, with modifications to make the standard more stringent, to further reduce the risk of injury associated with infant sleep products. The proposed changes included that infant sleep products, including those sleep products that are not covered by a voluntary standard or mandatory CPSC sleep product standard (*i.e.*, bassinets, cribs (full-size and non-full size), play yards, or bedside sleepers) (collectively unregulated infant sleep products) would fall within the scope of the rule, and be required to meet 16 CFR part 1218, Safety Standard for Bassinets and Cradles (part 1218 or the bassinet standard), and that the maximum seat back/sleep surface angle be limited to 10 degrees from horizontal. CPSC's Directorate for Engineering Sciences, Division of Human Factors (ESHF) staff examined warning, labeling, and instructional requirements from ASTM F3118-17a and ASTM F2194-16ε1, and recommended that infant sleep products be required to meet the warning, labeling, and instructional requirements in 16 CFR 1218, which is substantially similar to ASTM F2194-16ε1.

Since that time, multiple comments received during the public comment period expressed concern about certain unregulated infant sleep products, specifically in-bed sleepers, baby boxes, and compact bassinets, being subject to the infant sleep product rule. Regarding these products, commenters expressed the following concerns:

- Safety concerns previously raised about in-bed sleepers, baby boxes, and compact bassinets are not supported by incident data.

- Bed-sharing is a common practice both in the U.S. and abroad, and work should be done to advocate for safe bed-sharing practices.
- Adoption of the proposed rule may result in a disparity in safety among in-bed sleepers or a potential ban of in-bed sleepers.
- “Marketed and intended for sleep” needs to be defined.

Commenters who expressed these concerns recommended that CPSC continue to work with ASTM to develop separate voluntary standards for the aforementioned products. This memorandum, prepared by ESHF staff discusses the concerns raised above and staff’s recommendations for the draft final rule.

DISCUSSION

INCIDENT DATA OVERVIEW (Briefing Package TAB B)

As discussed in the memorandum from the Directorate for Epidemiology (Tab B, Chowdhury, 2021), staff received 71 new incident reports involving inclined sleep products since the publication of the 2019 SNPR. Ten incidents resulted in fatalities and 17 reported an injury. Hazard patterns were similar to the ones included in the 2019 SNPR.

In addition, CPSC staff reviewed the incident data involving “unregulated flat sleep products” as multiple public comments were provided about these currently-unregulated sleep products. Staff found 183 incidents related to unregulated flat infant sleep products, which included in-bed sleepers, baskets, baby boxes, compact bassinets, and baby tents, that reportedly occurred from January 1, 2019 through December 31, 2020. Out of the 183 incidents, 11 resulted in fatality. Seven of the fatalities involved infant suffocation, two involved positional asphyxia, and two were undetermined. Staff identified unregulated infant sleep products hazard patterns including lock/latch problems (63%), consumer comments and concerns about a perceived product hazard (16%), fall or containment issues involving an infant falling or rolling out of a product (7%), instability issues (7%), asphyxiation/suffocation hazard that primarily involved infants rolling over (5%); mold or material quality issues (2%), and undetermined hazards (2%).

Below, ESHF staff discusses four hazard patterns associated with unregulated infant sleep products and human behavior.

PREVALENCE OF BED-SHARING AND ASSOCIATED HAZARDS

The American Academy of Pediatrics (AAP) provides recommendations to create safe sleep environments for infants. AAP recommendations include “room sharing without bed sharing,” meaning that infants should sleep in the parents’ room, close to parents’ bed, but on a separate surface. AAP recommends this practice to continue for at least six months, but preferably a year. If a parent falls asleep in bed with an infant, the parent should place the infant on a separate sleep

surface as soon as the parent awakens. Infants should never be left to sleep on sofas, armchairs, or in sitting devices.¹

As expressed by multiple commenters, bed-sharing is a common practice in both the United States and abroad. A 2016 survey on bed-sharing practices in the United Kingdom concluded that approximately 28% (192/678) of respondents reported bed-sharing ‘intermittently’, while 27% (187/678) of respondents reported bed-sharing ‘often’.¹ The frequency of and justification for bed-sharing varies from household to household, though the following reasons are often cited by caregivers in regards to bed-sharing:

- Bed-sharing makes breastfeeding easier for parent(s),
- Bed-sharing increases the amount of skin-to-skin contact that the infant receives,
- Parent(s) perceive that their child sleeps better when bed-sharing,
- Bed-sharing helps the parent(s) get more sleep,
- Bed-sharing helps the parent(s) bond with their infant,
- Bed-sharing is a cultural norm for some parents, and
- Infant does not sleep well when not bed-sharing.

However, CPSC staff’s research demonstrates that, even when using an in-bed sleeper or other infant sleep product, bed-sharing contributes to an unsafe sleeping environment for infants. Bed-sharing is a known risk factor for Sudden Infant Death Syndrome (SIDS); a 2013 meta-analysis of infant fatalities found that bed-sharing increased the risk of SIDS fivefold among <3 month old breastfed infants.² Additionally, a 2008 survey of Canadian mothers concluded that approximately 13% of respondents who had bed-shared with their infant reported at least one instance in which they had rolled onto or partially onto their infant during bed-sharing.³ Based on this data, CPSC staff concludes that SIDS or a parent rolling over on an infant present foreseeable risks of injury or death to the infant, even if a caregiver is using an infant sleep product in the bed. For example, if an infant sleep product that is made entirely or primarily of soft materials is used to bed-share, a sleeping or semi-conscious parent may perceive that product to be a pillow or other form of bedding and may inadvertently roll onto or move the infant sleep product.

STABILITY AND TIPOVER HAZARDS

In addition to foreseeable risks involving SIDS and parents rolling onto their infants during bed-sharing, CPSC staff is concerned that if unregulated infant sleep products are not required to meet the stability requirements in part 1218 (sections 7.3 and 7.4 of ASTM F2194), these unregulated products may be more prone to tipping over. Tipover/stability-related hazards are a significant hazard in infant sleep products. Staff’s analysis of CPSC’s epidemiological data involving infant inclined sleep products and unregulated infant sleep products from 2019-2020 found 27 instability incidents resulting in one death. The stability requirements found in ASTM F2194 initially were enacted in order to address an observed phenomenon involving older

¹ <https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/safe-sleep/Pages/Safe-Sleep-Recommendations.aspx>

siblings pulling on the sides of bassinets in order to look into them. CPSC staff is concerned that if unregulated infant sleep products are exempt from the stability requirements in ASTM F1294, similar incidents may occur. For instance, in a non-fatal incident, a sibling of a seven-week-old infant pulled on a portable bassinet that was placed on a couch, causing the infant and product to fall off of the couch, resulting in a head injury. Additionally, incident data and staff research demonstrate that some unregulated infant sleep products are commonly used on/in beds, sofas/loveseats, and other relatively unstable surfaces. For example, in an examination of customer reviews of various infant sleep products, ESHF staff found multiple instances of customers indicating that they used the products on mattresses, on sofas, in cribs, in play yards, and in bassinets. Staff's research found that a number of the unregulated infant products have features (e.g., small size, light weight, portability) that may encourage consumers to use them on surfaces other than the floor. CPSC staff is concerned that, given the relative instability of these surfaces when compared to the floor, using infant sleep products on these soft or elevated surfaces may further diminish the stability of these small, portable products and may increase the likelihood of a tip-over/rollover. An adult or a child sharing a surface, such as a bed or sofa, can exacerbate this scenario. In the past, ESHF staff reviewed reports in which an adult's movement caused the sleeper to tilt and led the baby to roll sideways with the infant's face pushing up against the side of the product.

CPSC staff is aware of a death involving an infant sleeping on a soft in-bed sleeping pad placed in a play yard, in which the report states that the county medical examiner believes that the victim died while face down. In another fatal incident, the sleeper was placed inside a crib and the infant was found nonresponsive the next morning.

If the sleeping product is placed on a high surface, injuries/deaths from a fall may also occur. For example, in a non-fatal incident, a 6-month-old female flipped out of the in-bed sleeper placed on a bed, fell, and hit her head on the floor, resulting in a head injury.

To address these incidents involving product instability, the draft final rule finalizes the 2019 SNPR's proposal to require infant sleep products to meet an existing CPSC sleep standard, or to meet the stability requirements in the bassinet standard.

CONTAINMENT

The small size and portability of unregulated infant sleep products contributes to the lack of containment. According to the Epidemiology incident data (Tab B of staff briefing package), one death and 11 incidents occurred due to the failure of the unregulated product to contain the infant within the product. The draft final rule would require such products to meet the requirements of the bassinet standard, which requires a 7.5-inch side height in order to contain the infant. In Tab D of this briefing package, engineering staff concludes that the requirement in the bassinet standard is adequate to contain an infant up to 5 months old, and HF agrees with a 7.5 inch side height requirement.

REMARKETING OF INFANT SLEEP PRODUCTS

CPSC staff recognizes that it is foreseeable that some manufacturers will choose to remarket their products in response to the draft final rule. Some of these products can credibly be remarketed as a different type of infant product, such as a chair, swing, or carrier. However, for certain products, such as in-bed sleepers, baby boxes, and compact bassinets, remarketing as a product not intended for sleep is unlikely to be feasible. If the design and function of the product communicates to the consumer that the product is either intended for sleep or is seemingly well-suited for sleep, remarketing the product as not intended for sleep will not have a substantial effect on consumers' use of the product. This is especially true of products that are already widely established as sleep products or fulfill a demand that is not met by other products. For example, remarketing in-bed sleepers as not intended for sleep would not prevent consumers from using those products for sleep, as it fulfills the demand for a bed-sharing option that other products do not. Therefore, CPSC staff recommends that products that cannot reasonably be remarketed as not for sleep, either be remarketed for older children, if reasonable, or be subject to one of the current CPSC sleep standards.

CONCLUSION

While CPSC staff recognizes that bed-sharing is a common practice, staff does not recommend using in-bed sleepers as a safe sleep practice, due to the increased risk of SIDS, parent rollover, and the other hazards discussed above, such as instability resulting in falls and suffocation hazards. Exempting certain infant sleep products from 16 CFR part 1218 will result in the distribution and sale of products that are prone to tip-over/instability and fall hazards. Therefore, CPSC staff recommends that all products marketed, intended, promoted, or otherwise indicated as being for any kind of infant sleep for infants up to 5 months old, must conform to one of the current CPSC sleep standards, meaning the safety standards for bassinets, cribs (full-size and non-full size), play yards, or bedside sleepers.

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TAB E: Final Regulatory Flexibility Analysis of the Staff-Recommended Draft Final Rule for Infant Sleep Products and the Accreditation Requirements for Conformity Assessment Bodies for Testing Conformance to the Infant Sleep Products Standard and the Product Registration Rule

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UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
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Memorandum

Date: January 29, 2021

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

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

Robert L. Franklin
Senior Staff Coordinator
Directorate for Economic Analysis

FROM : Susannah S. Proper
Economist
Directorate for Economic Analysis

SUBJECT : Final Regulatory Flexibility Analysis of the Staff-Recommended Draft Final Rule for Infant Sleep Products and the Accreditation Requirements for Conformity Assessment Bodies for Testing Conformance to the Infant Sleep Products Standard and the Product Registration Rule

I. Introduction

On April 7, 2017, the Consumer Product Safety Commission (CPSC or Commission) published a notice of proposed rulemaking (NPR) for infant inclined sleep products in the *Federal Register* (82 *Fed. Reg.* 16,963). The proposed rule incorporated by reference the then-current voluntary ASTM International (ASTM) standard for infant inclined sleep products (F3118-17), with a modification to the definition of an “accessory inclined sleep product.” Based on subsequent information and events, the Commission issued a supplemental proposed rule (Supplemental NPR or 2019 SNPR) on November 12, 2019, proposing to adopt the current ASTM standard for inclined sleep products (ASTM F3118-17a), 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, and requiring *all* infant sleep

products not already covered by another CPSC sleep product standard to comply with the bassinet/cradle standard specified in 16 CFR Part 1218. In December of 2020, ASTM unsuccessfully balloted a change to the title, introduction, and scope of ASTM F3118 that would remove the word “inclined” from the title, introduction, and scope and change the applicable age to 12 months, among other changes to clarify the scope in relation to other ASTM standards. This draft final rule has the same requirements as enumerated in the 2019 SNPR, with a few clarifications based on the comments received, and references the current ASTM standard (ASTM F3118-17a).

This memorandum evaluates the potential economic impact of the draft final infant sleep products rule on small entities, as required by the Regulatory Flexibility Act (RFA).¹ Section 604 of the RFA requires that federal agencies prepare a final regulatory flexibility analysis (FRFA) when they promulgate a final rule, unless the head of the agency certifies that the rule will not have a significant economic impact² on a substantial number of small entities. Staff anticipates a possible significant economic impact for twelve small importers and nine small domestic manufacturers that supply infant sleep products to the U.S. market, as well as for hundreds of home-based small businesses. Accordingly, we have prepared a FRFA.

The scope of this FRFA and the number of firms impacted is different from the Initial Regulatory Flexibility Analysis (IRFA) that accompanied the 2017 NPR, because the scope of the NPR was inclined sleep products, while the scope of this draft final rule is *all* infant sleep products that are not already covered by another CPSC sleep standard (unregulated infant sleep products). This change in scope from the proposed rule was specified in the 2019 SNPR. Some inclined sleep products have been recalled or otherwise voluntarily removed from the market since 2017, so some firms that were forecast to be impacted in the IRFA are not likely to be impacted by this draft final rule because the firms have already stopped selling those products. However, a significant economic impact is possible for suppliers of unregulated infant sleep products without inclined sleep surfaces that were not analyzed in the IRFA, as well as remaining suppliers of inclined products. Unregulated infant sleep products without inclined sleep surfaces include baby boxes, compact and travel bassinets that do not meet the bassinet standard, in-bed sleepers, baby tents marketed for infant sleep, baby pods, and baby nests.

The FRFA must describe the impact of the rule on small entities and identify any alternatives that may reduce the impact. Specifically, the FRFA must contain:

1. a statement of the need for, and objectives of, the rule;
2. a summary of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a statement of the assessment of the agency of such issues, and a statement of any changes made in the rule as a result of such comments;
3. the response of the agency to any comments filed by the Chief Council for Advocacy of the Small Business Administration in response to the proposed rule, and a detailed

¹ 5 U.S.C. §§ 601-612.

² We assume that an impact of more than 1% of annual revenue is significant. The impact consists of the costs of relabeling and redesigning products to be compliant with the standard, including the costs of recordkeeping and third-party testing, or removing non-compliant products from the marketplace.

- statement of any change made to the proposed rule in the final rule as a result of the comments;
4. a description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available;
 5. a description of the projected reporting, recordkeeping and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record; and
 6. a description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected.

II. Objectives of the Draft Final Rule

The objective of the draft final rule is to reduce the risk of injury and death associated with unregulated infant sleep products that are not already covered by an existing CPSC sleep product standard. CPSC staff identified eight hazard patterns among 451 reported incidents with inclined products in the 2019 SNPR, including multiple fatalities and injuries. Since the 2019 SNPR, CPSC staff received a total of 71 additional incident reports related to infant inclined sleep products. In 2019 and 2020, CPSC staff received a total of 183 incident reports in seven hazard patterns related to unregulated flat (not inclined) infant sleep products. These incidents include both injuries and fatalities.³

Section 104 of the CPSIA requires the CPSC to examine and assess the effectiveness of any voluntary consumer product safety standards for durable infant or toddler products and promulgate consumer product safety standards that are substantially the same as the voluntary standards, or more stringent than the voluntary standards, if the Commission determines that more stringent requirements would further reduce the risk of injury associated with the products. CPSC has promulgated mandatory safety standards for cribs, play yards, cradles, bassinets, and bedside sleepers that are based on ASTM voluntary standards. Unregulated infant sleep products are not currently subject to any mandatory sleep product safety standard. As discussed above, these products have hundreds of reported incidents, including multiple fatalities and injuries each year. The draft final rule will make all infant sleep products subject to at least one of the CPSC sleep product standards, all of which are substantially the same as, or more stringent than, the corresponding ASTM standards.

a. Requirements of the Staff-Proposed Draft Final Rule

The staff-recommended draft final rule would incorporate by reference the voluntary standard for inclined infant sleep products (*ASTM F3118-17a*), with modifications to make the standard more stringent. As specified in the 2019 SNPR, the draft final rule would modify ASTM F3118-17a to require that infant sleep products covered by the draft final rule have a sleep angle of 10 degrees

³ Data reporting for 2019-20 is incomplete so there may be more incidents in the future.

or less, and must also meet the requirements of a CPSC sleep standard (cribs, play yards, non-full-size cribs, bedside sleepers, or bassinets). Additionally, if a product does not meet a CPSC sleep standard, the default requirements for an infant sleep product are the requirements for a bassinet/cradle standard at 16 CFR part 1218. Given the requirements of the bassinet/cradle standard, that means that the products must have sides of a certain height and rigidity, legs or a stand, and meet the stability tests in the bassinet/cradle standard, rather than the current requirements in ASTM 3118-17a. If finalized, the draft final rule would become a mandatory consumer product safety rule under the CPSIA. If it becomes a mandatory standard, firms whose infant sleep products do not comply will need to evaluate their products, determine what changes would be required to meet the standard, and decide how to proceed. Noncompliant products would need to be removed from the U.S. market, modified to meet the mandatory standard, remarketed for children older than 5 months, or remarketed as not intended for infant sleep. New infant sleep products introduced to the market would also need to comply with the standard, or one of the other 5 CPSC mandatory sleep product standards. The draft final rule defines an “infant sleep product” as “a product marketed or intended for infant sleep for children up to 5 months old.” CPSC interprets this definition to include products that are marketed for “napping”, “snoozing”, “dreaming” or any other word that implies sleeping, or that are called a “bed”, and items marketed with a picture of a sleeping infant, to be an infant sleep product.

The following section lays out the requirements for compliance with the rule, and considers the implications on small firms supplying infant sleep products to the U.S. market. Subsequent sections continue the discussion, focusing on the domestic small business impacts and implications for particular types of products.

b. ASTM F3118-17a

ASTM F3118-17a, the current voluntary standard for inclined infant sleep products, forms the basis of the staff-recommended final infant sleep product standard. As written, the standard is intended to address injuries associated with inclined sleep products, meaning products with seatback angles between 10 to 30 degrees. However, pursuant to CPSC recall efforts, most of these products have been removed from the market, and staff found that the requirements in the standard are inadequate to address the risk of injury associated with inclined sleep, based on the Mannen Study. Accordingly, staff’s recommended draft final rule would modify the scope of ASTM F3119-17a to cover all infant sleep products, inclined and flat products, that are not within the scope of one of the other CPSC sleep standards (full size cribs, non-full size cribs, play yards, bassinets and cradles, and bedside sleepers). The scope of the rule would include unregulated flat sleep products, such as in-bed sleepers, baby boxes, compact bassinets, and baby tents.

ASTM 3118-17a itself includes no reporting or recordkeeping requirements. However, when the draft final rule becomes effective, manufacturers and importers of infant sleep products will be subject to the third-party testing requirements under the CPSIA, including its recordkeeping requirements.

To comply with the draft final rule, all suppliers must ensure that their infant sleep products comply with this rule or one of the other mandatory CPSC sleep standards, which may require

physical modifications to an existing product, new warning labels and instructions, and third-party testing. As an alternative to modifying their products to conform with this rule, suppliers may decide to exit the market sector by either discontinuing existing products or re-labeling and remarketing them as not intended for infant sleep, or by modifying their products to comply with a different safety standard, particularly those for infant bouncer seats or hand-held carriers. For some products where the physical design is distinctly intended for sleep, remarketing for a non-sleep use by children 5 months and under may not be possible, although the products could be remarketed for older children or pets. The impact on any particular firm will depend on how much modification to the product is required to achieve compliance with this rule, how much of their product line is infant sleep products, and whether remarketing the item as not for infant sleep would reduce demand.

c. Third Party Testing

Under section 14 of the CPSA, once the new infant sleep requirements become effective, all suppliers will be subject to the third party testing and certification requirements under the CPSA and the Testing and Labeling Pertaining to Product Certification rule (16 CFR 1107) which requires that manufacturers and importers certify that their products comply with the applicable children's product safety standards, based on third party testing, and subject their products to third party testing periodically. Third party testing costs are in addition to the costs of modifying the infant sleeper products to meet the standard. For infant sleep products, the third-party testing costs are expected to be about \$1,500 per testing cycle per model, including both the costs of the testing and the costs of the samples to be tested. This is consistent with the IRFA in the 2019 SNPR, which estimated a cost of \$1,100 for testing alone, not including the cost of the samples to be tested; we did not receive any comments on the 2019 SNPR providing a different estimate. Based on comments received on the bassinet/cradle final rule published in 2013, one-time costs of redesigning a product to meet the standard could be as high as \$500,000 for products requiring major redesign. As allowed by the component part testing rule (16 CFR 1109), importers may rely upon third party tests obtained by their suppliers, which could reduce the impact on importers. In addition, businesses selling products covered by this rule were already required to certify compliance to general children's product rules for lead, phthalates, and small parts with third party testing, so those third-party testing costs would not be considered new costs of compliance for this rule.

III. Products and Small Entities to Which the Draft Rule Would Apply - Overview

a. Overview of Products Covered by This Rule

This rule is intended to cover all infant sleep products not already in the scope of the CPSC mandatory safety standards for full size cribs, not full-size cribs, play yards, bassinets and cradles, or bedside sleepers.

An "infant sleep product," as defined in ASTM F3118-17a and this draft final rule, has four key components:

- The product is intended for infants up to 5 months old.

- The product’s sleep surface in all positions must be 10 degrees or less from horizontal.
- The product must be marketed or intended to provide sleeping accommodations. CPSC staff considers that any items marketed for “napping”, “snoozing”, or “dreaming”, or any other word that implies sleeping, or that are called a “bed”, as well as items marketed with a picture of a sleeping infant, to be an infant sleep product.
- The product is not in the scope of any other CPSC infant sleep product standard. Additionally, a crib mattress, as defined in ASTM F2933-19, alone, is not an infant sleep product.

The infant sleep products within scope of this rule include a variety of products. The inclined types include frame-type sleep products, inclined accessories to play yards, compact foam inclined “nappers”, and hammocks. None of these products (described immediately below) are covered by an existing CPSC sleep standard.

- Frame-type inclined sleep products typically have a hard plastic or metal frame and resemble an infant car seat or bouncer seat. They are freestanding products with legs or other hard frame support.
- Foam inclined napper products typically don’t have a frame, and are intended to be placed on a floor or other hard surface.
- Infant hammocks are mesh or cloth products that can have one to four hanging points. Some come with their own wooden or metal hanging frame, while others are intended to be suspended from the ceiling or from the top frame of a crib or play yard.
- Inclined accessory products are products that attach to the top rail or frame of a play yard, sometimes marketed as “nappers” or “bassinets.”

The draft final rule would also cover several types of flat sleep products which do not have inclined sleep surfaces and are also not covered by an existing CPSC sleep standard. These products include infant sleep products such as baby boxes, in-bed sleepers, baby nests and pods, rigid-sided and rigid-framed compact bassinets without a stand or legs, various designs of “travel bassinets” with soft padded or mesh sides, and small travel tents marketed as “baby tents”.

These products and the impacts on the suppliers of each category of product are discussed in more detail later in this analysis.

b. Products that are out of scope

Products with inclined or adjustable seat back positions that are covered by other CPSC standards, such as infant bouncer seats, strollers, hand-held carriers, frame carriers, and infant swings are excluded from the scope of the ASTM infant inclined sleeper standard and will also be excluded from the scope of the staff-recommended draft final rule, unless the product is specifically marketed for infant sleep. If the product packaging, marketing materials, inserts, or instructions indicates that the product is for sleep, or includes pictures of sleeping infants, then CPSC will consider the product to be marketed for sleep. Products that are compliant with another CPSC infant sleep product standard, such as the bassinet standard, or the crib standard,

are excluded from the scope of the draft final rule. Sleep wedge pillows and sleep positioners are out of scope, and may be covered by FDA regulations as a medical device if they are marketed to treat a medical condition such as acid reflux. Infant pillows are subject to 16 CFR 1500.18 “Banned toys and other banned articles intended for use by children.” Hammocks intended as photo props are out of scope. Hammock accessories intended for shopping carts are also not in scope, as those products are not intended for infant sleep. Bath chairs with inclined backs are out of scope, as they are covered by another standard and are not intended for infant sleep. Pet beds, toy hammocks, and play tents labeled for children over 5 months are out of scope. Loungers, floor chairs, and rockers are out of scope of the draft final rule, unless they are marketed for infant sleep on the product itself or the packaging, marketing materials, inserts, or instructions, or the product is advertised with pictures of sleeping infants.

Some suppliers of products that are out of scope for the draft final rule may need to change the product warning labels, packaging, or instructions to make it clearer that their products are not intended for infant sleep. The cost of complying with a different standard, such as the infant bouncer seat or hand-held carrier standard, is not considered to be an impact of this rule because this rule does not require suppliers to comply with those different standards.

c. Overview of Market for These Products

Items covered by this rule may be purchased at general retailers, online retailers, mattress and bedding stores, and baby specialty stores. At least 60 small U.S.-based manufacturers and importers are in this market, as well as 5 large domestic companies, and dozens of foreign companies, some of which ship these items directly to customers in the U.S. via online marketplaces. Over a thousand home-based manufacturers, of which hundreds are based in the U.S., sell soft-sided baby nests and pods, in-bed sleepers, and infant hammocks directly to consumers via online marketplaces and as third-party sellers via the websites of major retailers. We estimate total sales in this market at more than \$125 million per year, to at least a third of U.S. households with newborns.

These products compete both with infant sleep products that are compliant with one of the existing CPSC sleep standards and with other small, portable products that are not marketed for sleep. One goal of the draft final rule is to make it clearer to consumers which products are certified as compliant with a CPSC sleep standard, regardless of the product name or advertising.

The proliferation of physically different products with similar names (particularly “bassinet”), the many suppliers in the market, and new product types each season reflect a competitive market for innovative sleep products. These items are marketed as filling a need for a small, portable sleeping or napping space. Many items are also marketed specifically to facilitate bed-sharing. In addition to the demand for secondary sleeping options, some of these compact and relatively inexpensive sleep products are also marketed as primary sleep spaces for families with limited living space and budget. Baby boxes, in-bed sleepers, and hammocks in particular are marketed as primary sleep spaces for babies.

However, staff found no evidence that consumer demand for compact, inexpensive, and portable sleep spaces cannot be met by products compliant with an existing CPSC sleep standard. Many

small bassinets that are compliant with the CPSC bassinet standard sell for \$50 to \$75, and have a footprint similar to the unregulated infant sleep products covered by this rule. As for bed-sharing, bedside sleepers retail for as little as \$100. Cradles compliant with the bassinet/cradle standard have a similar swinging function to a hammock with a frame, often at a lower retail price. Innovative products compliant with the existing CPSC sleep standards have been introduced in recent years, including small, foldable play yards, oval cribs and bassinets, bassinets that are attached to an adult chair, bassinets with rocking functions, and bedside sleepers with a rocking base.

IV. Suppliers to this market

Manufacturers of infant sleep products are categorized under many different North American Classification System (NAICS) categories, because there is not a NAICS code specifically for infant sleep products. These items are made by companies that have baby furniture, baby bedding items, mattresses, other durable baby items including strollers or car seats, toys, or general merchandise as their primary business. Businesses are generally considered small per the Small Business Administration (SBA) size standards if they have fewer than 100 employees for importers or wholesalers, or fewer than 500 employees for most of the relevant types of manufacturers for this rule. The SBA size standard for mattress manufacturing is 1,000 employees.

The relevant NAICS codes include:

314999 (All Other Miscellaneous Textile Product Mills)

337910 (Mattress Manufacturing)

339930 (Doll, Toy, and Game Manufacturing)

339999 (All Other Miscellaneous Manufacturing)

423220 (Home Furnishing Merchant Wholesalers)

424330 (Women's, Children's, and Infants' Clothing and Accessories Merchant Wholesalers)

The SBA size standards for "small" for the relevant NAICS codes mean that most suppliers in this product category are considered "small." A U.S. company that has a factory employing 100 people might be a top 10 supplier in a particular infant sleep product category, but would be considered "small" by SBA standards. Similarly, an importer with a U.S. warehouse staff of 50 people would also be considered "small."

Prior to the recalls of some infant inclined sleep products, large domestic and foreign companies and the larger "small" companies by SBA size standards were responsible for most of the sales volume for the hard frame inclined sleep products and inclined play yard sleeper accessories. Many of the inclined sleep products were available at big box chain retailers, and a few were available at mattress retailers. The larger companies have recalled or discontinued these products, and most big box stores have stopped stocking them. However, inclined sleep products are still available from small manufacturers and importers, and discontinued items made by large companies are still available from online merchants. Small companies have always accounted for a majority of the suppliers of the unregulated flat sleep products and infant hammock categories. A large number of suppliers exists for these products; the market is fragmented with

many sellers. Many of the products covered by the draft final rule, particularly the soft-sided products and the products sold by small businesses, are only available online.

The majority of the suppliers to which this draft final rule would apply are small by SBA standards. At least 60 small U.S.-based manufacturers and importers are in this market, as well as 5 large domestic companies, and dozens of foreign companies, some of which ship these items directly to customers in the U.S. via online marketplaces. In addition, more than a thousand home-based businesses supply unregulated infant sleep products that would be subject to the draft final rule, of which hundreds ship from the U.S. Some firms sell these items under multiple brand names and models, including small manufacturers that make “store brands” for larger companies. The number of importers selling unregulated infant sleep products is approximate because the proliferation of online retail makes it possible for importers to quickly change their product offerings based on demand for particular products. The number of foreign companies is approximate for the same reason. In addition to the foreign companies that ship from U.S. distribution sites, dozens of third-party sellers are on major internet retail sites that ship products to U.S. consumers directly from a foreign country. The analysis in this FRFA focuses on the impact on small U.S. manufacturers and importers that ship from the U.S., as well as U.S.-based home businesses, but the large and foreign companies will also be impacted by the cost of complying with this rule. The large number of companies in the unregulated infant sleep products market covered by this rule reflects both a strong market demand for these products and a competitive market with relatively low margins.

V. Impact of Draft Rule by Product Category

As discussed above, a variety of currently unregulated inclined and flat sleep products would be impacted by the draft final rule. The impact on small businesses would vary by product category. This section discusses the potential impacts by product category. We describe each product, provide information on the types of firms that supply the product, and describe the impacts for each product type for complying with this rule or taking action to exit the market sector.

a. Inclined sleep products – prices, market demand, and impact of this rule on suppliers

Hard frame inclined sleepers, compact foam inclined sleepers, and play yard accessories

Freestanding inclined hard frame sleepers retail for \$40 to \$120, depending on brand and features, such as, attached toys, fabric coverings, battery-operated sounds, adjustable positions, etc. Compact foam inclined sleepers retail for about \$100. Hard-framed inclined play yard accessories are not sold separately; they are included in the price of the play yard.

In recent years, sales of inclined sleepers have amounted to at least 722,000 units per year.⁴ The sales of these products alone total nearly a quarter of all households with newborn infants, given

⁴ The recalled inclined products alone had sales of nearly 6.5 million from May 2010 to August 2019. Assuming that the recalled products represented most of the market, 6.5 million divided by 9 years is 722,000.

that just under 3.8 million live births occurred in the U.S. in 2018.⁵ (Also, more than 4000 adoptions from foreign countries occurred, but most of those were at least 1 year old by the time the adoption was finalized.⁶) We assume that some of the market for inclined sleepers has shifted to other flat infant sleep product categories covered by this rule, and to small portable sleep products compliant with existing standards. Since the NPR was published in 2017, some inclined sleep products have been recalled or otherwise removed from the market. However, while resale of recalled products is prohibited, discontinued items that were not recalled are still available on the secondary market, as well as additional physically similar products sold by small companies that were not recalled. JPMA has two manufacturers that are certified as compliant to the current ASTM F3118 standard for inclined sleepers. While larger companies have removed most of their inclined products from the market or remarketed them as chairs or loungers, some smaller importers and foreign direct shippers still offer them as sleep products. Some play yards with inclined sleep accessories are still available. To date, the lack of a CPSC mandatory standard means that new entrants are free to enter this market sector with new inclined sleep products that do not comply with the existing ASTM standard, ASTM F3118-17a, or any other ASTM or CPSC sleep standard. Many of the recalled items were still available from smaller Internet merchants in the spring and summer of 2020. Some items that were not recalled, but merely discontinued by the manufacturer, are still available for sale from retailers, at least until the remaining stock is sold.

Once the draft final rule is published and becomes effective, suppliers of inclined sleep products must either redesign existing products to comply with the standard and conduct third-party testing to demonstrate compliance, stop selling the products, or remarket the products as not intended for infant sleep. The impact of those options will depend upon how much redesign the product requires, and what portion of the company's sales are inclined sleep products. The impact on small companies that sell many different products in different categories, which is relatively common, especially for importers, will likely not be as significant as the impact on small companies that sell only a few types of products or that concentrate on sleep products covered by this rule. The impact of remarketing products for a different use, such as for an older child, a pet, or not for sleep, will depend on the extent to which consumers demand the product for the different use. Given the proliferation of floor chairs, lounge chairs, rockers, and bouncer seats on the market, it seems likely that consumers find value in physically similar products that are marketed for a different use, and that remarketing will not reduce demand. U.S. sales of the combined category of bouncer seats, rockers, and sleepers totaled more than 2 million units and \$126 million dollars in 2018.⁷

Suppliers of the hard-plastic framed rocker-type items may choose to redesign their items to meet the requirements of a different mandatory safety standard, particularly the one for infant bouncer seats. Most of the hard-framed products were made by large or foreign companies, although the market volume has shifted to smaller companies as the larger companies have

⁵ <https://www.cdc.gov/nchs/nvss/births.htm>

⁶ https://travel.state.gov/content/travel/en/InterCountry-Adoption/adopt_ref/adoption-statistics-esri.html

⁷ Baby feeding, care, and travel accessory unit sales in the United States in 2018, by product type - <https://www.statista.com/statistics/891908/baby-feeding-care-and-travel-accessory-unit-sales-by-product-type-us/>
And Baby feeding, care, and travel accessory sales in the United States in 2018, by product type <https://www.statista.com/statistics/891889/baby-feeding-care-and-travel-accessory-sales-by-product-type-us/>

already removed these items from the market or remarketed them as chairs, rockers, or chair/swing combos. Two small domestic companies that make inclined sleep products may experience a significant economic impact⁸ as these were some of their best-selling products, and one of them also supplied the product as a “store brand” to another company. The other sells multiple types of sleepers within the scope of the draft final rule. Redesigning, re-labeling, or discontinuing the products could be a significant impact on these firms. The rest of the small domestic companies that sold this product and small importers will likely not be significantly impacted because they sell many other products that would not be subject to the draft final rule.

Suppliers of inclined compact foam products will need to redesign their products with an incline of 10 degrees or less and meet other requirements of this standard, remove these products from the market, or relabel them as not being intended for sleep by children under 5 months of age. Some of these products have restraining harnesses to keep the infant from sliding down on the slanted product, which is not compliant with any of the existing CPSC sleep standards. Some suppliers have already remarketed the products as loungers or floor chairs without changing the design. Several of the companies that sell these products sell larger wedge pillow products for adults and older children as “body pillows” or sleeping positioners, so the infant sleep products are not their only product line. Redesign or remarketing could have a significant impact for the three small domestic companies and one importer that have such products, as well as other products in the scope of this rule, as a large portion of their product line.

Suppliers of inclined play yard accessories will need to redesign their products with an incline of 10 degrees or less and meet other requirements of this standard, remove these products from the market, or relabel them as not being intended for sleep by children under 5 months of age, if appropriate. Most play yard suppliers have already discontinued or recalled the inclined accessory products and replaced them with flat products instead. The ASTM standard for non-full-size-cribs and play yards, F406-19, already specifies that bassinet, changing table, or similar accessories must comply with the applicable requirements of ASTM standards addressing those product types. Play yard suppliers were already required to comply with the requirement that bassinet accessories meet the bassinet standard. Because the main product is the play yard, not the particular accessories, and suppliers were already required to comply with the bassinet standard for bassinet-type accessories, this rule should not have a significant impact on any of the suppliers of play yards, unless they had “napper” or “inclined sleeper” accessories that did not meet the bassinet standard. The impact could be significant for one small domestic company that still sells inclined play yard accessories, and has other products in the scope of this rule.

Baby Hammocks

Hammocks range in price from about \$50 for a simple fabric hammock without a frame to over \$300 for one with a wooden or metal stand. Crib hammocks, which are intended to attach to cribs or play yards of any brand, retail for about \$50 to \$100. A few play yards are sold with a

⁸ Please note that the number of companies impacted for each product type sums to more than the total number of impacted companies for the rule as a whole, because several small companies sell products in multiple product categories impacted by this rule.

shallow mesh-sided insert with a flat; these are discussed in the next section as a category of flat products.

Baby hammocks are widely available from small domestic companies, importers, and home-based sellers. The internet sites of several major general retailers sell these items from third party sellers. Hammocks are made from a variety of fabrics and may include padded sides or bottoms. They may come without a frame, or with a wooden or metal stand. Some items are solid fabric, while others are mesh or crochet. The market is fragmented and all of the sellers in the U.S. are small companies, although some are importers of items made by large foreign companies. The large number of sellers, including at least one company that sells only baby hammocks and dozens of home-based sellers, suggests that thousands of baby hammocks are sold each year.

Suppliers of baby hammocks are unlikely to be able to redesign their product to meet any of the existing CPSC infant sleep standards. An inclined sleep angle is inherent in the design of hammocks, which shift shape as the infant moves. Sleeping pads in the bottom of a hammock would still leave the product with sides that shift shape in use. For hammock accessory products sold separately that attach to the corners of a crib or play yard, there is no standard installation that could be tested to meet incline, gap, side heights, or stability requirements: the incline would depend on the size of the crib or play yard and the weight of the infant, and the gaps between the hammock side and the side of the crib or play yard would depend on the size of the crib or play yard. Therefore, re-labeling and remarketing baby hammocks as being not for sleep or as being intended only for children at over 5 months of age may be the only compliance option, other than removing the products from the market altogether. Since the NPR was published, some of these products have been withdrawn from the market by small companies that make and import other types of baby products or adult hammocks. However, many home-based suppliers remain in the market, as well as several small domestic businesses, one of which appears to have infant crib hammocks as its only product. Multiple importers based in the U.S. also sell hammocks with frames made by foreign companies, but those companies will not be significantly impacted because they sell many other products that would not be impacted by the draft final rule. Several foreign companies that make baby hammocks will have to stop distributing them in the U.S., or conspicuously label them as being for use only by children over 5 months of age. If the products are removed from the market, the impact will likely be significant for one small domestic company for which baby hammocks constitute most, if not all, of their product line, as well as possibly significant for several small importers that do not appear to have many other products. The impact will likely be significant for dozens of home-based manufacturers that have crib hammocks or other fabric hammocks without a frame as their main or only product, if they choose to exit the market. However, it is possible that some sellers of hammocks will simply relabel and remarket them for older children or as toy storage hammocks. The demand for these products for older children or toy storage uses is unknown.

b. Flat sleep products without an incline - prices, market demand, and impact of this rule on suppliers

Flat, soft-sided sleep product types - The flat, soft-sided sleep products that are not covered by an existing CPSC sleep standard include baby pods or baby nests, which are marketed for use on either a hard surface or as in-bed sleepers, as well as soft-sided “bassinets.” Some soft-sided products are marketed for use inside a crib or bassinet. Some are marketed as portable or travel infant beds. These products, which are not now covered by any sleep standard but would be under the draft final rule, include:

- Baby pods and baby nests have a soft floor, usually padded in some way, with low soft fabric or mesh sides, resembling a small pet bed. They can be rectangular, oval, or figure-8 shaped. Some come with a wedge pillow. They are sometimes marketed as suitable for use inside a crib or play yard.
- Soft-sided “travel bassinets” or “travel beds” can have either a soft or semi-rigid floor. Some come with straps and zippers so that they can be rolled up and carried like a backpack when not in use. Some are marketed as “3 in 1” products that can also be used as a changing mat and include pockets for diapers. Some have a “cocoon” design with a soft padded top intended to cover the body of the occupant.
- Products that are marketed as both a hand-held carrier and a (soft) bassinet, suitable for napping or sleeping.
- In-bed sleepers with low, soft sides and a soft floor, specifically intended and marketed for bed-sharing.
- Play yard accessories with mesh or fabric sides that attach to the rails of the play yard and that are marketed for infant sleep, including “napping”. These items are already required to be compliant with the bassinet standard if they are marketed as bassinets. Items marketed as changing pads are not considered to be infant sleep products.

The prices for baby nests, baby pods, and in-bed sleepers range from about \$40 to \$200, with the lower priced items tending to come from home-based manufacturers and foreign direct shippers and the more expensive items from larger U.S. companies that are still small by SBA standards. Smaller products intended only for infants under 6 months also tend to be cheaper than larger products intended for children up to 2 years old. The various soft-sided travel bassinets and “travel beds”, some of which fold up into a backpack, have a similar price range. Almost all the companies in this product category are small businesses. Accessories to play yards are not sold separately, and are sold by both large and small businesses.

At least 30 small businesses, mostly importers, sell the soft-sided, flat sleep products.⁹ Dozens of foreign companies ship these sleep products directly to U.S. customers via U.S. internet retailers, and over a thousand home-based sellers of baby pods and baby nests. Some of the foreign direct shippers connect with potential customers through social media, and thus do not use any U.S.- based distributor or importer. In fall of 2020, a prominent internet retailer had more than 100 different baby nests for sale, including many direct to consumer products shipping from foreign countries. Over 30 of the top 50 best-selling products in the “infant and toddler travel beds” category on the same retailer in fall 2020 were soft-sided, flat products marketed as suitable for infant sleep, including products marketed for bed-sharing, and baby tents. An internet marketplace for home-based sellers and crafters has over a thousand sellers of baby

⁹ This number is approximate, as the proliferation of internet retailing allows importers to quickly enter and exit the market, and to switch their product line based on demand

nests, of which hundreds ship from the U.S. Sufficient consumer interest in this market sector exists, such that an ASTM subcommittee is working to develop a standard specifically for in-bed sleepers.

The estimated annual sales of in-bed sleepers alone are 1 million units,¹⁰ based on both public comment and staff analysis. The Durable Nursery Products Exposure survey (DNPES) indicated that 38% of parents slept with their child under 1 year of age at least once a week, with 18% sleeping with their child every night. The CDC similarly found¹¹ that 24.4% of parents bed-shared with their infant “often or always” and 37% shared “rarely or sometimes.” If parents that regularly sleep with their infants commonly purchase or make a soft-sided baby nest or other type of in-bed sleeper, then these products could be owned by 25% of households with newborns, representing about 1 million units sold per year, which is consistent with the estimate from a public comment on the 2019 SNPR. Baby nests and pods are marketed as a primary sleep environment for newborns, as well as for napping.

Many of the suppliers of flat, soft-sided products would likely be significantly impacted by the draft final rule. This is because compliance with any of the sleep product standards, particularly the stability, side height, and occupant containment requirements, would be difficult for a product with low, soft sides. A product with low, soft sides cannot meet the bassinet standard by simply adding a stand, nor can it meet the hand-held carrier standard by simply adding handles. Adding rigid higher sides would be contrary to the intended product use as in-bed sleepers. Re-labeling the products as being not intended for infant sleep might not be an option if the product is clearly intended for infant sleep, and is not large enough for an older child, although these items could be remarketed as pet beds. At least nine small importers and four domestic manufacturers that supply these products have these products as most or all of their product line. There are also potentially hundreds of small, home-based businesses for which such products appear to be their major product line. The impact for suppliers that have these products as most of their product line would likely be significant. In addition, the many home-based businesses do not currently have warning labels, instruction manuals, or certification to other CPSC or ASTM standards. Some products are already being remarketed as loungers, nappers, or “for tummy time,” but will be required to comply with the draft final rule if they are marketed for sleep, including napping.

Flat play yard accessories are already required to meet the bassinet or other applicable standard. The ASTM standard for non-full-size-cribs and play yards, F406-19, already specifies that bassinet, changing table, or similar accessories must comply with the applicable requirements of ASTM standards addressing those accessories. Most flat play yard accessories are hard-framed, not soft-sided, and are discussed in the next section. Because the main product is the play yard, not the particular accessories, and suppliers were already required to comply with the bassinet standard for bassinet-type accessories, this rule should not have a significant impact on any of the suppliers of flat play yard accessories, unless they have “napper” accessories that are not

¹⁰ A public comment on the 2019 SNPR estimated the annual sales of “in-bed sleep products” at 500,000 to 1.5 Million units, which is consistent with the estimates in the DNPES and from CDC on prevalence of bed-sharing.

¹¹ Bombard JM, Kortsmitt K, Warner L, et al. Vital Signs: Trends and Disparities in Infant Safe Sleep Practices — United States, 2009–2015. *MMWR Morb Mortal Wkly Rep* 2018;67:39-46. DOI: <http://dx.doi.org/10.15585/mmwr.mm6701e1>

compliant with the bassinet standard. One importer has only one model of play yard with a flat mesh accessory as their main product; that importer could be significantly impacted if their product is not compliant and they cannot find another supplier with a compliant product.

Flat, Rigid-Sided and Rigid-Framed Compact Bassinets, Travel Bassinets, and Similar Products

This category includes flat, free-standing products that resemble a bassinet without a stand or legs. Baby boxes and other rigid-sided products without a stand are marketed for infant sleep, sometimes as “compact” or “travel” bassinets. Some compact bassinets have mesh sides with a rigid metal or plastic frame. Larger rigid-sided items that comply with the play yard standard, and play yard accessories that are compliant with the bassinet standard, are out of scope for the draft final rule. Most flat, rigid-sided products are rectangular, but oval and round ones are also available. As noted above, some flat soft-sided items are also marketed as “travel” bassinets. The term “bassinet” is used in product names for rigid-sided items with a stand that meet the CPSC bassinet standard, but also to flat and inclined items without a stand, some with soft padded sides, which do not meet the bassinet standard. The draft final rule is, in part, intended to make it clearer to consumers which products are safe for infant sleep, regardless of the product name.

Rigid-sided and rigid-framed compact bassinets and travel bassinets typically sell for about \$50 to \$150, which is comparable to the lower end of the price range of bassinets that comply with the bassinet standard. Retail prices for baby boxes start at about \$50 to \$75, depending on the brand and decorative design, although some are sold only as part of a \$300 or more bundle with clothes, diapers, and other baby items. Baby boxes were given away for free by some State governments and hospitals, so the cost to the consumer was \$0, although those organizations purchased them from a small domestic company that is no longer offering them. Play yard accessories are not separately priced or sold separately; they are included with the play yard.

These products have a variety of names. Several small domestic manufacturers and small importers, as well as large domestic and foreign companies, sell small rigid-sided or rigid-framed products that resemble a bassinet without a stand as “compact”, “portable” or “travel” bassinets or as infant “travel beds.” About a dozen sellers ship these products from the U.S. and a few foreign companies sell through internet marketplaces. The presence of several large domestic and foreign companies in this market, as well as introductions of innovative products each year, indicate that a strong consumer demand for these products, which supports the ASTM bassinet and cradle sub-committee’s efforts to include a requirement specifically for compact bassinets. Staff believes it likely that some of the demand for inclined rigid-sided products has shifted to this market sector. Unlike the soft-sided products, this sector does not have many home-based businesses or foreign direct shippers.

Baby boxes are a sub-type of compact bassinet that are made of cardboard. They are sold by two small domestic companies and one foreign company in the U.S. and can also be purchased directly from several foreign companies. The sales are relatively small; estimated at under 20,000 per year.¹² This means that less than 1% of households with newborns purchase these items. They are sometimes marketed as “Finnish” baby boxes, because the government of

¹² A public comment estimated 2018 sales from 2 of the 3 U.S. baby box companies at more than 10,000.

Finland provides new parents with a baby box or cash equivalent. As noted, some States and local hospitals gave away baby boxes to new parents or made them widely available through social service agencies in the past.¹³ Like other compact bassinets, baby boxes are marketed as a primary sleep environment for newborns.

Compact bassinets with rigid sides or rigid-framed sides but without a stand or legs cannot meet the stability or physical requirements of the CPSC bassinet/cradle standard or this standard, independent of whether the product has an incline. Suppliers may choose to offer their products with a stand to meet this standard, or add a handle and redesign the product to meet the hand-held carrier standard. In either case, the cost of redesigning the product could be significant. These products usually already have flat floors and rigid sides, as required by the bassinet/cradle standard, but may not meet the side-height requirement of the bassinet/cradle standard. However, the cost to redesign could still be significant, as even a simple re-design could cost hundreds of thousands of dollars per model and require new third-party testing, and all of the product marketing, instructions, and packaging would have to be revised. Adding a stand would also increase the retail price of the product, which would likely reduce sales, assuming that demand is responsive to price and that other products like hand-held carriers are considered by consumers to be reasonable substitutes. These products likely cannot be remarketed for another use by infants 5 months and under, as the physical design suggests the product is for sleep, although they could be remarketed for older children or for pets, depending on whether the size is appropriate for those uses. For the importers, the impact is likely not significant, as they do not have these products as most of their product line and can therefore either stop selling the product or obtain a compliant product from a different supplier at minimal cost to them. For the two domestic manufacturers of these products that have these products as most of their product line, or sell multiple products covered by this rule, the cost of compliance could be significant. Baby boxes have similar compliance impacts to the larger category of compact bassinets. Some compact bassinets are marketed as suitable for bed-sharing, so may be considered as rigid in-bed sleepers. Suppliers of baby boxes and in-bed sleepers with rigid or rigid-framed sides may also choose to offer their products with a stand to meet the bassinet standard. Given that these products already have rigid sides and flat sleeping surfaces, the redesign may be relatively minor, but could still cost hundreds of thousands of dollars to implement and test, especially given the need to adapt them to meet stability requirements. These suppliers could also choose to add a handle to these products and make other design, instructions and labeling changes in order to comply with the hand-held carrier standard. Labeling these products as not for infant sleep is likely not an option, as these items are intended for sleep, and are too small to be used by older children. Remarketing as storage boxes is possible, but likely a much lower price point. The impact could be significant for two suppliers of baby boxes.

Flat play yard accessories are already required to meet the bassinet or other applicable standard. The ASTM standard for non-full-size-cribs and play yards, F406-19, already specifies that bassinet, changing table, or similar accessories must comply with the applicable requirements of ASTM standards addressing those accessories. Because the main product is the play yard, not the particular accessories, and suppliers were already required to comply with the bassinet standard for bassinet-type accessories, this rule should not have a significant impact on any of the suppliers of flat rigid-sided play yard accessories, with the possible exception of a few

¹³ Similar programs now offer free cribs or play yards.

“napper” products from small importers. Those importers should be able to find a new compliant supplier relatively easily, or relabel the items as not for sleep.

Baby Tents

Baby tents, which are a small mesh or solid fabric product with a fabric floor are marketed for sun protection, play, and baby sleep. They are sometimes marketed as a combination of tent and “travel beds” or “travel bassinets.” Some baby tents come with flaps, covers, or shades so that the baby can sleep in darkness. Some products come with poles or stakes to fasten the tent to the ground or beach. Some tents have a shallow fillable pool/sandbox in the floor, which indicates they are not intended primarily for sleep, but rather for play.

Baby tents retail for about \$20 to \$75; larger and more expensive tents are available, but are marketed for older children. Baby tents are offered by about a dozen small importers and a few large companies on major Internet general retailer websites and in general retail stores. Dozens of foreign companies ship these baby tents directly to U.S. customers via U.S. Internet retailers; the majority of suppliers in this category are the foreign direct shippers. Baby tents are marketed as a specialty item for outdoor use, particularly beach trips or camping, to shade the baby from sun and provide a place for play and sleeping. Indoor “play” tents are also marketed for sleep, but those products are mostly marketed for children over 3 years of age. Indoor play yards with tent-like covers are in the scope of the play yard standard. While baby tents are a relatively niche product compared to some of the other types of sleepers, there appears to be sufficient demand for baby tents to support the market presence of dozens of companies, including a few large companies selling a variety of other baby products.

Baby tents cannot meet any of the CPSC sleep standards, due to the physical form of these products, which includes slanted flexible sides connected to the floor, sometimes with hanging cords and anchoring spikes. Therefore, re-labeling these products as not for infant sleep or removing the products from the market are the only compliance options. We assume that most suppliers will choose to remarket their items as not for sleep or for older children, and that this will not reduce sales, because the advertised primary purpose of the product is shade and insect screen. Also, most suppliers in this product sector are importers with many other unrelated products or foreign direct shippers. Staff believes it unlikely most of the suppliers in this category will experience a significant economic impact as a result of this rule. One small importer does not appear to have any other products that might be significantly impacted if they cannot find a compliant supplier.

c. Summary of Costs and the Economic Impact of the Draft Final Rule

Suppliers that choose to stay in the market for infant sleep products will need to comply with the draft final rule, or another CPSC sleep standard, and certify compliance through third party testing. Suppliers that choose to relabel their products as bouncer seats or swings will need to meet the standards for those products. Suppliers that relabel their products for use by children over 5 months will still need to meet general testing and certification requirements required for

all children's products, such as testing for lead content and phthalates, as well as small parts, but they were already required to meet those requirements.

Based on costs for compliance with other ASTM and CPSC standards for durable nursery products, the expected cost to comply with third party testing will be about \$1,500 per model tested, including the costs of the samples to be tested. This is for compliance with the specific standard for infant sleep products only; the costs for complying with general requirements for children's products should not be new costs for any suppliers. Some of the companies that are small by SBA standards have up to a dozen models of different products impacted by this rule, each of which will have to be tested for compliance with this standard. This would suggest testing costs of about \$18,000 per testing cycle.

The suppliers of soft-sided products and hammocks are unlikely to be able to redesign their products to meet any of the sleep standards, so they will need to decide whether to exit the market or relabel their products for use by older children. The impact is likely to be significant for suppliers of these products if these products constitute a substantial portion of their product line, and they choose to exit the market rather than remarketing the items for older children or pets.

Some manufacturers and importers, both large and small, may be able to minimize the impact of this rule by marketing their products as not for infant sleep, thus effectively putting their products out of scope of this rule. This may involve conspicuously labeling and marketing their items as not for sleep by children under 5 months. Some flat, rigid-sided products could demonstrate compliance with this standard and the bassinet standard with the addition of a stand or other rigid support. Some non-compliant items might be remarketed for pet use, which has apparently happened with some former children's products, but the market for such products is probably limited. Remarketing these products could still result in significant impact of suppliers if such relabeling results in a substantial reduction in product demand.

While some items can be credibly remarketed as not for infant sleep, such as items that resemble chairs or swings, the design of other items suggest they are intended for infant sleep, including hammock crib accessories, baby boxes, and in-bed sleepers, as are most compact bassinets and anything marketed as a "bed". Some of these products could be marketed for children over 5 months, depending on the size of the product, but many are too small for a larger child. Suppliers of products where the design and function of the product communicates to the consumer that the product is intended for infant sleep may experience a significant economic impact if those products are a substantial portion of their product line.

Most home-based manufacturers will have the choice of either remarketing their products as not for infant sleep or stopping the sale of the products. The cost of redesigning the product to comply with the standard could be a significant portion of revenue for home-based manufacturers, and redesign might not even be possible for some products commonly sold by home-based manufacturers, such as baby hammocks and flat products with low, soft sides. Additionally, even if redesign were possible, the testing costs alone could be sufficient to induce these home-based manufacturers to withdraw from the market for these products. The economic impact of the rule on these home-based manufacturers is likely to be significant. In some cases,

these manufacturers might be able to relabel their products for older children, or for pet use. In the case of hammocks, the items could also be marketed for toy storage. However, the demand for infant sleep products for these types of alternative uses is likely to be limited.

We discussed earlier the impacts for specific types of sleeper markets. In summary, the suppliers of inclined sleepers can redesign their items to meet this standard, remove them from the market, relabel them for use by older children, or remarket them as some type of chair. Some inclined items have already been remarketed as types of chairs or chair/swing combination products. The impact would depend on the demand for these products as chairs; the current remarketing suggests that companies have found there is indeed demand for these products as chairs. Suppliers of inclined play-yard accessories have similar options; it appears that most play-yard suppliers have chosen to remove these items from the market and replace them with flat accessories instead. Because play-yards were already required to comply with the bassinet standard if in bassinet mode, this may not be a significant impact. Suppliers of compact rigid-sided and rigid-framed products without a stand may be able to redesign their products to meet this standard, or remarket them for use by older children. The size of some of these products would be appropriate for use by older children. Some suppliers of soft-sided “travel” and “compact” bassinets are unlikely to be able to redesign their products to comply with this standard, but may be able to remarket them for use by older children. Similarly, suppliers of in-bed sleepers and baby hammocks are unlikely to be able to redesign their products to comply with this rule, but some may be able to remarket them for use by older children or pets, depending on the size of the products, although demand for those uses may be limited.

In general, suppliers of products with limited remarketing options, where the size of the product is not conducive to use by older children, the soft sides cannot easily be redesigned to meet this standard, and the physical configuration of the product limits uses other than sleep, are likely to be significantly impacted. Some suppliers may be able to remarket their infant sleep products for alternative uses. However, this market is probably limited; otherwise, some of these suppliers would already have been producing products for these alternative uses. At least nine small domestic companies and twelve small importers are likely to be significantly impacted because products in scope of this rule represent most or a substantial portion of their product line. Hundreds of home-based manufacturers based in the U.S. supply baby nests, baby pods, in-bed sleepers, hammocks, and crib hammocks are likely to be significantly impacted, although some may be able to relabel their items as not for sleep or for older children. If the products cannot be remarketed, many of these home-based manufacturers may eliminate infant sleep products from their product lines; it also possible that a significant proportion may go out of business.

In summary, taking all of these factors into account, the draft final rule is likely to have a significant economic impact on a substantial number of small entities.

VI. Issues Raised by Public Comments Specifically on Expected Impact on Small Businesses

The IRFA in the 2019 SNPR requested public feedback on the effective date, and on how firms would respond to the 2019 SNPR (e.g., would firms remarket, redesign, or drop products subject to the proposed rule).

We received multiple comments on the proposed effective date of 12 months after publication. The comments did not represent a consensus. The suggested effective dates ranged from immediately to much later than 12 months. Comments in support of an earlier effective date urged an earlier effective date to more quickly address the pattern of injuries and fatalities. These comments came from consumer safety advocates and medical professionals. Comments in support of a later effective date noted that businesses would need more time to redesign products. These comments came from suppliers of such products. Some of these commenters also recommended further research and work with ASTM to develop additional standards for specific products, particularly compact bassinets and in-bed sleepers. Comments similarly did not represent a consensus on whether the proposed effective date should be a “sold by” date, or a “manufactured by” date.

We didn’t receive any comments specifically on the impact of the rule on small businesses of any type from commenters identifying as small businesses, other than the issue of 12 months being insufficient time to redesign products. We received multiple comments from other types of commenters, including parents of deceased children, consumer safety groups, and medical professionals, expressing concern that many of these items would be remarketed as not for sleep but would still be used for sleep. While some of the unregulated products may be remarketed as not for infant sleep, the draft final rule provides parents and other caregivers clearer information as to the manufacturer’s intended safe use.

VII. Other Potential Impacts of the Staff-Recommended Draft Final Rule

The draft final rule would make it illegal to sell, offer for sale, manufacture for sale, distribute in commerce, or import into the United States products not compliant with the rule 12 months after the publication of the rule in the *Federal Register*. This means that parents and other caregivers would not be able to purchase these items. The large volume of these products sold or home-made reflect that these products all address a demand for a compact sleep space for babies, so it is reasonable to assume that demand will continue for new or redesigned products that meet one of the CPSC sleep standards. As discussed earlier, products that are compliant with the current CPSC sleep standards are already widely available, provide compact sleep spaces, and are in the same general price range as the items covered by this rule.

Several public commenters suggested that this rule would cause caregivers to resort to less safe sleep solutions, such as putting infants to sleep in car seats, or using pillows to position infants on adult beds. Caregivers may already make home-made sleep places or mis-use other types of products, and staff is unaware of data to support the assertion that this rule would further encourage such practices. Directions for making home-made baby nests were widely available on the Internet before CPSC published the 2017 NPR. The DNPES, which was done in 2014, found that a majority of parents were using products for sleep that are not marketed for sleep,

such as swings, bouncer seats, and hand-held carriers at least once a week.¹⁴ In addition, many inclined products have already been removed from the market or re-labeled as not for sleep since publication of the 2017 NPR. While some of the inclined products may be remarketed as not for infant sleep, the draft final rule will provide parents and other caregivers clearer information as to the manufacturer's intended safe use.

The effective date is a "sold by" date. This means that retailers will need to sell or otherwise dispose of their stock by that date. Given that this rule has been in progress for several years through a notice and comment rulemaking, and that many of the inclined products have already been withdrawn from the market, this should not have a significant impact on small retailers.

This rule would require all infant sleep products not in the scope of other CPSC sleep standards to comply with this rule. This means that new products would have to comply with this rule, or one of the other sleep standards. Suppliers may introduce new products that comply with any of those standards, such as an innovative bassinet design that meets all the requirements of the bassinet standard. They may also work with ASTM to revise one of the ASTM sleep standards to cover their new product, and then CPSC could consider such revision as part of CPSC's existing procedures for accepting revisions to voluntary standards that are the basis for CPSC mandatory standards. Suppliers of innovative products may also work with ASTM to develop a separate, new sleep standard, then petition the CPSC to recognize another ASTM standard as a sleep standard.

VIII. Impacts of Test Laboratory Accreditation Requirements on Small 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 third-party conformity assessment body that has been accredited by CPSC. These third-party conformity assessment bodies test products for compliance with applicable children's product safety rules. Testing laboratories that want to conduct this testing must meet the Notice of Requirements (NOR) for third party conformity testing. CPSC has codified NORs in 16 CFR part 1112. Staff recommends that the Commission propose to amend 16 CFR part 1112 to establish a NOR for testing laboratories to test for compliance with the draft final rule for infant sleep products. This section assesses the impact of this amendment on small laboratories.

CPSC conducted a FRFA when it adopted part 1112. 78 FR 15836 (Mar. 12, 2013). 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 laboratories that anticipated receiving sufficient revenue from the mandated testing to justify accepting the requirements as a business decision.

For the same reasons, including the NOR for infant sleep products in part 1112 would not have a significant adverse impact on small laboratories. Moreover, CPSC expects that laboratories that

¹⁴ The DNPES reported that in households with children under 6, children slept in bouncer seats at least once a week in 70% of households that owned a bouncer seat, slept in swings at least once a week in 91% of households with a swing, and slept in hand-held carriers at least once a week in 87% of households with hand-held carriers.

are already accredited to test to the bassinet/cradle standard would find it relatively easy to become accredited to test to this standard, because the primary substantive requirement added by this standard is the sleep surface angle. This cost should be very small for laboratories that are already accredited for other CPSIA section 104 rules. Therefore, the Commission could certify that the NOR for the infant sleep product standard will not have a significant impact on a substantial number of small entities.

IX. Other Federal Rules Which May Duplicate, Overlap, or Conflict with the Draft Final Rule

CPSC staff has not identified any other Federal rules that duplicate, overlap, or conflict with the draft final rule.

X. Efforts to Minimize the Impact on Small Entities (Alternatives)

CPSC has attempted to minimize the impact of the draft final rule on small entities by defining the scope of this rule to only include infant sleep products that are:

1. not within the scope of another standard
2. marketed or labeled for infant sleep, including napping
3. marketed or labeled for use by children up to 5 months old.

This gives small businesses the opportunity to remove their products from the scope of this standard by marketing them as not intended for sleep, or only intended for use by older children, or for pets. Companies can also redesign their products to meet the requirements of another standard, such as infant bouncer seats or hand-held carriers. In some cases where there is another use for the product, the only change required to make a product subject to one of these other standards is to relabel or remarket the product, removing any references to its use for sleeping.

CPSC also published the 2019 SNPR, which means firms have been aware of this rulemaking effort and have had several years to prepare for implementation of the draft final rule. Many companies that had inclined products that were in the scope of the 2017 NPR have removed those products from the market since 2019, or remarketed them as loungers, bouncer seats, or other products not for sleep.

Given the number of small baby nest and hammock home-based manufacturers, the Commission could consider exempting small batch manufacturers from the testing requirements proposed under the rule. However, under Section 14(d)(4)(C)(ii) of the Consumer Product Safety Act, the Commission cannot “provide any alternative requirements or exemption” from third party testing for “durable infant or toddler products,” as defined in section 104(f) of the Consumer Product Safety Improvement Act of 2008. Consequently, staff cannot recommend a small batch exemption absent a statutory change.

The ASTM F3118 committee considered wording that would allow manufacturers to choose whether to comply with F3118 *or* another ASTM sleep standard, to allow innovative products to

enter the market more easily. This draft final rule requires suppliers to comply with this rule or one of 5 existing CPSC mandatory standards for full-size cribs, non-full-size cribs, bassinets and cradles, play yards or bedside sleepers. The approach considered by ASTM to allow other ASTM sleep product standards would allow suppliers to sell products that did not meet an existing CPSC sleep standard, such as a drop side crib, so long as that product had a sleep surface of less than 10 degrees and otherwise complied with ASTM F3118. Staff cannot recommend this approach, which would effectively allow potentially unsafe, non-compliant sleep products to re-enter the market.

Finally, the IRFA discussed allowing a later effective date. A later effective date would reduce the economic impact on firms in two ways. Firms would be less likely to experience a lapse in production/importation, which could result if they are unable to comply and third-party test within the required timeframe. Also, firms could spread costs over a longer time period, thereby reducing their annual costs, as well as the present value of their total costs. Staff received comments both supporting and opposing a later effective date. Given that many of the products have already been removed from the market or otherwise remarketed to be out of scope of this rule, reducing the impact on domestic small businesses, and that companies already had notice that this draft final rule was in progress since November 2019, staff recommends a 12-month effective date.

**TAB F: Infant Sleep Products: Summary of Recalls –
August 2019 through January 2021**

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

Memorandum

DATE: April 7, 2021

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

THROUGH: Robert S. Kaye, Director
Office of Compliance and Field Operations
Jennifer T. Timian, Director, Division of Regulatory Enforcement
Carolyn T. Manley, Assistant Division Director,
Division of Regulatory Enforcement

FROM: Keysha L. Walker, Compliance Officer, Division of Regulatory
Enforcement

SUBJECT: Infant Sleep Products: Summary of Recalls – August 2019 through
January 2021

Compliance staff provides this summary of recalls from August 2019 through January 2021 in support of the draft final rule for infant sleep products.

Summary of Recalls Involving Infant Inclined Sleep Products

Since issuance of the Supplemental Notice of Proposed Rulemaking (SNPR) in 2019, six additional recalls have occurred involving infant inclined sleep products that do not fall within the scope of an existing CPSC infant sleep standard (meaning the mandatory standards for bassinets and cradles, play yards, cribs (full-size and non-full-size), and bedside sleepers). In summary, the six recalls affected approximately 268,300 units. CPSC did not conduct any recalls for unregulated flat products from August 2019 through January 2021.

Table I below provides a summary of the information involving the six recalls.

TABLE I – Summary of Inclined Infant Sleep Products Recalls

Recall Date	Firm	Hazard	Number of Recalled Units/Product Type	Number of Incidents Reported by Firm (Injuries Reported)	Press Release Number
January 29, 2020	Summer Infant (USA), Inc.	Suffocation	46,300 Inclined Sleep Products	No Injuries Reported	20-059 ¹
January 29, 2020	Evenflo Company, Inc.	Suffocation	3,100 Inclined Sleep Products	No Injuries Reported	20-060 ²
January 29, 2020	Delta Enterprise Corp.	Suffocation	5,900 Inclined Sleep Products	No Injuries Reported	20-061 ³
January 29, 2020	Graco Children’s Products Inc.	Suffocation	111,000 Inclined Sleep Products	No Injuries Reported	20-062 ⁴
February 20, 2020	Kolcraft Enterprises Inc.	Suffocation	51,000 Inclined Sleep Accessories Included with Bassinets	No Injuries Reported	20-075 ⁵
December 16, 2020	Graco Children’s Products Inc.	Suffocation	51,000 Inclined Sleep Accessories Included with Play Yards	No Injuries Reported	21-052 ⁶
Total	6		268,300	None Reported	

¹ <https://www.cpsc.gov/Recalls/2020/Summer-Infant-Recalls-SwaddleMe-By-Your-Bed-Inclined-Sleepers-to-Prevent-Risk-of-Suffocation>

² <https://www.cpsc.gov/Recalls/2020/Evenflo-Recalls-Pillo-Portable-Napper-Inclined-Sleepers-to-Prevent-Risk-of-Suffocation>

³ <https://www.cpsc.gov/Recalls/2020/Delta-Enterprise-Corp-Recalls-Incline-Sleeper-with-Adjustable-Feeding-Position-for-Newborns-to-Prevent-Risk-of-Suffocation>

⁴ <https://www.cpsc.gov/Recalls/2020/Graco-Recalls-Little-Lounger-Rocking-Seats-to-Prevent-Risk-of-Suffocation>

⁵ <https://www.cpsc.gov/Recalls/2020/kolcraft-recalls-inclined-sleeper-accessory-included-with-cuddle-n-care-and-preferred>

⁶ <https://www.cpsc.gov/Recalls/2020/graco-recalls-inclined-sleeper-accessory-included-with-four-models-of-playards-to>