

# **Ballot Vote Sheet**

**TO:** The Commission

Alberta E. Mills, Secretary DATE: September 14, 2022

THROUGH: Austin C. Schlick, General Counsel

Jason K. Levine, Executive Director

**FROM:** Daniel R. Vice, Assistant General Counsel, Regulatory Affairs

Mary A. House, Attorney, Regulatory Affairs

**SUBJECT:** ASTM's Notice of a Revised Voluntary Standard for Bassinets and Cradles

BALLOT VOTE DUE:	September 20, 2022
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Section 104(b)(4)(B) of the Consumer Product Safety Improvement Act of 2008 (CPSIA) sets forth a procedure for updating mandatory standards that incorporate by reference, in whole or in part, a voluntary standard for a durable infant or toddler product. 15 U.S.C. § 2056a(b)(4)(B). The Safety Standard for Bassinets and Cradles, 16 CFR part 1218, incorporates by reference ASTM F2194-13, *Standard Consumer Safety Specification for Bassinets and Cradles*, with modifications to make the standard more stringent. 78 *Fed. Reg.* 63,019 (Oct. 23, 2013). Moreover, the Safety Standard for Infant Sleep Products, 16 CFR part 1236, references the bassinet standard of part 1218 as an existing infant sleep standard. Products that meet an existing sleep standard do not fall within the scope of the infant sleep product rule, while sleep products subject to the infant sleep product rule must comply with part 1218 to be sold in the United States. Accordingly, revisions to ASTM F2194 that modify the bassinet standard also modify part 1236.

On July 18, 2022, ASTM notified the Commission that it had approved and published a revised version of the voluntary standard for bassinets and cradles, ASTM F2194-22<sup>£1</sup>. Pursuant to the section 104 update procedure, CPSC staff is forwarding to the Commission a briefing package assessing whether ASTM F2194-22<sup>£1</sup> improves the safety of bassinets and cradles subject to part 1218 and part 1236. Based on CPSC staff's assessment of the revised voluntary standard, public comments on the revised standard, and the Commission's mandatory rules for bassinets and cradles and infant sleep products, staff recommends that the Commission determine that ASTM F2194-22<sup>£1</sup> does not improve the safety of bassinets and cradles, nor the safety of infant sleep products, and notify ASTM that CPSC is retaining the existing consumer product safety standard for bassinets and cradles.

U.S. Consumer Product Safety Commission 4330 East-West Highway Bethesda, MD 20814 cpsc.gov National Product Testing & Evaluation Center 5 Research Place Rockville, MD 20850



# **Ballot Vote Sheet**

Please indicate your vote on the following options:

(Date)
tory standard for bassinets and cradles and dire ration a draft Federal Register notice to revise the ence in 16 CFR part 1218.
(Date)
ļ

Attachment: September 14, 2022 Staff Briefing Package: ASTM's Notice of a Revised Voluntary Standard for Bassinets and Cradles

U.S. Consumer Product
Safety Commission
4330 East-West Highway
Bethesda, MD 20814

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# **Staff Briefing Package**

ASTM's Notice of a Revised Voluntary Standard for Bassinets and Cradles

September 14, 2022

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This report was prepared by the CPSC staff.
It has not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.

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# **Briefing Memorandum**



# Memorandum

DATE: September 14, 2022

**TO:** The Commission

Alberta E. Mills, Secretary

THROUGH: Austin C. Schlick, General Counsel

Jason K. Levine, 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:** ASTM's Notice of a Revised Voluntary Standard for Bassinets and Cradles

# I. Background

In 2013, the U.S. Consumer Product Safety Commission (CPSC or Commission) promulgated a final rule, 16 CFR part 1218 (part 1218), Safety Standard for Bassinets and Cradles, which incorporated by reference the voluntary standard for bassinets and cradles, ASTM F2194 – 13, *Standard Consumer Safety Specification for Bassinets and Cradles*, with modifications to make the standard more stringent (78 *Fed. Reg.* 63,019 (Oct. 23, 2013)). The 2013 modifications in part 1218 clarified the scope of the mandatory standard, changed the bassinet flatness test to provide an exemption from the flatness requirement for bassinets with seams less than 15 inches wide, made an addition to the stability requirement, and made a change to the stability test procedure to use a smaller CAMI dummy<sup>1</sup> for testing. Taken together, the modifications from the voluntary standard made the mandatory standard more stringent, to further reduce the risk of injury associated with bassinets and cradles.

After CPSC issued the final rule in October 2013, ASTM International (ASTM) published several revisions to ASTM F2194: 2013a, 2016, and 2016<sup>£1</sup>. ASTM F2194-16<sup>£1</sup> incorporated the modifications made in part 1218; however, CPSC did not receive notification from ASTM requesting the 2016<sup>£1</sup> revised voluntary standard be incorporated by reference into part 1218. Therefore, the bassinet mandatory regulation has not been updated since establishing the

<sup>&</sup>lt;sup>1</sup> Designed ASTM testing device. CAMI dummies are based on child anthropometric data and come in multiple sizes.

standard in 2013.

In June 2021, the Commission established a Safety Standard for Infant Sleep Products, 16 CFR part 1236, 86 Fed. Reg. 33,022, 33,034-35 (June 23, 2021) (part 1236 or ISP Rule), that also makes the requirements in part 1218 the basis for the safety requirements of infant sleep products. The rule requires that products that are marketed or intended for infant sleep for infants up to five months of age, must meet the requirements of the ISP Rule, unless they already fall within an existing CPSC sleep standard (bassinets and cradles, full-size cribs, non-full-size cribs, play yards, or bedside sleepers). The ISP Rule requires products within the scope of the rule to measure the sleep surface incline, which must be ten degrees or less, and then to meet the requirements of part 1218, including the definition of a bassinet/cradle, which means the product must have a stand. Thus, the requirements of the existing mandatory standard for bassinets and cradles sets a safe sleep floor for infant sleep products.

More recently, on January 1, 2022, ASTM approved, and in June 2022 published, a revised voluntary standard for bassinets and cradles, ASTM F2194 – 22. This revision to the standard adds a new category of product, *i.e.*, compact bassinets/cradles, in addition to new requirements for these products, such as new performance requirements and new marking and labeling requirements. The revised standard also includes new requirements for battery compartments, and revised warning labels, and instructional literature. In July 2022, ASTM published ASTM F2194 – 22 <sup>81</sup> to make editorial corrections.

On July 18, 2022, pursuant to section 104(b)(4)(B) of the Consumer Product Safety Improvement Act (CPSIA), ASTM notified the CPSC that ASTM published a revised  $2022^{\epsilon 1}$  version of ASTM F2194. Section 104(b)(4)(B) instructs the voluntary standards organization, in this case ASTM, to notify CPSC of revisions to voluntary standards that have been adopted, in whole or in part, as a consumer product safety standard promulgated by the Commission, as stated below:

(B) COMMISSION ACTION ON REVISED VOLUNTARY STANDARD - If an organization revises a standard that has been adopted, in whole or in part, as a consumer product safety standard under this subsection, it shall notify the Commission. The revised voluntary standard shall be considered to be a consumer product safety standard issued by the Commission under section 9 of the Consumer Product Safety Act (15 U.S.C. 2058), effective 180 days after the date on which the organization notifies the Commission (or such later date specified by the Commission in the Federal Register) unless, within 90 days after receiving that notice, the Commission notifies the organization that it has determined that the proposed revision does not improve the safety of the consumer product covered by the standard and that the Commission is retaining the existing consumer product safety standard.

Accordingly, by statute, the revised ASTM F2194 –  $22^{\epsilon_1}$  shall be considered a consumer product safety standard issued by the Commission, effective 180 days after July 18, 2022 (January 14, 2023), unless the Commission specifies a later effective date in the *Federal Register*, or notifies ASTM within 90 days of July 18, 2022 (by October 16, 2022) that the Commission has determined that the proposed revision does not improve the safety of bassinets and cradles and that the Commission will retain part 1218 unmodified (ASTM F2194 – 13 with modifications) as the mandatory standard for bassinets and cradles.

This memorandum describes and analyzes the differences between the Commission's existing mandatory standard for bassinets and cradles, part 1218, ASTM F2194 – 22, and ASTM F2194 –  $22^{\epsilon 1}$ , the latest revised voluntary standard. The memorandum explains staff's recommendation to reject ASTM F2194- $22^{\epsilon 1}$ , and to retain existing part 1218 as the mandatory safety standard for bassinets and cradles. CPSC staff reviewed ASTM F2194- $22^{\epsilon 1}$  and concludes that, overall, the revised standard does not improve the safety of bassinets and cradles. Staff bases this recommendation, as discussed below, on several changes in the revised standard that decrease safety. Staff recommends that the Commission reject ASTM F2194 –  $22^{\epsilon 1}$  as a consumer product safety standard, and within 90 days of the July 18, 2022 notice (by October 16, 2022), inform ASTM of this determination. The updated ASTM F2194 –  $22^{\epsilon 1}$  makes bassinets less safe and additionally reverses the minimum infant sleep product characteristics that the Commission relied upon when they issued the infant sleep products rule (ISP Rule). Staff assesses that infant sleep products without a stand are a fall hazard that may lead to injury, notably head injuries, and/or death.

# II. Discussion

Since CPSC promulgated a final rule for bassinets and cradles in October 2013, which incorporated by reference ASTM F2194 - 13 with modifications, ASTM has published four revisions to ASTM F2194. However, CPSC was not notified of these revisions until the most recent version, ASTM F2194 - 22 $^{\epsilon 1}$ .

- A. Revisions to the Voluntary Standard Through 2016
  - 1. Review of Differences Between 16 CFR Part 1218 and ASTM F2194 13a

The only difference between part 1218 and ASTM F2194 – 13a, is the addition in the voluntary standard of a fall hazard warning statement for products with a bassinet bed that is removable from the base/stand. ASTM added this warning to remind consumers to check that a removable bassinet bed is correctly attached, by pulling up on the bassinet bed once it is attached to the stand.

2. Review of Differences Between 16 CFR Part 1218, ASTM F2194 – 16, and F2194 – 16<sup>81</sup>

ASTM approved ASTM F2194 - 16 on April 15, 2016, and it published the revision in May 2016. ASTM also made editorial revisions in May 2016 and published them as ASTM F2194 - 16<sup> $\epsilon$ 1</sup>. Substantive changes include:

#### F2194 - 16

- Note 1 in the Scope section clarifies that multimode products that have a sleep surface of 10 degrees or less from horizontal when in the bassinet/cradle position are included in the scope of the standard.
- Terminology section includes four new definitions:
  - Bassinet bed
  - False latch/lock visual indicator
  - o Intended use orientation
  - Removable bassinet bed

- Definition of "play yard bassinet" clarifies that the mattress can be folded, segmented, or both.
- Section 6.7 adds an exclusion from the segmented mattresses flatness test for mattresses with seams less than 15 inches in length.
- Adds section 6.10 Removable Bassinet Bed Attachment to Base/Stand.
- Adds section 7.12 Removable Bassinet Bed Attachment Tests.
- X1. RATIONALE section adds explanation for adding the removable bassinet bed attachment requirements.
- X1. RATIONALE also explains why the stability testing changed the CAMI dummy from the "infant" to the "newborn."

# $F2194 - 16^{E1}$

• Corrects the reference figures for CAMI Dummy, MARK II, and CAMI Newborn Dummy.

Because the changes in F2194 – 16 and F2194 –  $16^{\epsilon 1}$  made the voluntary standard substantially similar to the mandatory standard, staff considers the changes an improvement in safety.

We note that the Commission previously found that ASTM F2194-16<sup>ε1</sup> is substantially similar to the existing mandatory standard. 86 *Fed. Reg.* 33,022, 33,034-35 (June 23, 2021). As part of the final rule establishing a Safety Standard for Infant Sleep Products, 16 CFR part 1236, the Commission evaluated ASTM F2194-16 <sup>ε1</sup>, stating:

In 2016, ASTM approved and published the most recent version of the standard, ASTM F2194–16<sup>£1</sup>, 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<sup>£1</sup>, 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 F2194–16<sup>£1</sup> in this preamble to the final rule, and CPSC will update the reference in part 1218 to ASTM F2194–16<sup>£1</sup> as soon as feasible.

ld.

B. Assessment of ASTM F2194 – 22 and F2194 –  $22^{\varepsilon 1}$ 

Below staff summarizes the substantive revisions in ASTM F2194 - 22 and F2194 - 22<sup> $\epsilon$ 1</sup> and assesses each revision's impact to safety.

# Substantive Revisions to ASTM F2194 – 22 that Do Not Improve Safety

# a. Scope

ASTM F2194-22 adds a new product category within the scope of the standard, compact bassinets/cradles. Staff assesses that the addition of compact bassinets/cradles within the scope of ASTM F2194 – 22 is a reduction in safety because, as defined in the standard, these products are not required to have a stand and because ASTM F2194-22 requires a less stringent stability test for this product category. Because compact bassinets are smaller and more portable, caregivers place these products in less safe locations, such as elevated and soft surfaces (tables, counters, couches, and beds). CPSC's data demonstrate that infants have suffered serious head injuries and death when using these products in unsafe locations. See Directorate for Engineering Sciences, Division of Human Factors' (ESHF) memo in Tab A for discussion of consumer behavior with portable, compact products.

# b. Definitions

As mentioned in the scope section above, the inclusion of compact bassinet/cradles in the standard, with separate, less strict requirements, is a reduction in safety. As defined in section 3.1.3 of ASTM F2194-22, these products are intended to be less than 6 inches "between the lowest point of the underside of the sleep surface support and the product support surface (floor)." However, staff is aware of head injury incidents and deaths with "portable, compact" infant products, such as compact bassinets and bouncers, that, while intended and marketed to be used on the floor, are used on elevated, soft and hard surfaces that result in the infant falling. See Directorate for Epidemiology, Division of Hazard Analysis' staff memorandum in Tab B for discussion of fall hazards data.

As discussed in more detail in Tab A, ESHF staff demonstrates that consumers use portable, compact infant products in a variety of locations, regardless of warnings that the product is for floor use only. Bassinets are already defined in part 1218 as products having a base or stand. Moreover, under current requirements in the ISP Rule, products marketed or intended for infant sleep are required to meet the requirements of an existing sleep regulation (play yards, full-size cribs, non-full-size cribs, bedside sleepers, or bassinets and cradles), or else meet the requirements for bassinets, including meeting the definition of a "bassinet," meaning they must have a stand or base. ASTM F2194-22 would, however, remove this requirement for compact bassinets/cradles, which includes products without a stand, or with a short stand, to allow for more portability. However, that very portability is what enables consumers to use the product in a variety of unsafe locations, including unstable, soft, and hard elevated surfaces, such as couches, beds, and tables.

The ISP Rule intentionally relied on the definition of "bassinets" in part 1218, which states that bassinets should have legs/base/stand, to discourage consumers from placing infant sleep products on unstable, soft, and hard elevated surfaces. Moreover, products with legs shorter than 6 inches that previously met the definition of a "bassinet" and were required to meet the stability requirements for bassinets, are now defined as a "compact bassinet/cradle," and are now subject to a less stringent stability test, as explained in section c, below. Moreover, products without a stand, such as baby boxes, that are now considered "infant sleep products"

subject to the ISP Rule, and cannot be sold in the U.S., would also be "compact bassinets/cradles" in the revised voluntary standard. Under the ISP Rule, to be sold, such products are now required to have a sleep surface of ten degrees or less, and meet the requirements for "bassinets/cradles" in part 1218, meaning they must have a stand and pass the existing stability test. If ASTM F2194-22 becomes the new mandatory standard for bassinets, such flat infant sleep products without a stand would meet the requirements for "compact bassinets/cradles" and would fall outside of the ISP Rule, meaning they would be allowed for sale, because they would meet an existing sleep standard, bassinets, and would only need to pass the new, less stringent, stability test.

Based on the lack of a requirement for a base or stand to discourage use of compact bassinets on elevated and soft surfaces, which is less stringent than the existing part 1218 and the ISP Rule requirements, staff recommends rejecting the addition of compact bassinets/cradles in ASTM F2194-22.

# c. Performance and Testing Requirements

ASTM separated the stability performance requirement in section 6.4 of ASTM F2194-22 into two subsections, 6.4.1 for a bassinet/cradle and 6.4.2 for a compact bassinet/cradle. Although both sections require that the product "... not tip over and shall retain the CAMI dummy ...," the tests for meeting this requirement are different, with the new stability test for a compact bassinet/cradle being less stringent than the existing stability test for bassinets. The section 6.4.1 stability performance requirement excludes compact bassinets/cradles from the stability test in section 7.4.1, which involves a two-part test of placing weights on the product and, with a newborn CAMI dummy in the product, pulling both horizontally and vertically. The test was developed to address an observed hazard involving older siblings pulling on the sides of bassinets to look into them.

ASTM F 2194-22 adds a new section 7.4.2, with a new test that applies only to a compact bassinet/cradle. This test involves placing the product on a smooth, inclined surface, 20 degrees from horizontal, with an infant CAMI dummy inside, but without any pull force on the side of the product. Removing the side pull force results in a test less stringent than the stability test in part 1218, which incorporates the stability test requirements in ASTM F2194-13.

As discussed in Tab C, ESMC staff conducted comparison testing of compact bassinets/cradles to both stability test requirements in the standard. Staff determined that compact bassinet/cradle are unsafe because they fail the stability test in part 1218 (which applies 5 lb. of horizontal force and 23 lb. of vertical force at the product's uppermost horizontal side rail), but will pass the 20-degree tilt test in the revised voluntary standard.

Based on staff's testing, CPSC staff concludes that this new stability test for compact bassinet/cradles is inadequate to address the risk of injury from an unstable compact bassinet/cradle, and therefore, staff recommends that the Commission reject the ASTM revised standard. Staff has urged ASTM to work on establishing requirements for a stand for regular bassinets, but so far, ASTM has made no progress on this request, and instead, it has continued its work to add compact bassinets to the standard, providing a definition that is contrary to the recent ISP Rule now in effect.

# 2. Other Substantive and Non-Substantive Revisions to ASTM F2194 – 22 and F2194 – 22<sup>81</sup>

ASTM F2194 - 22 and F2194 - 22<sup> $\epsilon$ 1</sup> have other substantive and non-substantive revisions that staff considers beneficial to the bassinet standard. However, in light of ASTM including compact bassinets/cradles without providing requirements for a base/stand, and given the less stringent stability requirements, these revisions do not change staff's recommendation to reject the ASTM update.

#### The revisions involve:

- clarifying of the scope, by providing examples of products within and outside the scope of the standard:
- requiring that multimode products test to each standard related to each use mode;
- including ANSI Z535 warning reference documents;
- adding "mattress" definition;
- clarifying that all bassinets/cradles side heights be 7.5 inches above mattress;
- updating warnings and literature to be consistent with ASTM Ad Hoc Language recommendations;
- adding bibliography section to reference standards for other juvenile products mentioned in the standard; and
- editorial revisions, such as spacing, formatting, and renumbering figures.

#### C. Incident Data

In the 2021 Infant Sleep Product Final Rule, staff presented data on all unregulated flat infant sleep product incidents that were reported to have occurred between January 2019 and December 2020. Staff identified 183 incident reports (11 fatal and 172 nonfatal – including 16 injuries). Staff identified seven distinct hazard categories: Lock/Latch Problems, Consumer Comments, Falls/Containment Issues, Instability Issues, Asphyxiation/Suffocation Hazards, Miscellaneous Product-Related Issues, and Undetermined Issues.

Specifically, the falls/containment incidents also relate to placement of flat infant sleep products. Ten infants, ranging in age from 1 month to 9 months, required emergency department (ED) visits after falling out of the sleeper product. 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. The 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). These incident data provided the basis for the Commission requiring a stand for light, portable infant sleep products in the ISP Rule, which was recently upheld by the D.C. Circuit Court of Appeals. See Finnbin, LLC v. CPSC, Case No. 21-1180 (D.C. Cir. Aug. 2, 2022).

Additionally, Tab B, the Directorate for Epidemiology, Division of Hazard Analysis' staff memorandum, specifically identifies and discusses fall hazard data from compact bassinets and small, portable infant products similar to compact bassinets, *i.e.*, in-bed sleepers and bouncers. The incidents reportedly occurred between January 1, 2017, and February 28, 2022 (March 10, 2022 for bouncers).

Staff's data search identified 216 incidents associated with compact bassinets, for infants aged 6 months and under. Among the 216 reported incidents, 4 were fatalities, 6 resulted in injuries (5 of

the injured were treated and released from hospital emergency departments and 1 was hospitalized), and 206 were noninjury incidents. For in-bed sleepers, 14 incidents were reported, 10 reported a fatality, 2 involved injuries that were treated at hospital emergency departments, and 2 were noninjury incidents.

CPSC staff is aware that caregivers often place small, portable products, in which an infant may sleep, on elevated or soft surfaces. For example, infant bouncer seats are typically small, portable products. Staff reviewed the CPSC epidemiologic databases for bouncer seats, specifically focusing on incidents where the bouncer seat was clearly described as having fallen from an elevated surface, such as an adult bed, countertop, or couch. Among the incidents that involved infants aged 6 months or less, staff identified a total of 168 incidents. Among the 168 incidents, three were fatalities, 164 involved an injury, and one was a noninjury incident. Of the emergency department-treated injuries, 17 were serious enough to require hospitalization. The distribution of the elevated surfaces where the bouncer seats were placed (before the injuries occurred), shows 69 (of the 164) were placed on tabletops; 62 (of the 164) on countertops; 15 (of the 164) were on couches/ sofas/ chairs/ ottomans; and 10 (of the 164) were on beds. Other elevated surfaces include the tops of washing machines/ dryer/ freezers, for example. While one noninjury incident reportedly occurred when the infant was in a bouncer seat on a bed, two of the three fatalities also reported the bouncer was on a bed.

# D. Impact on Infant Sleep Products Regulation

Pursuant to the Consumer Product Safety Improvement Act of 2008 (CPSIA), CPSC issued a 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. The rule, effective on June 23, 2022, requires that infant sleep products must meet the requirements of one of the existing mandatory standards for infant sleep (full-size cribs, non-full-size cribs, play yards, bassinets, or bedside sleepers). If a product does not meet one of these existing regulations, the ISP Rule requires that the sleep surface angle be 10 degrees or less, and that the product meet the requirements of 16 CFR part 1218, Safety Standard for Bassinets and Cradles, including conform to the definition of a "bassinet/cradle," which means the product must have a stand. As stated in the ISP Rule, portable, compact infant sleep products were not regulated under any of CPSC's mandatory standards for infant sleep, and yet, they were marketed and promoted as safe sleep products. The Commission determined that these products, at a minimum, should meet the requirements of the bassinet/cradle regulation to ensure that all products marketed or intended for infant sleep provide a flat, stable, contained environment for infant's sleep.

If the Commission allows ASTM F2194-22<sup>£1</sup> to become the mandatory standard for bassinets and cradles, compact bassinets and other portable infant sleep products, currently not allowed to be sold under the ISP Rule, would be allowed if they meet the revised requirements for bassinets. As discussed above, the requirements for compact bassinets/cradles do not require a stand, and the stability requirements for compact bassinets are less stringent than the existing stability requirement in part 1218. Accordingly, staff concludes that allowing ASTM F2194-22<sup>£1</sup> to become the mandatory standard for bassinets/cradles would result in a reduction in safety for bassinets and cradles subject to the rule and would also reverse the safe sleep requirements for flat infant sleep products in the ISP Rule.

# E. Response to Public Comments

On July 18, 2022, ASTM notified the Commission that it had approved and published a revised version of the voluntary standard, ASTM F2194-22<sup>£1</sup>. Between July 28, 2022, and August 11, 2022, the Commission requested public comment on the question of the effect the revised voluntary standard will have on the safety of consumer products covered by the standard. CPSC received six public comments.

Three commenters urged the Commission to reject the new standard and to retain the current regulation (American Academy of Pediatrics (AAP), Consumer Reports, and Kids In Danger and Consumer Federation of America (submitted together)). All three commenters expressed concern with the inclusion of portable, compact bassinet/cradles, the reduction in the stability requirements for compact bassinet/cradles, and the impact accepting the new revised voluntary standard will have on the ISP Rule. AAP specifically noted that ". . . CPSC's landmark Infant Sleep Product (ISP) Rule relies on the existing bassinet standard to create a minimum safety standard for all infant sleep products not covered by a mandatory product safety standard. Changing the bassinet standard would weaken the ISP Rule and put infants at risk of injury and death."

The other three commenters (Juvenile Products Manufacturers Association (JPMA), Graco, and Iron Mountain) urged the Commission to accept the new voluntary standard. They each indicated that by accepting the revised voluntary standard as the new mandatory standard for bassinets and cradles, the previously unregulated compact bassinet/cradle would be included within the scope of the rule. Iron Mountain indicated that the new category of compact bassinet/cradles would have to meet stability tests that ". . . were derived from other low-to-the-ground products like bouncers and floor seats with the side height requirement being the same a traditional bassinet."

Staff concludes that including compact bassinets/cradles in the bassinet/cradle voluntary standard results in a reduction in safety. Although compact bassinets/cradles have not been addressed previously in the bassinet regulation, effective June 23, 2022, under the ISP Rule, such products became subject to the existing bassinet regulation. As noted above, compact bassinets/cradles and other infant sleep products not covered by a CPSC infant sleep regulation, must meet the bassinet/cradle standard, including conforming to the definition of a "bassinet/cradle," requiring a stand, and meeting the existing, more stringent, stability test.

As one commenter (Iron Mountains) noted, the stability test developed for compact bassinets/cradles is similar to the stability requirements for bouncers and floor seats. However, unlike bassinets, bouncers and floor seats are intended to be used with adult supervision, with restraints, and on the floor. Still, as the fall hazard data demonstrate, bouncer seats are frequently used unsupervised, without the restraints, and on elevated surfaces, which has resulted in head injuries and deaths. Infant sleep products must exhibit the highest level of safety because they are intended to be used unsupervised, without active restraints, including use of a stable stand. Moreover, ASTM F2194-22<sup>£1</sup> allows certain bassinets to use tests without side force requirements, thus, reducing their stability.

# F. Staff's Assessment of the Revised Standard

Staff concludes, based on its assessment, including a review of the incident data, human factors analysis, and engineering analysis and testing, that the revisions in ASTM F2194  $-22^{\epsilon 1}$  will not

improve the safety of bassinets/cradles covered by the standard. Including compact bassinets/cradles within the scope of the revised voluntary standard, with product characteristics that the Commission specifically stated in the ISP Rule were not safe for infant sleep, and allowing a less-stringent stability test for these products, contradicts the Commission's safe sleep goals in part 1218 and in the ISP Rule. Staff found that the new stability test is inadequate to address the risk of tip-over incidents associated with compact bassinets/cradles. Therefore, staff recommends that the Commission retain the existing consumer product safety standard.

# G. Effect of the Changes on CPSC Acceptance of Third Party Testing Laboratories

The notice of requirements (NORs), as set forth in the final rule for bassinets/cradles, provided the criteria and process for the Commission's acceptance of accreditation of third party conformity assessment bodies for testing bassinets/cradles to 16 CFR part 1218 (incorporating ASTM F2194 – 13 with modifications). The NORs for all standards for durable infant or toddler products are listed in the Commission's rule, "Requirements Pertaining to Third Party Conformity Assessment Bodies," codified at 16 CFR part 1112. CPSC staff is recommending no change to the existing regulation for bassinets and cradles, and accordingly no change in part 1112 is necessary if the Commission accepts staff's recommendation. The existing NOR for this standard will remain in place, and CPSC-accepted, third party conformity assessment bodies will stay the same.

# H. Effective Date

Pursuant to section 104(b)(4)(B) of the CPSIA, because CPSC staff assesses that ASTM's revised voluntary standard does not improve the safety of bassinets/cradles, staff recommends that the Commission reject ASTM F2194  $-22^{\epsilon 1}$  as a consumer product safety standard issued by the Commission effective 180 days after notice of the revision. Staff recommends that the Commission direct the staff to notify ASTM within 90 days of July 18, 2022 (by October 16, 2022) that the Commission has determined that the proposed revision does not improve the safety of bassinets and cradles and that the Commission will retain ASTM F2194 - 13, with modifications, as the mandatory standard.

# III. Recommendation

Staff concludes, based on its assessment, that the revisions in ASTM F2194 –  $22^{\epsilon 1}$  will not improve the safety of bassinets/cradles covered by the standard. The addition of compact bassinets/cradles to the voluntary standard decreases the safety of bassinets and cradles, and also contradicts the Commission's safe sleep requirements, as set forth in the ISP Rule. Therefore, staff recommends that the Commission reject ASTM F2194 –  $22^{\epsilon 1}$  as a consumer product safety standard issued by the Commission.

# Tab A: ASTM's Revised Voluntary Standard for Bassinets and Cradles: ESHF Staff's Assessment of Revisions

# Memorandum

DATE: September 14, 2022

TO: Celestine T. Kish, Project Manager

**Division of Human Factors** 

**Directorate for Engineering Sciences** 

THROUGH: Mark Kumagai, Associate Executive Director

Directorate for Engineering Sciences

Rana Balci-Sinha, Division Director

Division of Human Factors

**Directorate for Engineering Sciences** 

FROM: Zachary Foster, Industrial Engineer

**Division of Human Factors** 

Directorate for Engineering Sciences

SUBJECT: ASTM's Revised Voluntary Standard for Bassinets and Cradles: ESHF Staff's

Assessment of Revisions

# I. INTRODUCTION

This memorandum provides the Directorate for Engineering Sciences, Division of Human Factors (ESHF) staff's assessment of whether the most recent revisions made to the scope, terminology, general requirements, marking and labeling requirements, and instructional literature requirements in ASTM F2194-22ε1, *Standard Consumer Safety Specification for Bassinets and Cradles*, improve the safety of bassinets and cradles. The current mandatory standard codified in 16 CFR part 1218 incorporates by reference ASTM F2194-13, with modifications to make the standard more stringent.

# II. BACKGROUND

On October 23, 2013, the Commission published a final rule that incorporated by reference ASTM F2194-13, *Standard Consumer Safety Specification for Bassinets and Cradles*, with modifications, as the mandatory standard for bassinets and cradles (78 FR 63019).

In 2016, ASTM published ASTM F2194-16, and made editorial revisions in ASTM F2194-16<sup>£1</sup>. The 2016 updates to the voluntary standard include the modifications to ASTM F2194-13 that were made mandatory in part 1218, with additional revisions. As part of the final rule establishing a Safety Standard for Infant Sleep Products, 16 CFR part 1236, the Commission evaluated ASTM F2194-16<sup>£1</sup>, stating that this revision "harmonized the voluntary standard with all modifications in part 1218" and included additional modifications that "are either non-substantive, or an improvement in safety." 86 FR 33022, 33034-35 (June 23, 2021). Although the revisions to ASTM F2194-16<sup>£1</sup> aligned the voluntary standard with the mandatory standard codified in part 1218, CPSC did not officially receive notice of the revision under CPSIA section 104(b)(4)(B). Therefore, part 1218 does not incorporate by reference ASTM F2194-16<sup>£1</sup>.

In January 2022, ASTM approved a revised version of the voluntary standard, ASTM F2194-22. In July 2022, ASTM made editorial revisions to the voluntary standard and published ASTM F2194-22<sup>£1</sup>. On July 18, 2022, ASTM notified CPSC that it published ASTM F2194-22<sup>£1</sup>. This revision substantively affects the requirements for bassinets and cradles in the voluntary standard.

# III. REVIEW OF 2022 REVISIONS TO ASTM F2194

# A. Substantive Revisions to ASTM F2194

ASTM F2194-22<sup>£1</sup> contains multiple revisions to the scope, terminology, test methods, marking and labeling requirements, and instructional literature requirements. Many of these changes relate to the introduction of a new product category – compact bassinets/cradles – in the voluntary standard. Revisions to the performance requirements and test methods are addressed in the Directorate for Engineering Sciences, Division of Mechanical and Combustion (ESMC) staff's memorandum (Briefing Package Tab C). In this memorandum, ESHF staff addresses changes to the scope, terminology, general requirements, marking and labeling requirements, and instructional literature requirements.

# 1. Scope

The main change to the scope of the voluntary standard is the addition of a new section 1.3, discussing products that are within the scope of the standard and products that are excluded from the scope of the standard. Most notably, ASTM added to the scope of the standard a new category of products: compact bassinets/cradles, as well as multiuse products, bassinet/cradle features that have a compact bassinet/cradle mode, and/or can be used as a compact bassinet/cradle. The revised standard specifically excludes in- bed portable sleepers and enclosed travel tents from the scope.

# 2. Terminology

ASTM F2194-22<sup>£1</sup> updates section 3 regarding terminology to include new definitions for "compact bassinet/cradle" and "mattress."

Per section 3.1.3 of the revised standard, a "compact bassinet/cradle" is defined as a bassinet/cradle having a distance of less than 6.0 in. (152.4 mm) between the lowest point of the

underside of the sleep surface support and the product support surface (floor). Moses baskets and bassinets/cradles that may have handholds, handle(s), or grip openings, and that are intended to carry an occupant whose torso is completely supported by the product, are also included under the definition of "compact bassinet/cradle."

Per section 3.1.8, a "mattress" is defined as a pad with a fabric, vinyl, or other material case filled with resilient material (*e.g.*, cotton, foam, fiberfill) used as or on the floor of the unit.

Additionally, ASTM revised the definition for "bassinet/cradle accessory" in section 3.1.2 to include language referencing compact bassinets/cradles.

# 3. General Requirements

Section 5 of the revised standard regarding general requirements contains only one substantive revision. ASTM added section 5.14 to the standard, which states that if the bassinet/cradle or compact bassinet/cradle can be converted into another product for which a consumer safety specification exists, the product shall comply with the applicable requirements of that standard when in that use mode.

# 4. Performance Requirements/Test Methods

ASTM revised the performance requirements and test methodology to address compact bassinets/cradles. Specifically, the standard contains revised sections 6.4 and 7.4 so that there are separate stability requirements and test methods for standard bassinets/cradles and compact bassinets/cradles, respectively. Staff notes that the side height requirement of 7.5 inches (Section 6.5.4 of ASTM F2194) remains in the voluntary standard and still applies to all bassinets/cradles, including compact bassinets/cradles.

# 5. Marking and Labeling

Section 8 on marking and labeling requirements contains several revisions. The standard has been revised to include specific marking requirements for battery-operated products (Section 8.4 – Battery-Operated Product Marking). Section 8.4.1 states that the product's battery compartment, battery compartment door/cover, or area immediately adjacent to the battery compartment must be marked or labeled permanently and legibly to show the correct battery polarity, size, and voltage. Products using one or more non-replaceable batteries are exempt from this requirement. However, section 8.4.2 states that products using one or more non-replaceable batteries accessible with the use of a coin, screwdriver, or other common household tool shall be marked or labeled permanently and legibly with a statement that the batteries are not replaceable. If marking or labeling the product is not practicable, then this statement shall be included in the instructions.

Section 8.5 – Warning Design for Product, also contains multiple revisions, many are intended to align the standard with current recommendations from ASTM's Ad Hoc Language Task Group.<sup>2</sup>

<sup>&</sup>lt;sup>2</sup> ASTM Ad Hoc Language Task Group (Ad Hoc TG), consists of members of various durable nursery product voluntary standards committees, including CPSC staff. The Ad Hoc TG's purpose is to harmonize the wording

Section 8.5 now specifies that warnings shall be in English at minimum, state that any additional markings or labels shall not contradict or confuse the required information and shall not mislead the consumer, and sets formatting requirements for warnings (e.g., font size, text alignment, safety alert symbol, bullet points for cautionary statements). Per Ad Hoc Recommendations, the standard uses ANSI Z535.4-2011, *Product Safety Signs and Labels*, as a reference for its warning formatting requirements. ANSI Z535.4 is the primary U.S. voluntary consensus standard for product safety signs and labels. ESHF staff consistently uses this standard when developing or assessing the adequacy of warning labels. Literature on the design and evaluation of on-product warnings frequently cites ANSI Z535.4 as the minimum set of requirements that products sold in the United States containing such labels should meet, and the ANSI Z535 series of standards are generally considered the benchmark against which warning labels are evaluated for adequacy, because these standards are seen as the state of the art.

Section 8.6 – Warning Statements, also contains multiple revisions. Section 8.6.1 specifies that the statement: "Failure to follow these warnings and the instructions could result in death or serious injury," shall be the first warning to appear in a message panel. Section 8.6.2.1 states that the suffocation hazard warning will immediately follow the statement in section 8.6.1 and shall address the following:

# SUFFOCATION HAZARD

Babies have suffocated:

- on pillows, comforters, and extra padding
- in gaps between a wrong-size mattress, or extra padding and product sides
- NEVER add soft bedding or padding.
- Use **ONLY** mattress provided by manufacturer.

Section 8.6.2.2 requires that the standard address the following statement:

Always place baby on back to sleep to reduce the risk of SIDS and suffocation.

Section 8.6.2.3 requires that compact products address the following statement:

Compact products shall also address the following: Product can roll over on soft surfaces and suffocate child. NEVER place product on beds, sofas or other soft surfaces.

The warning statements related to fall hazards remain largely unchanged. However, these statements, per section 8.6.2.1 are now required to appear after the suffocation hazard warning statements. Additionally, per section 8.6.2.5, the warning language, "FALL HAZARD," required for products where the bassinet bed is removeable from the base/stand without the use of tools, and it contains a lock/latch mechanism that secures the bassinet bed to the base/stand, is no longer required. The "FALL HAZARD" is no longer required because the message is required to be located in the fall hazard section of the warning, and therefore, it would be redundant.

Section 8.6.2.6 requires that compact products address the following statements:

of common sections (*e.g.*, introduction, scope, protective components) and warning label requirements across durable infant and toddler product voluntary standards.

- (1) Always use product on the floor. Never use on an unintended elevated surface.
- (2) Do not carry baby in the [manufacturer to insert type of product]. [Exception: A product that is intended to carry a baby is exempt from this requirement].
- (3) Compact bassinet/cradles constructed of cardboard shall also address:

Do not reuse [manufacturer to insert type of product] for second child.

Lastly, ASTM added three example warnings to the standard, one for bassinet/cradle products (FIG. 29 in the standard), one for compact bassinet/cradles (FIG. 30 in the standard), and one for compact bassinet/cradles made of cardboard (FIG. 31 in the standard). Below are the three new example warnings, as well an example warning that complies with part 1218 (Figures 1-3).

# A WARNING:

**WARNING:** Do not use this bassinet if you cannot exactly follow the accompanying instructions, Failure to follow these warnings and the instructions could result in serious injury or death.

FALL HAZARD: To help prevent falls, DO NOT use this product when the infant begins to push up on hands and knees or has reached manufacturer's recommended maximum weight of 15lbs. (6.8kg), whichever comes first.

# SUFFOCATION HAZARD INFANTS HAVE SUFFOCATED:

 In gaps between extra padding and side of the bassinet and

On soft bedding

Use only the pad provided by

manufacturer that is no thicker than 1 1/2" (3.5 cm) and is of such a size that, when pushed against any side of the product, it does not leave a gap of more than 1 1/4" (3 cm) between then mattress and sides.

**NEVER** add a pillow, comforter, or another matress for padding.

If a sheet is used with the pad, use only the one provided by the bassinet or cradle manufacturer or one specifically designed to fit the dimension of the bassinet mattress,

To reduce the risk of SIDS, pediatricians recommend healthy infants be placed on their backs to sleep, unless otherwise advised by your physician.

Do not leave child unattended in the bassinet when it is in the "rocking" mode. Always make sure the wheels or stands are in the locked "down" position.

Always attach all provided fasteners tightly according to the instructions. Check frequently. Do not use if there are any loose or missing parts or signs of damage. Do not substitute parts. Contact the manufacturer for replacement parts.

Toys are not to be "mouthed" by the baby and should be positioned clearly out of reach of the baby's face and mouth.

Do not place cords, straps or similar items that could become wound around the child's neck in or near this product and do not place product near a window or patio door,

When used as a changing table:

FALL HAZARD: To prevent death or serious injury, always keep child within arm's reach.

DCP141202-EN for CA-BWV6

Figure 1: Example warning label compliant with 16 CFR part 1218

# **WARNING**

Failure to follow these warnings and the instructions could result in death or serious injury.

# SUFFOCATION HAZARD Babies have suffocated:

- On pillows, comforters and extra padding.
- In gaps between a wrong size mattress, or extra padding and product sides.
- NEVER add soft bedding or padding.
- Use **ONLY** mattress provided by manufacturer.
- Always place baby on back to sleep to reduce the risk of SIDS and suffocation.
- If a sheet is used with the pad, use only the one provided by the product manufacturer or one specifically designed to fit the dimension of the product mattress.

FALL HAZARD: To help prevent falls,

Do not use this product when the infant begins to push up on hands and knees or has reached [Insert manufacturer's recommended weight], whichever comes first.

Figure 2: F2194-22<sup>£1</sup> warning label for Bassinets/Cradles

# **M** WARNING

Failure to follow these warnings and the instructions could result in death or serious injury.

# SUFFOCATION HAZARD Babies have suffocated:

- On pillows, comforters and extra padding.
- In gaps between a wrong size mattress, or extra padding and product sides.
- NEVER add soft bedding or padding.
- Use **ONLY** mattress provided by manufacturer.
- Always place baby on back to sleep to reduce the risk of SIDS and suffocation.
- If a sheet is used with the pad, use only the one provided by the product manufacturer or one specifically designed to fit the dimension of the product mattress.
- Product can roll over on soft surfaces and suffocate child.
   NEVER place product on

beds, sofas or other soft surfaces.

FALL HAZARD: To help prevent falls,

- Do not use this product when the infant begins to push up on hands and knees or has reached [Insert manufacturer's recommended weight], whichever comes first.
- Always use product on the floor. Never use on any elevated surface.
- Do not carry baby in the [Manufacturer to insert type of product].

# **WARNING**

Failure to follow these warnings and the instructions could result in death or serious injury.

# **SUFFOCATION HAZARD Babies have suffocated:**

- On pillows, comforters and extra padding.
- In gaps between a wrong size mattress, or extra padding and product sides.
- NEVER add soft bedding or padding.
- Use ONLY mattress provided by manufacturer.
- Always place baby on back to sleep to reduce the risk of SIDS and suffocation.
- If a sheet is used with the pad, use only the one provided by the product manufacturer or one specifically designed to fit the dimension of the product mattress.
- Product can roll over on soft surfaces and suffocate child.

NEVER place product on

beds, sofas or other soft surfaces.

FALL HAZARD: To help prevent falls,

- Do not use this product when the infant begins to push up on hands and knees or has reached [Insert manufacturer's recommended weight], whichever comes first.
- Always use product on the floor. Never use on any elevated surface.
- Do not carry baby in the [Manufacturer to insert type of product].
- Do not reuse [Manufacturer to insert type of product] for second child.

Figure 3: F2194-22<sup>£1</sup> warning label for Compact Bassinets/Cradles (left) and F2194-22<sup>£1</sup> warning label for Compact Bassinets/Cradles made of Cardboard (right)

#### a. Instructional Literature

The instructional literature requirements contain multiple revisions, many are intended to ensure that the instructional literature is consistent with on-product markings and warnings and align the standard with current recommendations from the Ad Hoc Language Task Group. The requirements now specify that instructions shall be in English at minimum (9.1), state that any additional instructions shall not contradict or confuse the required information and shall not mislead the consumer (9.6), and sets formatting requirements for warnings (e.g., font size, text alignment, safety alert symbol, bullet points for cautionary statements, 9.5). Per Ad Hoc Recommendations, the standard uses ANSI Z535.4-2011 as reference for its warning formatting requirements.

Additionally, instructions are now required to address battery-powered products. Section 9.2 – Cautionary Statements for Products that Operate using Replaceable Batteries sets the following requirements for instructions:

9.2.1 Instructions for all such products shall address the following:

**↑** CAUTION

To prevent battery leaks, which can burn skin and eyes:

- Remove batteries when storing product for a long time.
- · Dispose of used batteries immediately.
- 9.2.2 Instructions for products that use more than one battery in any one circuit shall also address the following under the same

CAUTION header:

- Always replace the entire set of batteries at one time.
- Never mix old and new batteries, or batteries of different brands or types.

Additionally, instructions are now required to address the following statements:

9.4.2 Do not use if any part of the (manufacturer to insert type of product) is broken, torn, or missing.

Additionally, the instructions for products constructed of cardboard must now address the following statements:

- 9.4.3.1 Use only on a flat, dry floor.
- 9.4.3.2 Do not place the (manufacturer to insert type of product) near a space heater, open fire or other source of strong heat.

Lastly, the standard now contains two example instructional literature warnings, one for bassinet/cradle products (FIG. 32 in the standard), and one for battery-powered bassinets/cradles (FIG. 33 in the standard). Figure 4 provides two example warnings:

# **A** WARNING

Failure to follow these warnings and the instructions could result in death or serious injury.

# **SUFFOCATION HAZARD Babies have suffocated:**

- On pillows, comforters and extra padding.
- In gaps between a wrong size mattress, or extra padding and product sides.
- NEVER add soft bedding or padding.
- Use **ONLY** mattress provided by manufacturer.
- Always place baby on back to sleep to reduce the risk of SIDS and suffocation.
- If a sheet is used with the pad, use only the one provided by the product manufacturer or one specifically designed to fit the dimension of the product mattress.

#### FALL HAZARD: To help prevent falls,

 Do not use this product when the infant begins to push up on hands and knees or has reached [Insert manufacturer's recommended weight], whichever comes first

# **A** WARNING

Failure to follow these warnings and the instructions could result in death or serious injury.

# SUFFOCATION HAZARD Babies have suffocated:

- On pillows, comforters and extra padding.
- In gaps between a wrong size mattress, or extra padding and product sides.
- NEVER add soft bedding or padding.
- Use **ONLY** mattress provided by manufacturer.
- Always place baby on back to sleep to reduce the risk of SIDS and suffocation.
- If a sheet is used with the pad, use only the one provided by the product manufacturer or one specifically designed to fit the dimension of the cradle mattress.

# FALL HAZARD: To help prevent falls,

 Do not use this product when the infant begins to push up on hands and knees or has reached [Insert manufacturer's recommended weight], whichever comes first.

# **A** CAUTION

- Remove batteries when storing product for a long time.
- · Dispose of used batteries immediately.
- · Always replace the entire set of batteries at one time.
- Never mix old and new batteries, or batteries of different brands or types.

Figure 4: Example Instruction Warnings; Bassinets/Cradles (left) and Bassinets/Cradles with Batteries (right)

# B. Non-Substantive Revisions to ASTM F2194

ASTM F2194-22<sup>£1</sup> contains multiple non-substantive revisions. These revisions include reordering/renumbering of sections and subsections, rewording of certain terms (*e.g.*, replacing "bassinets/cradles" with "products" in some places) or paraphrasing certain sections. Staff determines that these changes do not alter the requirements of the standard. Therefore, ESHF staff will not discuss these non-substantive revisions in detail.

#### IV. DISCUSSION

# A. Consumer Behavior Involving Compact Bassinets/Cradles

ASTM F2194-22<sup>£1</sup> defines a "compact bassinet/cradle" as a bassinet/cradle having a distance of less than 6.0 in. (152.4 mm) between the lowest point of the underside of the sleep surface support and the product support surface (floor). Unlike the previous version of the standard, ASTM F2194-22<sup>£1</sup> does not define all covered products as having a stand. Removing the requirement for a stand is intended to allow for product portability. However, staff's assessment is that portability, comprised of small, light-weight products, is what enables consumers to use the product in a variety of unsafe locations, including soft unstable surfaces, such as couches or beds, and hard elevated surfaces, such as tables or countertops.

According to testing performed by ESMC staff, the stability requirement for compact bassinets/cradles in ASTM F2194-22<sup>£1</sup> is less stringent than the stability requirements in part 1218

(Section 7.4 of ASTM F2194-13, see ESMC memo) for bassinets. ESHF staff concludes that less stringent stability requirements for compact bassinets/cradles may make them more prone to tipping over. Staff notes that the stability requirements in part 1218 were originally established to address an observed hazard pattern involving older siblings pulling on the sides of bassinets to look into them. For instance, in a nonfatal incident, a sibling of a 1-month-old infant pulled on a portable bassinet that was placed on a couch, causing the infant and product to fall off the couch, resulting in the infant receiving a head injury. ESHF staff is concerned that if compact bassinets are allowed in the standard, and the stability requirements are less stringent for compact bassinets, similar incidents could occur, especially because of the portability of compact bassinets.

Additionally, incident data and staff research (Chowdhury, 2022; see Tab B in briefing package) demonstrate that the portability of some compact bassinets/cradles, as well as other similar products, enables their use on relatively unstable surfaces, such as on/in beds and sofas/loveseats, and on elevated surfaces, such as tables and countertops. ESHF staff is aware of four incidents involving compact bassinets falling from elevated surfaces. One incident (200940506) involved a countertop, one (201234191) involved a couch, one (210105CFE0001) involved a bed, and one (210246657) involved a chair. The incident involving a bed resulted in a fatality, while the incidents involving a countertop and couch resulted in head injuries. ESHF staff is also aware of an incident involving an in-bed sleeper falling from an adult bed onto the floor (170722619); the severity of the incident is not specified.

CPSC staff is aware of fall hazards related to other small, portable products. For example, incident data in EPI staff's memo (Tab B) includes falls involving infant bouncer seats. EPI staff notes three fatal and 165 nonfatal incidents involving bouncer seats falling from soft or elevated surfaces. Specifically, countertops, beds, sofas/couches/chairs/ottomans, washing machines, dryers, and freezers were noted in the incident data as surfaces from which bouncers fell. Staff notes that the stability requirements for compact bassinets/cradles proposed in ASTM F2194-22<sup>£1</sup> are derived from the stability requirements for bouncer seats, as well as floor seats. Staff is concerned that compact bassinets designed without legs or a stand will lead caregivers to place these products on elevated surfaces, which would introduce new hazards for compact bassinets, similar to observed hazards for bouncer seats falling from elevated surfaces. Incident data indicate that bouncer seats are often used on soft or elevated surfaces, and that falls from these surfaces are not infrequent.

Additionally, in an examination of customer reviews of various compact bassinets/cradles, ESHF staff found multiple instances of customers indicating that they used the products in/on mattresses, sofas, tables, and countertops. CPSC staff is concerned that, given the relative instability of these surfaces when compared to the floor, using compact bassinet/cradles on these soft or elevated surfaces may further diminish the stability of these 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.

ASTM F2194-22<sup>£1</sup> defines a "bassinet/cradle" as a *small bed designed primarily to provide sleeping accommodations for infants, supported by free standing legs, a stationary base/stand, a wheeled base, a rocking base, or a base which can swing relative to a stationary base. While in a rest (non-rocking or swinging) position, a bassinet/cradle is intended to have a sleep surface less than or equal to 10° from horizontal. Although F2194-22<sup>£1</sup> does not define a minimum or maximum height for the freestanding legs, or base/stand, CPSC staff asserts that all bassinets should have a* 

legs/base/stand of a height that discourages use or placement of the bassinet (compact or regular) on unstable and/or elevated surfaces, and recommends that definitions and performance requirements be established for stand/base/frame.<sup>3</sup> Although the latest version of the ASTM standard requires a warning for compact bassinets to always be used on the floor, and staff agrees that is the most stable position for a compact bassinet to be used, the overall design of the product makes it more likely to be used in other locations that present a safety hazard.

# B. Compact Bassinet/Cradle Stability on Soft and Elevated Surfaces

As mentioned above, ASTM defines a "compact bassinet/cradle" as a bassinet/cradle having a distance of less than 6 inches between the lowest point of the underside of the sleep surface support and the product support surface (floor). These features make compact products easier than regular bassinets/cradles to carry, transport, and place in/on alternative surfaces. This portability makes compact bassinet/cradles more likely to be placed on soft surfaces, such as couches/sofas and beds, or on elevated surfaces, such as tables and countertops.

To assess the stringency of the new performance and testing requirements for compact bassinets/cradles, compared to the current requirements, ESMC staff conducted a series of stability tests. First, staff subjected eight compact bassinets to the current bassinet/cradle stability test specified in 16 CFR part 1218 on the floor and subjected them to the 20-degree tilt test in ASTM F2194- 22<sup>£1</sup>. Then ESMC staff tested the stability of the same eight compact products on four soft surfaces (Figure 5). Finally, staff compared the results of all tests. Test results are presented in Table 6.



Figure 5. Examples of Bassinet/Cradle Stability Testing on Soft Surfaces

<sup>&</sup>lt;sup>3</sup> Negative ballot vote letter F15 (22-04).

Table 6. Bassinet/Cradle Stability Test Results of Compact Products									
	16 CFR part 1218 Dual Force Application							Compact Stability Test Proposed in ASTM F2194- 22 <sup>ε1</sup>	
Compact Bassinet ID	L-Shaped Couch/Sofa	Adult Bed (Soft Memory Foam mattress)		Adult (Medium Memor mattr	Firmness y Foam	(Firm	Adult Futon Bed (Firm Foam mattress)		20-degree
	Corner (where sections meet)	Center	Edge	Center	Edge	Center	Edge	- Floor	Tilt Test
Α	Failed	Failed	Failed	Failed	Failed	Failed	Failed	Failed	Passed
В	Failed	Failed	Failed	Failed	Failed	Failed	Failed	Failed	Passed
С	Failed	Failed	Failed	Failed	Failed	Failed	Failed	Failed	Passed
D	Failed	Failed	Failed	Failed	Failed	Failed	Failed	Failed	Passed
Е	Failed	Failed	Failed	Failed	Failed	Failed	Failed	Failed	Passed
F	Failed	Failed	Failed	Failed	Failed	Failed	Failed	Failed	Passed
G	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed	Passed
Н	Failed	Failed	Failed	Failed	Failed	Failed	Failed	Passed	Passed

The test results show that all compact products, except compact bassinet "G," failed the bassinet/cradle stability test when tested on soft surfaces. Compact bassinet "H" passed the test on the floor, but it failed the test when tested on soft surfaces. These test results suggest that compact bassinets/cradles are likely to tip over when pulled by the top rail on a soft surface. ESHF staff assesses that this is a realistic scenario, as it is foreseeable that a child will pull on the top rail of the product when checking on the infant inside the product.

# C. Other Substantive/Non-Substantive Revisions

ESHF staff concludes that the revisions to ASTM F2194-22<sup>£1</sup> that are not related to the inclusion of compact bassinets/cradles within the scope of the standard may be potential improvements to safety or neutral.

# V. CONCLUSION

The portability of compact bassinets/cradles makes them likely to be placed on elevated and soft surfaces. As demonstrated, when compact products that meet the new compact stability requirement in ASTM F2194-22<sup>£1</sup> are placed on soft surfaces, and then tested for stability using the current requirement for bassinets/cradles, the compact products are less stable and are more likely to tip over. Additionally, the likelihood of placing compact bassinets on elevated, soft surfaces may lead to tip-over incidents from a soft and/or elevated surface, which is more hazardous, as children may fall and suffer fractures or suffocate on soft bedding. Lastly, the revised voluntary standard's stability test requirements for compact bassinets/cradles are less stringent than the stability requirements for bassinets/cradles, and compact bassinets/cradles are likely to fail the current bassinet stability requirements, per ESMC staff's assessment. For products that are considered compact bassinets/cradles under ASTM F2194-22<sup>£1</sup>, this differentiation in stability requirements represents a reduction in safety.

Staff concludes that some of the revisions discussed above, such as the markings/literature addressing battery-powered products and the standardization of warning formatting, are an improvement to safety. However, due to the testing results discussed above, as well as the incident data and consumer reviews indicating that the use of compact bassinets/cradles on unstable and/or elevated surfaces is foreseeable, ESHF staff concludes that allowing compact bassinets/cradles into the standard would be a reduction in safety. Therefore, staff concludes that new requirements in ASTM F2194-22<sup>£1</sup> regarding compact bassinets/cradles represents a reduction in safety.

Tab B: ASTM's Revised Voluntary Standard for Bassinets and Cradles: Data Memorandum Regarding Infant Falls Associated with Small Portable Nursery Products Where Infants Sleep



# Memorandum

DATE: September 14, 2022

**TO:** Celestine Kish

Bassinet/Infant Sleep Project Manager Directorate for Engineering Sciences

THROUGH: Steve Hanway, AED

Directorate for Epidemiology

FROM: Risana Chowdhury, DD

Division of Hazard Analysis Directorate for Epidemiology

**SUBJECT:** ASTM's Revised Voluntary Standard for Bassinets and Cradles: Data Memorandum

Regarding Infant Falls Associated with Small Portable Nursery Products Where Infants

Sleep

# Introduction

In this memorandum, the Hazard Analysis Division within the Directorate for Epidemiology (EPHA) summarizes data related to infants falling out of and with small portable nursery products, where the product was placed on elevated or soft surfaces, such as adult beds, countertops, and couches. EPHA's data memorandum supports CPSC staff's assessment of ASTM's revised voluntary standard for bassinets and cradles, *Standard Consumer Safety Specification for Bassinets and Cradles*, ASTM F2194-22<sup>£1</sup>, under section 104(b)(4) of the Consumer Product Safety Improvement Act of 2008 (CPSIA). For this data summary, EPHA staff relied on the latest datasets that staff compiled and reviewed in March 2022, to share with ASTM before the ASTM meetings on bassinets and cradles in May 2022. In the last year, staff provided datasets for small portable nursery products, including compact bassinets, in-bed sleepers, and bouncer seats, to their respective ASTM subcommittees. Because in-bed sleepers and bouncer seats, like compact bassinets, are small, portable nursery products where infants sleep, and the updated data for each were readily available and recently shared with ASTM, staff considered it relevant to discuss the fall hazards in all three of these products.

EPHA staff's March 2022 data search included incidents coded as involving "Bassinets" reported to have occurred between January 1, 2017, and February 28, 2022. Given that CPSC does not have a dedicated product code for "compact bassinets" or "in-bed sleepers," CPSC staff uses the product code 1537 (Bassinets or Cradles) to code each of these products in CPSC's epidemiological databases.

#### II. Discussion

# A. Compact Bassinets

For infants aged 6 months and under, staff's data search identified 216 incidents associated with compact bassinets. Among the 216 reported incidents, four were fatalities, six resulted in injuries (5 of the injured were treated and released from hospital emergency departments and 1 was hospitalized), and 206 were noninjury incidents. Most of the noninjury incidents involved a specific brand of compact bassinets and were reported through CPSC's "Retailer Reporting Program." Although there were multiple incidents indicating a fall of an infant out of a compact bassinet, the incident synopses listed below (in chronological order) identify the incident reports that clearly indicated the placement of the product on an elevated surface and the subsequent fall of the infant from the product. The fatalities are presented in bold font.

<b>Document No.</b>	<u>Narrative</u>
200940506	In July 2020, a 6-day-old infant in a wicker bassinet placed on a counter, fell to tile floor. Diagnosed with traumatic hematoma of forehead.
201234191	In October 2020, a 1-month-old infant was in a portable bassinet that was on a couch. Younger brother pulled the bassinet and it flipped onto the playmat. The infant sustained a head injury.
210105CFE0001:	In December 2020, a 2-month-old infant was in a compact bassinet, which was placed on top of a soft surface (bed), near a wall. When discovered, the infant was found to have deceased, outside the compact bassinet, trapped between the wall and the bed.
210246657	In December 2020, a 9-day-old infant fell from a chair while in a compact bassinet. No injury was recorded.

# B. In-Bed Sleepers

Staff's March 2022 data search for product code 1537 also identified 14 in-bed sleeper-related incidents that were reported to have occurred between January 1, 2017, and February 28, 2022. Of the 14 incidents, 10 reported a fatality, two involved injuries that were treated at hospital emergency departments, and two were noninjury incidents. Among these, one reported a fall from an elevated surface.

Document No.	<u>Narrative</u>
170722619	In July 2017, a 3-month-old was in a co-sleeper bassinet on parents' bed; parents think it moved while they were sleeping. Patient and
	bassinet fell on hardwood floor. A specific diagnosis is not stated.

# C. Bouncers

In March 2022, EPHA staff completed a data search for incidents associated with Baby Bouncer Seats (product code 1558) that were reported to have occurred between January 1, 2017, and March 10, 2022. This search of the CPSC epidemiologic databases was specifically focused on those incidents where the bouncer seat was clearly described as having fallen from an elevated surface, such as an adult bed, countertop, or couch. Among incidents that involved infants aged 6 months or less, staff identified a total of 168 incidents. Among the 168 incidents, three were fatalities, 164 involved an injury, and one was a noninjury incident. For the three fatal incidents, we present below the incident synopses (in chronological order; bold text indication of death).

Document No.	<u>Narrative</u>
170418CCC1732	In March 2017, a 5-month-old was in a bouncy seat on a kitchen countertop. The caregiver stepped out of the kitchen momentarily and found the bouncy seat on the floor, with the victim still strapped in. The infant died of a subdural hematoma.
201123HEP9001	In October 2020, a 2-month-old was in a bouncer chair on a bed with mother. Father found the deceased child wedged between the bed and wall.
211013HCC3047	In April 2021, a 3-month-old was co-sleeping with mother and other children on two mattresses pushed together. The victim was in a bouncy seat on top of the mattresses. The victim was found deceased the next morning in an area between the two mattresses. Cause of death was ruled as suffocation.

Given the numerous bouncer-related fall injuries, staff does not list all injury narratives here. Of the 164 injuries involving bouncers, 163 were treated in hospital emergency departments; the one remaining injury did not require any medical attention. Of the emergency department-treated injuries, 17 were serious enough to require hospitalization. A look at the distribution of the elevated surfaces where the bouncers were placed (before the injuries occurred), shows 69 (of the 164) were placed on tabletops; 62 (of the 164) on countertops; 15 (of the 164) were on couches/ sofas/ chairs/ ottomans; and 10 (of the 164) were on beds. Other elevated surfaces include the tops of washing machines, dryers, and freezers. For the only noninjury incident, the infant was in a bouncer seat on a bed.

# Tab C: ASTM's Revised Voluntary Standard for Bassinets and Cradles: Engineering Sciences Staff's Technical Assessment of Revisions



# Memorandum

DATE: September 14, 2022

**TO:** Celestine T. Kish, Project

Manager Division of Human Factors Directorate for Engineering Sciences

THROUGH: Mark Kumagai, Associate Executive Director

Directorate for Engineering Sciences

**FROM:** Caroleene Paul, Division Director

Division of Mechanical and Combustion

**Engineering Directorate of Engineering Sciences** 

Carlos G. Torres, Mechanical Engineer Division of Mechanical and Combustion

**Engineering Directorate of Engineering Sciences** 

**SUBJECT:** ASTM's Revised Voluntary Standard for Bassinets and Cradles: Engineering Sciences

Staff's Technical Assessment of Revisions

# I. Introduction

The current mandatory standard for bassinets and cradles, codified in 16 CFR part 1218, Safety Standard for Bassinets and Cradles (part 1218), incorporates by reference ASTM F2194-13, with several modifications to make the standard more stringent. This memorandum provides a technical assessment of the most recent revisions to the stability testing in ASTM F2194-22<sup>£1</sup> Standard Consumer Safety Specification for Bassinets and Cradles, to determine whether this revision improves the safety of bassinets and cradles.

# II. Background

On July 18, 2022, ASTM notified CPSC that it had published a revised 2022<sup>£1</sup> version of ASTM F2194 that substantively affects the requirements for bassinets and cradles. Specifically, the revised standard (ASTM F2194-22 <sup>£1</sup>) introduces a new compact bassinet/cradle product category and specifies a different test method for a compact bassinet/cradle to determine conformance with the stability performance requirement.

# III. Discussion

Comparison and Review of Stability Test in ASTM F2194 - 22<sup>\varepsilon1</sup>

# Existing stability requirement for bassinets

The stability test and performance requirement for a bassinet/cradle in ASTM F2194-22<sup>£1</sup> aligns with part 1218. The test consists of applying a 23-lb. vertical load, coupled with a 5-lb. horizontal load, at the uppermost horizontal side rail of a bassinet that is occupied by a newborn CAMI dummy (which weighs 7.5 lb.), Figure 1. The stability performance requirement specifies that the product shall not tip over and shall retain the CAMI dummy when subjected to the pull test.

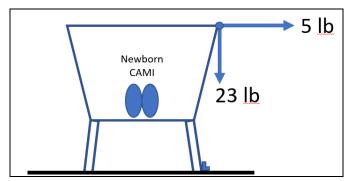


Figure 1. Bassinet Stability Test

The ASTM Subcommittee F15.18 on Cribs, Toddler Beds, Play Yards, Bassinets, Cradles, and Changing Tables developed the stability requirement for bassinets in ASTM F2194 (and incorporated in part 1218) when it was first published in 2002, to address fatal and nonfatal incidents involving bassinets that tipped over or fell off their base/stand when they were not properly locked/latched to their base/stand. The rationale for the stability test states: "dual application of the horizontal and vertical forces will simulate an angled load tipping the unit over. The 23-lb load is the mean strength of a male 2-year-old pulling." Based on the 20-year precedent of this test method and incident data suggesting it effectively reduced tip-over incidents, staff assesses that the stability requirement adequately addresses tip over of the product.

# New stability requirements for compact bassinets

ASTM F2194-22<sup>£1</sup> introduces a new product category, compact bassinets/cradles. The revised standard adds the following definition in Section 3.1 *Definitions*:

3.1.3 *compact bassinet/cradle, n* –a bassinet/cradle having a distance of less than 6.0 in. (152.4 mm) between the lowest point of the underside of the sleep surface support and the product support surface (floor).

In addition, the revised standard adds a new stability performance requirement for compact bassinets/cradles:

6.4.2 Stability – Compact bassinet/cradle – A product in all manufacturer's recommended use positions shall not tip over and shall retain the CAMI dummy when tested in accordance with 7.4.2

The new stability test specified in Section 7.4.2 for a compact bassinet/cradle consists of placing the product on a 20-degree inclined surface with an Infant CAMI dummy (which weighs 17.5 lb.) inside

the product, touching the inside wall of the product's lower side, and centered between both head and foot ends of the sleep surface, as shown in Figure 2.

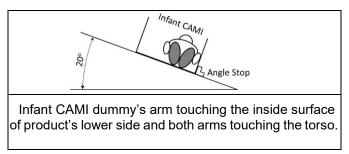


Figure 2. Compact Bassinet/Cradle Stability Test

# Staff's Evaluation of the New Compact Bassinet/Cradle Stability Test

Staff evaluated the effectiveness of the new compact bassinet/cradle stability performance requirement by testing eight compact bassinets/cradles samples of different dimensions and with different leg heights to the existing dual pull force stability requirement for bassinets specified in the current mandatory standard (part 1218) and to the new 20-degree tilt test specified for compact bassinets in ASTM F2194-22<sup>£1</sup>, Figure 3. Table 2 presents staff's test results. Six of the eight compact bassinets passed the 20-degree tilt test in the updated standard but failed the vertical/horizontal application of forces at the sidewall in part 1218. The two compact bassinet/cradles that passed the bassinet stability test in part 1218 were 18 and 29 inches wide.



Figure 3. Compact Bassinet/Cradle Tests to 20 deg tilt angle

Table 2. Comparison of Stability Tests Results							
Compact Bassinet ID	Compact Bassinet Width [in.]	Compact Bassinet Side Height [in.]	Compact Bassinet Leg Height [in.]	20-degree tilt test	16 CFR part 1218 Dual Force Application		
Α	16.5	11.5	0	Passed.	Failed.		
В	17.75	10.75	0	Passed.	Failed.		
С	16.5	10.5	0	Passed.	Failed.		
D	16.5	6.25	0	Passed.	Failed.		
Е	15.75	9.75	0	Passed.	Failed.		
F	16.5	11.5	0	Passed.	Failed.		
G	18.25	14.25	4	Passed.	Passed.		
Н	29.5	13.5	1	Passed.	Passed.		

Comparison of Compact Bassinet Stability Test specified in ASTM F2194-22<sup>£1</sup> (20-degree tilt test) and Bassinet Stability Test specified in Part 1218 (dual application of horizontal and vertical forces)

Staff's analysis and testing of 8 sample compact bassinet/cradles demonstrates that the 20-degree tilt test used in the 2022 standard is less stringent than the current pull test specified for bassinets in part 1218. Products that are unsafe because they fail the stability test in part 1218 (which applies 5 lb. of horizontal force and 23 lb. of vertical force at the product's uppermost horizontal side rail) will pass the 20-degree tilt test in the revised standard; therefore, staff concludes this is a clear reduction in safety. The test results for the eight sample compact bassinet/cradles (all with leg height less than 6 inches) showed that six of the eight compact bassinets failed the vertical/horizontal application of forces at the sidewall but passed the 20-degree tilt test. Thus, staff concludes the 20-degree tilt test used in the 2022 standard is less stringent and a reduction in safety because it would expose infants to unsafe products that do not meet the current stability test in part 1218.

The stability requirement in part 1218 specifically addresses the scenario of a 2-year-old male pulling down/out on the side of a bassinet, which is equally likely to occur on a compact bassinet/cradle, especially because these products are lower to the ground and are more likely to be placed in areas accessible to a sibling, either on the ground, or climbing on surfaces, such as tables, counters, beds, or couches (briefing package Tab A). The 20-degree tilt test in the revised standard does not simulate this scenario and cannot account for tip overs because the test is less stringent than the current pull test specified in part 1218.

# IV. Conclusion

ASTM F2194-22<sup>£1</sup> specifies a different stability test for a new product category, a "compact bassinet/cradle," defined as a bassinet having a distance of less than 6 inches between the bottom of the product and the floor/sleep surface.

Based on staff's analysis and testing, staff concludes that the 20-degree tilt test specified for compact bassinet/cradles in ASTM F2194-22<sup>£1</sup> is less stringent than the current pull force tests specified for bassinets in part 1218. Staff concludes this change in determining stability using the 20-degree tilt test is a reduction in safety for the following reasons:

- the tilt test is less stringent than the current mandatory test; six of eight tested compact bassinets failed the stability test requirements in 16 CFR part 1218 and passed the 20-degree tilt test for compact bassinets in ASTM F2194-22<sup>ε1</sup>, and
- the tilt test does not account for the reasonably foreseeable hazard scenario addressed in part 1218, in which a 2-year-old male pulls on the side of the compact bassinet/cradle and causes it to tip over with the infant inside.

Therefore, staff's analysis demonstrates that the 20-degree tilt test would reduce safety by increasing the tip over hazard associated with compact bassinets/cradles.