

*** Consumer Federation of America * Kids In Danger * Safe Infant Sleep***

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Office of the Secretary
Consumer Product Safety Commission
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Comments of Consumer Federation of America, Kids In Danger, and Safe Infant Sleep to the U.S. Consumer Product Safety Commission on the Notice of Proposed Rulemaking, Safety Standard for Bassinets and Cradles (Docket No. CPSC-2010-0028)

Consumer Federation of America (CFA), Kids In Danger (KID), and Safe Infant Sleep submit the following comments in response to the U.S. Consumer Product Safety Commission's ("CPSC" or "Commission") request for comments in the above-referenced matter.¹

Introduction

Caregivers and parents trust that products made for their children have been tested and proven safe. For decades, consumer and parent groups have advocated for safer infant sleep products. The Commission is now proposing to revise the existing rule for bassinets/cribbs to address the hazards identified in its Notice of Proposed Rulemaking (NPR) and ensure that the mandatory bassinet/cribble regulation provides the highest level of safety feasible.

CPSC staff identified seven fatalities and 13 injuries related to bassinets/cribbles from January 1, 2017 through December 31, 2022. CPSC staff also identified at least 182 non-injury incidents from January 1, 2021 through December 31, 2022. Two deaths, three non-emergency department (ED)-treated injuries, and 95 of the 182 noninjury product-related incident reports describe a bassinet or crib not sitting level. Two deaths, one ED visit, one non-ED injury, and 75 of the 182 non-injury product-related incidents are related to mattresses that were not flat or well-fitting. One reported hospitalization (laceration injury), one reported ED visit (broken metal piece injured infant), and seven of the 182 non-injury product-related incidents are related to structural robustness. Two deaths, one non-ED injury, and three of the 182 non-injury product-related incident reports are related to product design issues like instability, sitting too low to the ground, or having non-mesh walls. One fatality and three injuries relate to infants falling out of compact bassinets, where the product was placed on an elevated or soft surface, such as an adult bed, countertop, or couch.

¹ Notice for Rulemaking, Safety Standard for Bassinets and Cradles, <https://www.federalregister.gov/documents/2024/04/16/2024-07706/safety-standard-for-bassinets-and-cribbles> (April 16, 2024).

ASTM F2194-13, Section 3.1.1 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. Further, the bassinet/cradle is intended to have a sleep surface less than or equal to 10 degrees from horizontal. ASTM F2194-22 introduced the “compact bassinet,” which is defined as having less than 6.0 inches (152.4 mm) between the lowest point of the underside of the sleep surface support and the product support surface (floor). In September 2022, the Commission voted unanimously (5-0) to determine that ASTM F2194-22 does not improve the safety of bassinets and cradles or infant sleep products.

Proposed Rule

The proposed rule would apply to bassinets, cradles, combination products in bassinet/cradle mode, play yard and stroller bassinet accessories, low to the ground or portable bassinets, Moses baskets, play pens/travel bassinets, and after-market bassinet mattresses.

This rule would adopt ASTM F2194-22 with modifications. The proposed modifications remove the compact bassinet category and address five hazard patterns associated with young infants placed in or on:

- Non-level bassinets/cradles (suffocation hazard);
- Bassinets/cradles on elevated and soft surfaces such as beds, couches, tables, and countertops (falls, suffocation, skull fractures, and asphyxia hazards);
- Mattresses that are non-flat, too thick, too soft, ill-fitting, or unattached to the bassinet/cradle (suffocation hazard);
- Bassinets/cradles with design issues, such as low to the ground or unstable, or with loose sidewalls and/or non-mesh sidewalls (containment, tipping, gap entrapment, and suffocation hazards); and
- Products with electrical problems such as smoke, shock, and battery leakage (shock and burn).

The Commission is also proposing to align the rule's warnings with ASTM F2194-22 but not to include warnings related solely to compact bassinets. The NPR proposes to require warnings on all bassinets within the scope of the rule.

Requests for Comments

Proposed Side Height and Occupancy Surface Height Requirements

Our groups support external side/rail height and occupancy surface height requirements. External side height and occupancy surface height requirements are necessary to mitigate a known hazard pattern – bassinets falling from elevated surfaces. Side height and occupancy surface height requirements will discourage adults from placing bassinets on elevated surfaces because it will be more difficult to access the infant in a bassinet on an elevated surface. While our organizations strongly support requirements for

side height and occupancy surface height, we note that there are products on the market currently with 25.5"-26.5" side heights and 13.25"-13.75" occupancy surface heights. We respectfully ask the CPSC to evaluate the 27" side height and 15" occupancy surface height requirements to avoid eliminating safe products from the marketplace.

CPSC is correct to be concerned about small products being placed on raised surfaces or soft raised surfaces such as an adult bed or couch. The new rule should eliminate the smaller bassinets that are sometimes used for co-sleeping, etc. It is a known hazard pattern in almost every type of small sitting or resting product. However, for bassinets that are stroller attachments, it is unlikely a consumer would move a full-size stroller onto a bed or countertop, so the risk of placing it on a raised surface while attached is minimal, even when the dimensions are shorter than the proposed limits. Even some play yards currently with bassinet attachments could fail the required measurements, while not posing a risk of being put on a raised surface - and in most cases the bassinet cannot be used without the play yard base.

Proposed Sidewall Rigidity Requirements

Our groups support the proposed sidewall rigidity requirements. As noted in the NPR, the current mandatory rule in Part 1218 does not have a sidewall rigidity requirement. Many bassinets/cradles on the market have sidewalls constructed of fabric, foam, fiberfill, mesh, or cardboard, which can deflect downward, inward, and/or outward when subjected to a load. This poses a hazard to the infant, for example, if a sibling pulls on the side of the bassinet with non-rigid sidewalls causing the infant to not be properly contained in the bassinet.

Proposed Mattress Firmness Requirements

We agree with CPSC staff that the same mattress firmness test for crib mattresses should be used for bassinet/cradle mattresses, as well as after-market bassinet/cradle mattresses to reduce the risk of injury caused by poorly fitting and overly soft mattresses. The NPR proposes mattress firmness requirements consistent with the mandatory crib mattress requirements in 16 CFR Part 1241 to address incidents of the sleep surface conforming to infants' face, blocking breathing ability. The rule will prevent positional asphyxia.

Soft Sided Bassinets Firmness Requirement

Our groups support a side firmness requirement to address infants rolling their faces into the side of a soft sided bassinet. We note, however, that a test for soft sided bassinet firmness has not yet been proposed. We urge the CPSC to develop a suitable requirement and test to ensure soft sided products do not conform to an infant's nose or mouth.

Proposed Tilt and Incline Limitation Requirements

Our groups support tilt and incline limitation requirements. The changes proposed for the side-to-side tilt mitigate the potential for a rolling and suffocation hazard. Further, a performance and test requirement for the head-to-toe sleep surface angle limit will ensure safety with consistent and repeatable testing across test labs for all bassinets. Our organizations note, however, that other countries have added a margin of safety for infant sleep and regulate the head-to-toe angle of cribs, cradles, and bassinets not to exceed 7 degrees.² Because evidence-based medical recommendations confirm infants should sleep on non-inclined surfaces, we request the CPSC to review the enhanced margin of safety provided by a 7 degrees head-to-toe sleep surface angle limit.

We further suggest the CPSC to evaluate requirements for incline and tilt testing when a product is in motion. The current proposal only tests products at rest. Because Dr. Erin Mannen’s study on inclined sleep surfaces showed that inclines can lead to premature rolling, a moving/rocking product that is used with an infant might do the same, creating a hazardous situation especially if the infant is swaddled.

Proposed Warning Labels and Inclusion of After-Market Mattresses

Our groups support the warning labels. Further, we strongly support the inclusion of warning requirements for after-market mattresses in the final rule. There are incidents from the use of ill-fitting after-market mattresses. No after-market mattress currently on the market has the required warning label, which can lead to a serious risk for infants. This proposed change will mitigate the hazards presented by ill-fitting after-market mattresses.

Noise and Vibration Limit Requirements

We suggest the CPSC consider and begin to develop requirements for noise and vibration levels. Research demonstrates that exposure to excessive noise levels for prolonged periods can lead to hearing loss, which can impact other developmental milestones.³ As such, the American Academy of Pediatrics recommends that noise levels for infant products not exceed 50dB.⁴ The CPSC should review available evidence and analyze noise levels for infant products like bassinets.

Similarly, vibration is an added feature in many infant products, but in the last decade has become even more prominent in sleep products such as bassinets due to their calming effect. Research has shown that

² Health Canada, “Cribs, Cradles and Bassinets Regulations, SOR/2016-152” (Jun. 17, 2016)(online at: www.gazette.gc.ca/rp-pr/p2/2016/2016-06-29/html/sor-dors152-eng.html); Product Safety, New Zealand, “Unsafe goods notice: Inclined infant sleep products,” (Aug, 2020, last accessed Aug. 1, 2024) (online at: www.productsafety.govt.nz/for-businesses/making-sure-products-are-safe/unsafe-goods-notices/inclined-infant-sleep-products).

³ De Jong R, Davis G, Chelf C, Marinelli J, Erbele I, Bowe S. Continuous white noise exposure during sleep and childhood development: A scoping review. *Sleep Medicine*. 2024 Vol. 119; 88-94. <https://doi.org/10.1016/j.sleep.2024.04.006>.

⁴ Balk S, Bochner R, Ramdhanie M, Reilly B. Council on Environmental Health and Climate Change, Section on Otolaryngology-Head and Neck Surgery; Preventing Excessive Noise Exposure in Infants, Children, and Adolescents. *Pediatrics*. November 2023; 152 (5).

this calming effect is likely because vibration has on lowering heart rate.⁵ Because the lowering of an infant's heart rate can lower arousal, we suggest the CPSC evaluate the safety of such features and identify appropriate vibration thresholds.

Conclusion

Caregivers deserve products that are tested and proven safe, especially for products connected with infant sleep. Our groups support the proposed changes which will mitigate the hazards CPSC staff has identified, and we urge the CPSC to evaluate the safety issues our groups discussed above.

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⁵ Karlsson BM, Lindkvist M, Lindkvist M, Karlsson M., Lundström R, Håkansson S, Wiklund U, van den Berg J. Sound and vibration: effects on infants' heart rate and heart rate variability during neonatal transport. *Acta Paediatrica*. 2012; 101: 148-154. <https://doi.org/10.1111/j.1651-2227.2011.02472>. Lora-Martín A, Sequí-Sabater JM, del Rey-Tormos R, Alba-Fernández J, Sequí-Canet JM. Vibroacoustic Pollution in the Neonatal Ward. *Encyclopedia*. 2023; 3(2):449-457. <https://doi.org/10.3390/encyclopedia3020030>; Zhang N, Fard M, Bhuiyan M, Verhagen D, Azari M, Robinson SR. The effects of physical vibration on heart rate variability as a measure of drowsiness. *Ergonomics*. 2018; 61(9), 1259-1272. <https://doi.org/10.1080/00140139.2018.1482373>.