



Ballot Vote Sheet

TO: The Commission
Alberta E. Mills, Secretary

THROUGH: Austin C. Schlick, General Counsel
Daniel R. Vice, Assistant General Counsel, Regulatory Affairs

FROM: Pamela J. Stone, Senior Counsel

SUBJECT: Draft Final Rule: Ban of Inclined Sleepers for Infants

DATE: July 26, 2023

BALLOT VOTE DUE: Wednesday, August 2, 2023

On May 16, 2022, the President signed into law the Safe Sleep for Babies Act of 2021 (SSBA). The SSBA requires that inclined sleepers for infants, “regardless of the date of manufacture, shall be considered a banned hazardous product” under section 8 of the Consumer Product Safety Act, with the ban taking effect not later than 180 days after enactment of the Act (November 12, 2022). 15 U.S.C. § 2057d. The Office of the General Counsel is providing for Commission consideration the attached draft final rule to codify inclined sleepers for infants as a banned hazardous product at 16 CFR part 1310, so that the Code of Federal Regulations reflects the statutory ban on inclined sleepers for infants.

Please indicate your vote on the following options:

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

(Signature)

(Date)

- II. Approve publication of the attached document in the *Federal Register*, with changes.
(Please specify.)

(Signature)

(Date)



Ballot Vote Sheet

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

(Signature)

(Date)

IV. Take other action. (Please specify.)

(Signature)

(Date)

Attachments: Draft Final Rule: Ban of Inclined Sleepers for Infants
Staff Briefing Package: Ban of Inclined Sleepers for Infants Under the Safe Sleep for Babies Act

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1310

[CPSC Docket No. 2022-0025]

Ban of Inclined Sleepers for Infants

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: The Consumer Product Safety Commission is issuing this final rule to codify in its regulations the ban of inclined sleepers for infants pursuant to the Safe Sleep for Babies Act of 2021, which requires that inclined sleepers for infants, regardless of the date of manufacture, shall be considered a banned hazardous product under the Consumer Product Safety Act.

DATES: This rule is effective on **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

FOR FURTHER INFORMATION CONTACT: Will Cusey, Small Business Ombudsman, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7945 or (888) 531-9070; email: sbo@cpsc.gov.

SUPPLEMENTARY INFORMATION: Pursuant to section 2 of the Safe Sleep for Babies Act of 2021 (SSBA), 15 U.S.C. 2057d, the Consumer Product Safety Commission (Commission or CPSC) is issuing this final rule to reflect, in the Code of Federal Regulations, the statutory ban of inclined sleepers for infants that took effect by operation of law on November 12, 2022.

I. Background and Statutory Authority

On May 3, 2022, Congress passed the Safe Sleep for Babies Act of 2021, H.R. 3182, Pub. L. No. 117-126, which the President signed on May 16, 2022. Section 2(a) of the SSBA

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requires that, not later than 180 days after enactment of that law, “inclined sleepers for infants, regardless of the date of manufacture, shall be considered a banned hazardous product under section 8 of the Consumer Product Safety Act (15 U.S.C. 2057).” 15 U.S.C. 2057d(a). The SSBA defines inclined sleepers for infants as “product[s] with an inclined sleep surface greater than ten degrees that [are] intended, marketed, or designed to provide sleeping accommodations for an infant up to 1 year old.” 15 U.S.C. 2057d(b). The SSBA went into effect as a ban enforced by the Commission on November 12, 2022, which was the 180th day after its enactment, making it unlawful for any person to sell, offer for sale, manufacture for sale, distribute in commerce, or import inclined sleepers for infants as of that date. *See* 15 U.S.C. 2068(a)(1).

On July 26, 2022, CPSC published a notice of proposed rulemaking (NPR) stating the Commission’s intention to codify in its regulations the language in the SSBA requiring that inclined sleepers for infants be considered a banned hazardous product under section 8 of the Consumer Product Safety Act (CPSA). 87 FR 44309. CPSC requested and received comments from the public on the proposed rule. Specifically, CPSC requested comments regarding the effective date, interpretation of the SSBA language, and whether testing and certification to the ban should be required for sleep products for infants up to 1 year old. CPSC received a total of 67 comments from medical professionals, academic researchers, safety advocates, a children’s products design facility, and a trade association for children’s products. Those comments are summarized below in Section III.

II. Overview of the Final Rule Banning Inclined Sleepers for Infants

The Commission issues this final rule to codify the ban of inclined sleepers for infants pursuant to the SSBA as proposed, with a clarification in the purpose and scope section of the ban to make clear that the rule prohibits not only the sale of inclined sleepers for infants but also

the offer for sale, manufacture for sale, distribution in commerce, or importation into the United States, of these products. The final rule codifies the definition of “inclined sleeper for infants” as a product with an inclined sleep surface greater than ten degrees that is intended, marketed, or designed to provide sleeping accommodations for an infant up to 1 year old. The final rule also affirms that, regardless of the date of manufacture, inclined sleepers for infants are banned hazardous products as of November 12, 2022. The final rule is further discussed in the Staff Briefing Package: Ban of Inclined Sleepers for Infants Under the Safe Sleep for Babies Act.¹

III. Response to Comments

Of the 67 comments received by CPSC in response to the NPR, 55 were from medical professionals including doctors, pediatricians, nurses, academic researchers, and infant safety advocates who provided substantially similar comments expressing general support for the proposed rule. The comments are viewable online at www.regulations.gov under docket number CPSC-2022-0025.²

A. Effective Date

Comment A.1: The majority of commenters supported setting an effective date as soon as possible, but not later than the statutory effective date of November 12, 2022. No commenters advocated for a later date.

¹ Staff Briefing Package: Ban of Inclined Sleepers for Infants Under the Safe Sleep for Babies Act [\[add hyperlink\]](#)

² The Commission also received comments beyond the scope of this final rule. Those comments are summarized in the Staff Briefing Package and available at www.regulations.gov. Many of the commenters provided context for the SSBA, sharing data on the extent of Sudden Infant Death Syndrome (SIDS) in the U.S. over various time periods. The American Academy of Pediatrics (AAP), for example, provided data that shows SIDS deaths since 2000 in the U.S. have not declined, despite extensive outreach and education campaigns on safe sleep practices for babies. Several commenters referred to an AAP report on SIDS/SUID (Sudden Unexpected Infant Death) that estimated 3,500 infant deaths per year. March of Dimes noted that “Rates of preterm birth are increasing ... [with] disparities in birth outcomes between women and infants of color and their White peers. An estimated 700 women [die] from complications related to pregnancy each year and more than 22,000 babies die before their first birthday each year.”

Response A.1: The SSBA’s statutory ban of inclined sleepers for infants went into effect on November 12, 2022, and CPSC has been enforcing it since that time. Accordingly, the final rule will have an effective date 30 days after publication, which is the minimum period provided in the Administrative Procedure Act (APA). 5 U.S.C. 553(d). This effective date for the rule does not change the fact that inclined sleepers for infants have been banned pursuant to the SSBA as of November 12, 2022.

B. Interpretation

Congress enacted the SSBA after the Commission had implemented its Safety Standard for Infant Sleep Products (ISP Rule; 16 CFR part 1236). The ISP Rule became effective on June 23, 2022, and applies to products “marketed or intended to provide a sleeping accommodation for an infant up to 5 months of age” that are not subject to another CPSC sleep standard.³ The ISP Rule requires that the seat back or sleep surface angle for these products be 10 degrees or less from horizontal when measured as specified in part 1236. 86 FR 33022, 33060-61 (June 23, 2021). The SSBA, by its terms, applies to “inclined sleepers for infants,” defined as “a product with an inclined sleep surface greater than ten degrees that is intended, marketed, or designed to provide sleeping accommodations for an infant up to 1 year old.” 15 U.S.C. 2057d(b). Because the SSBA and the ISP Rule overlap but are not identical, the Commission sought comment on the following questions in particular:

1. *How should the Commission interpret and implement the phrase “sleeping accommodations” for purposes of the SSBA ban?*

³ The other sleep standards currently are 16 CFR part 1218 (bassinets and cradles); 16 CFR part 1219 (full-size cribs); 16 CFR part 1220 (non-full-size cribs); 16 CFR part 1221 (play yards); and 16 CFR part 1222 (bedside sleepers).

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Comment B.1: Several commenters (children’s product design facility Iron Mountains, the Juvenile Products Manufacturers Association (JPMA), and consumer advocacy groups Kids in Danger (KID) and Consumer Federation of America (CFA)) stated that CPSC should use the ISP Rule’s definition of “sleeping accommodations” to interpret the same language in the SSBA.

Commenters including KID, AAP, U.S. Public Interest Research Group (PIRG), Consumer Reports, CFA, March of Dimes, and Public Citizen, stated that “sleeping accommodations” should apply to products marketed for any kind of sleep, including napping or resting. KID stated that words such as “rest” or “nap,” or statements such as “not for overnight, unattended or extended sleep,” should not exclude a product from being considered a sleep product. PIRG suggested that while many infants can and do fall asleep anywhere, regardless of comfort, noise level or darkness, CPSC should define “sleeping accommodations” as products in which parents or caregivers believe an infant can sleep and stay unattended because of the way the product is designed, intended, or marketed. Consumer Reports stated that the term should apply broadly to include products remarketed as soothers or loungers.

The March of Dimes stated that CPSC should consider “sleeping accommodations” to be any product that is designed, intended, marketed, or commonly used by consumers for the purpose of putting a child to sleep, particularly if the sleep is unattended by an adult.

KID stated that the definition should include not just self-contained products, but also inclined sleep positioners, accessory products, and wedges that are used in the sleep environment.

Response B.1: The SSBA does not define “sleeping accommodations.” In the preamble to the ISP Rule, the Commission explained that sleeping accommodations are “products that are marketed or intended for both extended, unattended sleep, and also napping, snoozing, and other

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types of sleep in which a parent may or may not be present, awake, and attentive.” 86 FR 33047. The Commission agrees with commenters that “sleeping accommodations” should refer to products in which infants are placed for the purpose of napping or overnight sleep regardless of whether the sleep is “attended or supervised,” and that utilizing the same interpretation of sleeping accommodations in these overlapping rules will reduce confusion for the public and industry. Therefore, the Commission interprets the phrase “sleeping accommodations” in the SSBA consistent with the term as used in the ISP Rule. *See* 86 FR 33025-26.

2. *What, if any, effect should inclusion of the term “designed” in the SSBA have on the Commission’s interpretation and implementation of the SSBA as compared to the ISP Rule?*

Comment B.2: Comments from pediatricians and other medical professionals, as well as from AAP, stated that CPSC should be alert to changes to product marketing or categorization that could be cited as justification for the continued sale of dangerous products.

Multiple commenters, including KID, March of Dimes, CFA, Consumer Reports, and AAP, stated that by including the term “designed” in the statutory text, Congress sought to comprehensively ban all inclined sleep products and prohibit rebranding or reclassification of products to evade regulatory attention. These commenters stated that use of the word “designed” signals Congress’s intent to ban products that caregivers would reasonably see as suitable for sleep, regardless of how they are marketed.

One doctor (Hauck) advocated removing inclined products from the market, regardless of whether they are marketed for sleeping or awake infants, stating that “manufacturers will attempt to market these items for infants who are not shown to be sleeping ... [but] infants placed in these products will fall asleep and then be at risk for dying in them.” The AAP stated although

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caregivers may believe inclined sleep products aid with gastroesophageal reflux, research shows that placing infants on their backs on inclined surfaces is ineffective in reducing gastroesophageal reflux and may result in the infant sliding into a position that could compromise breathing.

PIRG and Public Citizen asserted that the addition of the word “designed” will allow CPSC to review the design as well as the marketing of inclined sleep products. These commenters stated that focusing on the manufacturer’s stated intent or consumer-facing marketing would enable manufacturers to argue that a product is not meant for sleep, when common sense dictates otherwise based on the design. These commenters urged the Commission to consider a product’s design, in addition to the company’s stated intention or marketing. Several commenters stated that if the product is not designed for any other purpose, then a logical conclusion is that the product is designed for sleep.

A children’s product design facility (Iron Mountains) stated that caregivers need products that restrain supervised, awake infants so that they can complete daily tasks and that swings, rockers, and bouncers are intended for such situations, and are the only alternative to the sofa or other unsafe surfaces. JPMA asserted that “infant rockers, swings, and bouncers are not designed to provide children with a place to sleep” and that any decision to include in the scope of the ban products that are not designed for sleep would misinterpret Congressional intent. JPMA further stated that if Congress had intended to include rockers, swings, and bouncers in the SSBA, it would have explicitly done so.

Response B.2: The Commission agrees that to give effect to the word “designed” within the definition of “inclined sleeper for infants” in the SSBA, the Commission should interpret that word as supplementing the accompanying words “intended” and “marketed.” In the ISP Rule, the

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Commission identified characteristics to be considered in evaluating whether a product is intended for sleep, including product packaging, marketing materials, instructions, product design, and pictures of consumer usage. *See, e.g.,* 86 FR 33048, <https://www.cpsc.gov/Business--Manufacturing/Business-Education/Business-Guidance/Infant-Sleep-Products-Business-Guidance-and-Small-Entity-Compliance-Guide>. To assess product design, the Commission will consider a number of factors, including those set forth in Response B.3 below.

In the absence of direct evidence regarding design, previous marketing for sleep, while not dispositive, will be persuasive evidence that an inclined product was designed to provide sleeping accommodations. Similarly, if an inclined product's design is substantially identical to another product that is an inclined sleeper for infants, that would be persuasive, though not dispositive, evidence that the product is designed to provide sleeping accommodations. Products that are designed to provide sleeping accommodations but also for one or more other purpose(s) likewise are covered by the language of the statutory ban, despite having the other, non-sleep use(s).

3. *In the SSBA, what product characteristics, if any, demonstrate that a product is “designed” for sleep?*

Comment B.3: Commenters from consumer safety advocacy groups, such as AAP, KID, PIRG, Consumer Reports, Public Citizen, and CFA, suggested product features they consider indicative of a product “designed” for sleep, including: padded sides; excess padding or pillow-like items; soothing sounds, lights, or vibrations; a nest-like appearance; muted color schemes, nighttime themes; illustrations of sleeping animals or closed eyes; warning labels that fail to warn against infant sleep generally and warn only against specific types of sleep, such as “prolonged,” “unattended,” or “overnight” sleep; and no features for another primary purpose,

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such as feeding or transportation of the child. The March of Dimes identified the following factors that it views as indicators a product is designed for sleep: a focus on comforting an infant to a point it could easily fall asleep in the product; nothing designed to stimulate an infant or prevent a child from sleeping; an absence of non-sleep related purposes, such as feeding or transportation; emphasis on the ability to leave a child unattended, where it may fall asleep.

Several commenters, including AAP, PIRG, Consumer Reports, and CFA, also stated that a product is designed for sleep if the purpose is to position an infant at an angle with the intent of leaving the infant in the product unattended during routine sleep, or if the product is intended to relax an infant in a way that it is reasonably expected the infant will fall asleep and be left unattended. PIRG gave examples of products with other primary purposes that involve supervised use, including high chairs, which are designed for feeding; car seats, which are designed for travel in a motor vehicle; and strollers, which are designed to contain a child being pushed on a walk.

JPMA stated that a “product designed for sleep would be constructed with features that are specifically intended to accommodate an unattended sleeping infant.” Iron Mountains stated that sleep products generally have “flat, horizontal occupant surfaces with no contour, shaping, or restraint” and are generally larger than “awake time” products. Iron Mountains further stated that a product is designed, intended, and marketed for sleep if it is visually very similar to a play yard, bassinet, crib, or bedside sleeper, and features include some of or all of the following: vertical side-walls, high side-walls indicating containment, typically a distinct angle between the occupant surface and the side walls, generally large size, flat and horizontal sleep surface with little or no contouring, and lack of a restraint.

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Response B.3: The Commission agrees with commenters' identification of characteristics that could be relevant to distinguishing whether products are designed for infant sleep for purposes of the SSBA, including, but not limited to, padded sides, excess padding or pillow-like items, soothing sounds, lights, or vibrations, nighttime themes, and labels that warn only against specific types of sleep and not sleep generally.

4. *How should the Commission interpret and implement the terms "marketed" and "intended" as a sleeping accommodation in the SSBA? Should these terms be interpreted and implemented the same as in the ISP Rule? Why or why not?*

Comment B.4: JPMA, AAP, PIRG, Consumer Reports, CFA, and KID stated that the terms "marketed" and "intended" should be interpreted and implemented under the SSBA consistent with how they are discussed in the preamble to the ISP Rule. AAP added that evaluation of marketing and intent should include assessment of marketing and promotional materials, audience targeting (including algorithms), the firm's public and private communications about a product, and the firm's foreseeable awareness about a product (including images, consumer comments, and discussion on social media and product review pages regarding the use of the product for routine sleep). KID added that while the terms "marketed" and "intended" overlap, together they "paint a line between infant products that have other purposes such as play, interaction, transport or feeding and those products [for which] ... sleep is clearly an intended purpose."

Response B.4: In the preamble of the ISP Rule, the Commission stated that "if a product's packaging, marketing materials, inserts, or instructions indicate that the product is for sleep, or includes pictures of sleeping infants, then CPSC will consider the product to be marketed for sleep." 86 FR 33063. The Commission also stated that staff will consider a

“[m]anufacturer’s intent, which can be evaluated through stated warning messages, marketing photos, product instructions and other factors.” *Id.* at 33051. Consistent with the comments received in response to the NPR for this final rule, and to promote ease of administration and clarity for regulated parties, the Commission adopts for administration of the SSBA and this final rule the same interpretation of “marketed” and “intended” as exists for the ISP Rule. Therefore, for example, if a manufacturer or importer markets a product as a space for infant sleep, the product will fall within the scope of the SSBA and this final rule and must meet the requirement to have a sleep surface angle of not greater than ten degrees.

5. *What is the significance of the age distinction between the ISP Rule and the SSBA’s ban? How might this difference bear on implementation of the SSBA as compared to the ISP Rule, including with respect to developmental differences between a newborn to 5 month old as identified in the ISP Rule, versus a newborn to 1 year old as identified in the SSBA?*

Comment B.5: JPMA stated that while most sleep products within the scope of the SSBA already fall within the scope of the ISP Rule because they are marketed for children 5 months or younger, the broader age range in the SSBA could prevent “bad actors” from re-marketing such products for infants 6 months to a year in an attempt to evade the ISP Rule.

AAP and Consumer Reports commented that important differences exist in the hazards for younger versus older infants, because there are significant developmental differences between infants who are newborn to 5 months old and those between 5 months and 1 year of age. AAP identified the following differences between older and younger infants:

- Older infants have greater arm strength and the ability to roll and change body positions, including from supine to prone;

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- Older infants have increased head and neck muscle strength;
- Older infants generally have the ability to lift and hold up their heads;
- Older infants have more mature brain development, which enables regulation of autonomic nervous functions, including breathing;
- Older infants in the 9-to-12-month range tend to face more danger from strangulation from straps, restraints, and other loose hazards on sleep products;
and
- Younger infants are at greater risk of positional asphyxia and the other biomechanical hazards.

Public Citizen recommended that the Commission address the differences in hazard patterns by age group and make sure products for children up to 1 year of age are included in the scope of the final rule. KID stated that the risk to infants over 5 months is important and noted they had recommended expanding the age range in response to the NPR for the ISP Rule. KID emphasized that the SSBA will prevent new inclined sleep products marketed for 6 months and older from entering the marketplace, deter remarketing of existing products, and provide CPSC with the authority to remove all inclined sleepers marketed for children up to 1 year from the marketplace.

CFA stated that the SSBA, by including infants up to 1 year, broadens CPSC's authority to include inclined sleep products for infants over 5 months. CFA also noted that the expanded age range prevents suppliers from remarketing infant products to an older age group to evade the ISP Rule, when those products are not suitable for an older child.

Response B.5: As commenters note, AAP's safe sleep guidance states that infants less than 1 year old should sleep on a firm, flat, surface, such as a crib, bassinet, play yard, or bedside

sleeper.⁴ Consistent with that guidance, the SSBA and this final rule prohibit inclined sleeping accommodations with an incline of greater than 10 degrees for all children from birth up to 1 year of age.

6. *How, if at all, should the SSBA's ban of inclined sleepers for infants affect the ISP Rule or the Commission's application of it?*

Comment B.6: Commenters largely expressed support for the continued implementation and enforcement of the ISP Rule, without change. AAP and Consumer Reports stated that the SSBA should build upon the successful foundation of the ISP Rule to offer clarity on the importance of banning all inclined infant sleep products, such as by including more extensive examination of products to ensure that if a product is not intended for another purpose (such as travel or eating) and can be used for routine sleep, it does not have an incline greater than 10 degrees.

Response B.6: Although the ISP Rule and the SSBA differ somewhat, commenters did not identify any conflict between them. Therefore, the Commission finds no reason to propose changes to the ISP Rule.

7. *To the extent inclined sleepers remain on the market that are not banned by this rule, and that are not regulated under the ISP Rule, should CPSC require testing and certification to this ban, to demonstrate that a product is not within the scope of the ban?*

Comment B.7: Commenters differed as to whether testing and certification under the SSBA are needed and what such testing would achieve. JPMA opposed testing and certification

⁴“Place infants on their backs for sleep in their own sleep space with no other people. Use a crib, bassinet, or portable play yard with a firm, flat mattress and a fitted sheet. Avoid sleep on a couch or armchair or in a seating device, like a swing or car safety seat (except while riding in the car).” www.aap.org/en/patient-care/safe-sleep/.

to demonstrate that inclined sleep products are not banned products pursuant to the SSBA. JPMA further stated that a product with an incline of less than 10 degrees would not meet the definition of an “inclined sleeper for infants” in the SSBA.

Consumer groups supported SSBA testing and certification. AAP stated that CPSC should use its authority to require testing and certification to ensure that noncompliant products are not sold. KID and Consumer Reports supported testing and certification to demonstrate which products are out of scope of the ban and thus allowed for sale, stating that testing and certification could demonstrate that an inclined sleep product either for older children or with an incline under 10 degrees is not within the scope of the ban. Consumer Reports stated that testing and certification would help to eliminate potential loopholes and avoid muddling the longstanding “bare is best” messaging for safe infant sleep. CFA also supported testing, urging the CPSC to use all of its authority, including enforcement, testing, and certification, to protect infant sleep environments.

Response B.7: The NPR noted that when a ban does not remove all products in a product category from the market, CPSC may require testing and certification to demonstrate that a product is not within the scope of the ban. Few bans completely remove all products in a specific category from the market, instead removing a subset of products with hazardous characteristics, while allowing sale of other products in the category subject to regulation. The Commission has previously stated that manufacturers of products in a category where a subset of the products are subject to a ban must issue certificates. 28 FR 28079, 28082 (May 13, 2013). Moreover, section 14(a)(1) of the CPSA requires that products subject to a rule, ban, standard, or regulation, be tested and certified as compliant. 15 U.S.C. 2063(a)(1).

Congress did not prohibit all inclined sleepers for infants in the SSBA—only those intended, marketed, or designed for infants from birth to 1 year that have an incline greater than ten degrees. Therefore, products may remain in the marketplace that could be subject to regulation. Though the Commission is not implementing a testing and certification program at this time, it may consider testing, certification, and registration requirements in the future, based on additional information collected by the agency.

IV. Changes Included in the Final Rule

The final rule contains three changes from the NPR: the effective date and two minor technical or clarifying revisions.

A. Effective Date

The APA generally requires that the effective date of a rule be at least 30 days after publication of the final rule. 5 U.S.C. 553(d). The NPR proposed an effective date of November 12, 2022, which was the date that the SSBA took effect. Because that date has passed, and because commenters supported CPSC implementing the rule expeditiously, the Commission is finalizing this rule with a 30-day effective date, the minimum permitted under the APA, and has revised 16 CFR 1310.4 accordingly. Section 1310.4 was further revised to clarify that the ban of inclined sleepers for infants was effective as of November 12, 2022, pursuant to the SSBA, but that the final rule is effective as of **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. The promulgation of this final rule does not change the fact that inclined sleepers have been banned pursuant to the SSBA since November 12, 2022.

B. Technical and Clarifying Revisions

For the final rule, the Commission has updated the language proposed in the NPR by replacing the public law citation for the SSBA (Pub. L. No. 117-126) with the newer U.S. Code citation (15 U.S.C. 2057d).

The Commission also revised proposed 16 CFR 1310.1, *Purpose and scope*, to more fully describe the substantive effect of Congress's classification of inclined sleepers for infants as banned hazardous products. Section 1310.1 of the final rule makes clear that the rule prohibits not only the sale of inclined sleepers for infants but also, in accordance with section 19(a)(1) of the CPSA, the offer for sale, manufacture for sale, distribution in commerce, or importation into the United States, of these products. 15 U.S.C. 2068(a)(1).

V. Preemption

Section 3(b)(2)(A) of Executive Order 12988, *Civil Justice Reform* (Feb. 5, 1996), directs agencies to specify the preemptive effect of any rule. 61 FR 4729 (Feb. 7, 1996). Because the SSBA states that inclined sleepers for infants are banned hazardous products, any state performance standards allowing the sale of inclined sleepers for infants, as those products are defined in the SSBA and this rule, would be inconsistent with federal law and therefore preempted by this ban.

VI. Regulatory Flexibility Act

The Regulatory Flexibility Act, 5 U.S.C. 601-612, requires that agencies review proposed and final rules for their potential economic impact on small entities, including small businesses, and identify alternatives that may reduce such impact, unless the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. In the NPR, the Commission certified that the rule will not have a significant economic

impact on substantial number of small entities and received no comment on that issue. 87 FR 44309.

VII. Environmental Considerations

The Commission’s regulations at 16 CFR part 1021 address whether the agency must prepare an environmental assessment or an environmental impact statement. Under those regulations, certain categories of CPSC actions that have “little or no potential for affecting the human environment” do not require an environmental assessment or an environmental impact statement. 16 CFR 1021.5(c). This final rule codifying section 2 of the SSBA falls within the categorical exclusion, so no environmental assessment or environmental impact statement is required.

VIII. Paperwork Reduction Act

This final rule contains no information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA; 44 U.S.C. 3501–3521).

IX. Congressional Review Act

The Congressional Review Act (CRA; 5 U.S.C. 801-808) states that, before a rule can take effect, the agency issuing the rule must submit the rule and certain related information to each House of Congress and the Comptroller General, 5 U.S.C. 801(a)(1), and indicate whether the rule is a “major rule” as defined in 5 U.S.C. 804(2). The CRA further states that the Office of Information and Regulatory Affairs (OIRA) determines whether a rule qualifies as a “major rule.” OIRA has determined that this rule is not a “major rule” under the CRA. To comply with the CRA, the Commission will submit the required information to each House of Congress and the Comptroller General.

List of Subjects

16 CFR Part 1310

Administrative practice and procedure, Consumer protection, Infants and children.

For the reasons stated in the preamble, the Commission adds part 1310 to title 16 of the Code of Federal Regulations as follows:

PART 1310 – BAN OF INCLINED SLEEPERS FOR INFANTS

Sec.

1310.1 Purpose and Scope

1310.2 Definition

1310.3 Banned Hazardous Product

1310.4 Effective Date

Authority: 15 U.S.C. 2057d.

§ 1310.1 Purpose and Scope

The purpose of this rule is to prohibit the sale, offer for sale, manufacture for sale, distribution in commerce, or importation into the United States, of any inclined sleepers for infants, as defined in part 1310.2 and as set forth in the Safe Sleep for Babies Act of 2021 (15. U.S.C. 2057d).

§ 1310.2 Definition

Inclined sleeper for infants means a product with an inclined sleep surface greater than ten degrees that is intended, marketed, or designed to provide sleeping accommodations for an infant up to 1 year old.

§ 1310.3 Banned Hazardous Product

Any inclined sleeper for infants, as defined in section 1310.2, regardless of the date of manufacture, is a banned hazardous product under section 8 of the Consumer Product Safety Act (15 U.S.C. 2057).

§ 1310.4 Effective Date

By statute, the effective date of this ban is November 12, 2022. The effective date of this rule is **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

Dated: _____

Alberta E. Mills
Secretary, Consumer Product Safety Commission



Staff Briefing Package: Ban of Inclined Sleepers for Infants Under the Safe Sleep for Babies Act

July 26, 2023

For additional information, contact:

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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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Memorandum

TO: The Commission
Alberta Mills, Secretary

DATE: July 26, 2023

THROUGH: Austin C. Schlick, General Counsel
Jason K. Levine, Executive Director
DeWane Ray, Deputy Executive Director for Operations

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

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

SUBJECT: Staff Briefing Package: Ban of Inclined Sleepers for Infants Under the
Safe Sleep for Babies Act

I. Introduction

On July 26, 2022, the Consumer Product Safety Commission (CPSC) issued a notice of proposed rulemaking (NPR) to codify in its regulations the ban of “inclined sleepers for infants” pursuant to the Safe Sleep for Babies Act of 2021 (SSBA). 15 U.S.C. § 2057d; 87 Fed. Reg. 44,309. The SSBA requires that inclined sleepers for infants, regardless of the date of manufacture, shall be considered a banned hazardous product under section 8 of the Consumer Product Safety Act (CPSA). 15 U.S.C. § 2057. The SSBA defines inclined sleepers for infants as “product[s] with an inclined sleep surface greater than ten degrees that [are] intended, marketed, or designed to provide sleeping accommodations for an infant up to 1 year old.” 15 U.S.C. § 2057d(b). The SSBA went into effect as a ban enforced by the Commission on November 12, 2022, which was the 180th day after its enactment.

The Commission requested comment on the NPR, receiving 67 comments from medical professionals, academic researchers, safety advocates, a children’s products design facility, and a trade association for children’s products. Section III of this memo and Tab A summarize the comments and provide staff’s recommended responses. Based on the comments, staff recommends that the Commission issue a draft final rule to codify the SSBA’s ban of inclined sleepers for infants, with one clarification in the purpose and scope section of the ban to more fully describe the Commission’s authority over banned hazardous products.

This final rule briefing package reviews the background on the SSBA, discusses the comments received on the NPR, and provides staff’s recommendations regarding the final rule.

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II. Background

A. *Safe Sleep for Babies Act*

On May 3, 2022, Congress passed the Safe Sleep for Babies Act of 2021, H.R. 3182, Pub. L. No. 117-126, which the President signed on May 16, 2022. Section 2(a) of the SSBA requires that, not later than 180 days after enactment, “inclined sleepers for infants, regardless of the date of manufacture, shall be considered a banned hazardous product under section 8 of the Consumer Product Safety Act (15 U.S.C. 2057).” 15 U.S.C. § 2057d(a). The SSBA defines inclined sleepers for infants as “product[s] with an inclined sleep surface greater than ten degrees that [are] intended, marketed, or designed to provide sleeping accommodations for an infant up to 1 year old.” 15 U.S.C. 2057d(b). The SSBA went into effect as a ban enforced by the Commission on November 12, 2022, which was the 180th day after its enactment, making it unlawful for any person to sell, offer for sale, manufacture for sale, distribute in commerce, or import inclined sleepers for infants. See 15 U.S.C. § 2068(a)(1).

B. *NPR to Codify the Ban of Inclined Sleepers for Infants*

On July 26, 2022, CPSC published an NPR stating the Commission’s intention to codify in its regulations the language in the SSBA requiring that inclined sleepers for infants be considered a banned hazardous product under section 8 of the CPSA. 87 Fed. Reg. 44,309. The Commission received 67 comments from medical professionals, academic researchers, safety advocates, a children’s products design facility, and a trade association for children’s products, mostly in support of the rule. Section III of this memorandum and Tab A summarize and respond to the comments.

C. *Products Within the Scope of the Ban*

Products impacted by the ban in the SSBA and this rule are products that have an inclined sleep surface greater than ten degrees that are intended, marketed, or designed to provide a sleeping accommodation for infants up to 1 year old. In 2021, the Commission issued the Safety Standard for Infant Sleep Products (ISP rule, 16 C.F.R. part 1236), effective June 23, 2022, which requires that infant sleep products be tested to confirm the seat back/sleep surface angle is 10 degrees or less from horizontal and meet the requirements of the bassinet standard (16 C.F.R. part 1218), at a minimum. The ISP rule covers all sleep products for children up to 5 months old, so most newly manufactured sleeping accommodations for infants of this age range should have been compliant with the instant rule since June 2022. Therefore, this rule primarily has an impact on inclined products for an age range that includes 6 months to 1 year old.

The categories of products that may include inclined sleep products subject to the SSBA include:

- wooden climbing arches that flip over to be an inclined rocking sleeper with a padded cushion (often marketed as “Montessori” or “Waldorf” arches);
- infant/toddler rockers, often with multiple recline positions, that are marketed at least in part for sleep;
- swings or bouncers that are marketed at least in part for sleep;
- baby and toddler hammocks; and

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- high chairs with a reclining seat marketed for sleep.

Not all products in the categories listed list above are necessarily intended, marketed, or designed to provide sleeping accommodations for infants, however. For example,

- Rockers, swings, or bouncers can have a purpose of entertaining an awake infant, and may not be intended, marketed, or designed to provide sleeping accommodations.
- Baby and toddler hammocks inherently have an inclined sleep surface, and are designed for sleep. Hammocks are within the scope of this rule if they are intended, marketed, or designed for infants up to one year old. However, hammocks marketed for older children would be out of scope.
- Most toddler climbing arch/rocking napper products are marketed for one year and up.

III. Comments on the NPR (Tab A)

Tab A of this Staff Briefing Package summarizes the comments and provides staff's responses and recommendations. The Commission received 67 comments on the NPR, mostly from medical professionals, academic researchers, and safety advocacy groups. CPSC also received comments from one children's product design facility and a trade association for children's products. CPSC received one comment from a medical professional who also identified as a bereaved parent of a SIDS infant.¹

Fifty-five substantially similar comments from individual pediatricians, other types of doctors, nurses, medical professionals, academic researchers, and infant safety advocates generally supported the rule. These commenters advocated for an effective date as soon as possible. They also encouraged CPSC to continue outreach efforts, and to rigorously enforce both the SSBA and the ISP rule. Commenters mentioned the need for CPSC to be responsive to "changes to product marketing or categorization [that] could enable the continued sale of dangerous products under dubious auspices."

Most commenters agreed that "sleeping accommodations" should be defined as discussed in the preamble to the ISP rule, although some contended that it should be expanded to take into account products that are "designed" for sleep that might not fall within the scope of the ISP rule, or might be former sleep products now being marketed as different products and not for infant sleep. Commenters also disagreed whether CPSC should require testing and certification.

As explained in Tab A, CPSC staff recommends that the Commission use the same definition for "sleeping accommodations" as is used in the ISP rule. Staff notes that while the ISP rule applies to products "marketed or intended as a sleeping accommodation," and the Commission interpreted the word "intended" to include considerations of product design, the SSBA includes the word "designed" as a distinct element. To ensure compliance with the ban, staff also anticipates recommending, after further staff work, that the Commission consider future rulemaking to require testing and certification of all infant sleep products that are intended, marketed, or designed as a sleeping accommodation for an infant up to 1 year old, using the same sleep surface angle test from the ISP rule; staff notes

¹ CPSC did not receive any comments from manufacturers of children's products, state and local governments, other federal government agencies, the WTO contacts for foreign countries, or members of Congress.

that sleep products for children up to 5 months old already require testing and certification to applicable CPSC rules. Tab A contains additional explanation and detail.

In the NPR, the Commission certified under the Regulatory Flexibility Act that the proposed rule would not have a significant impact on a substantial number of small entities. 87 Fed. Reg. 44,309. The Commission received no comments on this certification.

IV. Change to the Final Rule

Staff recommends that the rule be finalized as proposed, with one clarification to the purpose and scope of the ban in section 1310.1. The NPR stated the purpose of the rule was to “prohibit the sale of inclined sleepers for infants...” However, the Commission’s authority with respect to banned hazardous products is more broadly stated under the CPSA, as set forth in section 19(a)(1) of the CPSA, 15 U.S.C. § 2068(a)(1), prohibiting the sale, offer for sale, manufacture for sale, distribution in commerce, or importation into the United States of any banned hazardous product. Accordingly, in the final rule, staff recommends clarifying that the purpose of the rule is to “prohibit the sale, offer for sale, manufacture for sale, distribution in commerce, or importation into the United States,” of any inclined sleeper for infants.

VI. Effective Date

The Administrative Procedure Act (APA) generally requires that the effective date of a rule be at least 30 days after publication of the final rule (5 U.S.C § 553(d)). In this case, by statute, the ban of inclined sleepers for infants is already effective, as of November 12, 2022. The final rule codifies the statutory ban on inclined sleepers for infants already in effect, without any additional requirements, therefore, staff recommends an effective date of 30 days for the rule. This effective date for the rule does not change the fact that inclined sleepers for infants have been banned pursuant to the SSBA as of November 12, 2022.

VII. Staff Conclusion and Recommendations

Staff recommends that the Commission issue a final rule, Ban of Inclined Sleepers for Infants, to codify the SSBA in the Code of Federal Regulations as proposed, with one clarification in the purpose and scope section to more fully state the Commission’s authority with respect to banned hazardous products. Staff recommends an effective date of 30 days after publication of the final rule; a later date is not recommended because the final rule codifies a ban already in effect since November 12, 2022.

Tab A: Ban of Inclined Sleepers for Infants: Staff's Response to Comments on the Proposed Rule

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Memorandum

TO: Celestine T. Kish,
Project Manager Infant Sleep Products
Division of Human Factors
Directorate of Engineering Sciences

DATE: June 7, 2023

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

FROM: Infant Sleep Products Team

SUBJECT: Ban of Inclined Sleepers for Infants: Staff's Response to Comments
on the Proposed Rule

I. Background

On May 3, 2022, Congress passed the Safe Sleep for Babies Act of 2021 (SSBA), which requires that, not later than 180 days after enactment, “inclined sleepers for infants, regardless of the date of manufacture, shall be considered a banned hazardous product under section 8 of the Consumer Product Safety Act (15 U.S.C. 2057).” 15 U.S.C. § 2057d(a). Section 2(b) of the SSBA defines “inclined sleepers for infants” as “a product with an inclined sleep surface greater than ten degrees that is intended, marketed, or designed to provide sleeping accommodations for an infant up to 1 year old.” On July 26, 2022, the Commission published a notice of proposed rulemaking (NPR) to codify the ban in 16 C.F.R. part 1310. 87 Fed. Reg. 44,309. The NPR sought comments on how the Commission should implement this statutory ban of inclined sleepers.

The Commission received 67 comments on the NPR, mostly from medical professionals, academic researchers, and safety advocacy groups. CPSC also received comments from one children's product design facility and a trade association for children's products. CPSC received one comment from a medical professional who also identified as a bereaved parent of a SIDS infant.²

This memorandum summarizes the comments received by topic and provides staff's proposed responses for Commission consideration.

II. General Comments

CPSC received 55 substantially similar comments in general support of the rule from individual pediatricians, other types of doctors, nurses, medical professionals, academic researchers, and infant safety advocates. Attachment One to this memorandum contains the text of this form letter. About half of these commenters self-identified as members of the American Academy of Pediatrics (AAP). Other commenters identified as members of the International Society for the Study and

² CPSC did not receive any comments from manufacturers of children's products, state and local governments, other federal government agencies, the WTO contacts for foreign countries, or members of Congress.

Prevention of Perinatal and Infant Death (ISPID), the Injury Free Coalition for Kids, the Canadian Nurses Association, the American Nurses Association, and the faculties of various medical schools. One medical professional also identified as a bereaved parent of a SIDS infant.

These commenters generally supported the rule and advocated for an effective date as soon as possible. They also encouraged CPSC to continue outreach efforts, and to ensure that both the SSBA and the Safety Standard for Infant Sleep Products (the ISP rule) are rigorously enforced. Commenters mentioned the need for CPSC to be responsive to “changes to product marketing or categorization [that] could enable the continued sale of dangerous products under dubious auspices.”

Some commenters provided additional information about the extent of SIDS deaths in the U.S., and the impact of safe sleep guidelines on reducing SIDS deaths. Several commenters observed that while widespread safe sleep guidelines outreach had reduced SIDS deaths over time, the sale of inclined products has reversed this trend.

III. Comments in Response to Questions Posed in the NPR

CPSC received comments from safety advocacy groups, a children’s product trade association, a children’s product design facility, and academic researchers addressing the specific questions posed in the NPR. Below staff summarizes comments and proposed responses on the questions from the NPR, and then summarizes additional issues raised by commenters.

Issue 1: The Commission proposes to implement the inclined sleeper ban in the SSBA with an effective date of November 12, 2022. The NPR requested comments on alternative dates, and the legal justification for any alternative date after November 12, 2022.

Comments: Individual commenters recommend an effective date as soon as possible, as did the AAP and other safety advocacy groups. Consumer Reports recommends an effective date of as soon as possible, but no later than November 12, 2022. Consumer Federation of America (CFA) states there is no reason to extend the effective date after November 12, 2022. Kids in Danger (KID) comments that 180 days after enactment of the SSBA is longer than necessary, because many retailers aren’t selling inclined products anymore, and also suggests a date as soon as possible. No commenters suggest an effective date after November 12, 2022.

Response: The inclined sleeper ban in the SSBA was effective on November 12, 2022, and CPSC has been enforcing the ban since then consistent with CPSC’s statutory authority. Because the ban is already in effect, staff recommends an effective date for the rule of 30 days after publication of the final rule, the minimum period allowed under the Administrative Procedure Act. 5 U.S.C. 553(d). This effective date for the rule does not change the fact that inclined sleepers for infants have been banned pursuant to the SSBA as of November 12, 2022.

Issue 2: How should the Commission interpret and implement the phrase “sleeping accommodations” for purposes of the SSBA ban?

Comments: A children’s product design facility (Iron Mountains) and the Juvenile Products Manufacturers Association (JPMA) state that CPSC should adopt the ISP rule’s definition of “sleeping accommodations” when applying the SSBA’s ban on inclined sleepers for infants. KID, a

consumer advocacy group, and CFA also state that the definition should be the same as in the ISP rule.

Many commenters, including KID, the AAP, U.S. Public Interest Research Group (PIRG), Consumer Reports, CFA, March of Dimes, and Public Citizen state that “sleeping accommodations” should apply to products marketed for any kind of sleep, including napping or resting. KID states that as with the ISP rule, words such as “rest” or “nap,” or statements such as “not for overnight, unattended or extended sleep” should not exclude a product from being considered a sleep product. PIRG notes that while many infants can and do fall asleep anywhere, regardless of comfort, noise level or darkness, CPSC should define “sleeping accommodations” as those products which many parents or caregivers could believe are appropriate products in which the infant can sleep and can stay unattended because of the way the product is designed, intended or marketed. Consumer Reports states that the term should also apply to products remarketed as soothers or loungers.

The March of Dimes states that CPSC should consider “sleeping accommodations” to be any product that is designed, intended, marketed, or commonly used by consumers for the purpose of putting a child to sleep, particularly if the sleep is unattended by an adult, which could include several factors, including:

- “A focus on comforting an infant to a point it could easily fall asleep in the product;
- A product not designed to stimulate an infant or which would prevent a child from sleeping, including a lack of numerous components designed to stimulate an infant;
- A product which design excluded non-sleep related purposes, such as feeding or transportation;
- A product designed to be able to leave a child unattended, where it may fall asleep.”

KID states that the definition should not just apply to self-contained products, but should also apply to inclined sleep positioners, accessory products, and wedges in the sleep environment that were not included within the scope of the ISP rule.

Response: Staff appreciates comments provided to the Commission on the definition of “sleeping accommodations.” The draft final rule is simply codifying the text of the SSBA and the SSBA does not define “sleeping accommodations,” therefore, staff recommends finalizing the rule as proposed. As guidance in interpreting the term “sleeping accommodations,” staff notes that the preamble to the final ISP rule stated that “sleeping accommodations” refer to products that are marketed or intended for both extended, unattended sleep, and also napping, snoozing, and other types of sleep in which a parent may or may not be present, awake, and attentive.” 86 Fed. Reg. 33,047. Staff agrees that “sleeping accommodations” for both the ISP rule and the SSBA should include products in which infants are placed for naps and overnight sleep regardless of whether the sleep is “attended or supervised.”

Staff also notes that CPSC has developed criteria for considering when a product is a “sleeping accommodation” for the ISP rule. See [[Infant Sleep Products Business Guidance and Small Entity Compliance Guide | CPSC.gov](#)].

Issue 3: What, if any, effect should inclusion of the term “designed” in the SSBA have on the Commission's interpretation and implementation of the SSBA as compared to the ISP Rule? For example, what significance, if any, might “designed” have for inclined products that are not marketed for sleep but in which an infant may fall asleep, such as bouncers, swings, and rockers?

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Comments: Comments from individual AAP members and other medical professionals, as well as from AAP itself, state that CPSC should be responsive to changes to product marketing or categorization that could enable the continued sale of dangerous products. These commenters did not identify any specific products to which their concerns apply.

Multiple safety advocate groups, including KID, March of Dimes, CFA, Consumer Reports, and the AAP, state that inclusion of the term “designed” in the statutory text indicates that Congress sought to comprehensively ban all inclined sleep products and foresaw potential challenges in the rebranding or reclassification of products to evade regulatory attention. These commenters state that use of the word “designed” represents a deliberate intent by Congress to give CPSC the authority to address products that may be marketed as not for sleep, but that parents would reasonably see as suitable for sleep.

An individual doctor (Hauck) notes that “Unfortunately, manufacturers will attempt to market these items for infants who are not shown to be sleeping and parents may be adversely influenced to purchase them. All too often, infants placed in these products will fall asleep and then be at risk for dying in them.” This commenter advocates removing all inclined products from the market, regardless of how they are marketed.

PIRG and Public Citizen note that the word “designed” wasn’t in the ISP rule, which Public Citizen says provides a loophole for manufacturers from the requirements of that rule. These commenters state that focusing on the manufacturer’s stated intent or consumer-facing marketing provides manufacturers deniability and the ability to hide behind an argument that a product is not meant for sleep, when common sense dictates otherwise based on the design. These commenters urge the Commission to consider a product’s design, in addition to the company’s stated intention or marketing, or lack thereof, to provide the Commission with more opportunities to protect babies.

A children’s product design facility (Iron Mountains) states that the ISP rule definitions should not be changed in response to the term “designed” in the SSBA. JPMA notes that “infant rockers, swings, and bouncers are not designed to provide children with a place to sleep”, and that any decision to include products that aren’t designed for sleep in the scope of the ban would be a misinterpretation of Congressional intent. JPMA further states that if Congress had intended to include rockers, swings, and bouncers in the SSBA, they would have explicitly done so.

Response: Staff appreciates comments provided to the Commission on the definition of “designed.” The draft final rule is simply codifying the text of the SSBA and the SSBA does not define “designed,” therefore, staff recommends finalizing the rule as proposed. As guidance in interpreting the term “designed,” staff notes that the preamble to the ISP rule states that the Commission considers a product’s design when evaluating whether a product is “intended” for sleep. The ISP final rule preamble states that “[p]roducts that have no use other than infant sleep, based on the product’s design, cannot be labelled as not intended for infant sleep to avoid meeting the requirements of the final rule.” 86 Fed. Reg. at 33,046. In the discussion of comments on the NPR, the preamble also states that “not all manufacturers can simply remarket the product if the physical form of the product demonstrates that it is intended for sleep.” 86 Fed. Reg. at 33,052. In the discussion of the impact of the rule on suppliers, the preamble states that suppliers of products where “the physical configuration of the product limits uses other than sleep, are likely to be significantly impacted”, because such products could not be remarketed for another use. 86 Fed. Reg. at 33,067.

Products that have a clear purpose other than infant sleep may not fall within the ISP rule or the SSBA. Some products engage and stimulate infants' social and motor development. Products such as swings, bouncers, and rockers provide a space to contain an awake infant and also to entertain and engage infants, allowing them to observe and interact with their environment and to engage, strengthen, and/or develop social, visual, or motor skills. If infants are only placed supine in flat products, they are not given the opportunity to develop these skills while in those products. For example, research conducted in response to the "Back to Sleep" campaign shows that infants who are sleeping supine and do not have adequate prone/tummy time exhibit delayed motor development. Staff is concerned that if inclined infant products that engage and stimulate infants less than 12 months of age were categorically removed from the market on the basis that they are "sleeping accommodations," then infants may experience delayed development. Furthermore, these products allow caregivers to attend to other children and other pressing needs while their awake and alert infant is in a secure location. Parents need a place to put a child that works in varied locations of the home. Eliminating all inclined products that are not for sleep would remove an important capability for caregivers and could lead to regrettable substitutions where infants are laid on sofas or other unsafe surfaces. However, even if the product is not designed for sleep, if a manufacturer promotes or markets their product as a space in which an infant may sleep, the product will fall within the scope of the ISP rule and the SSBA.

Issue 4: What product characteristics, if any, demonstrate that a product is "designed" for sleep?

Comments: Commenters from consumer safety advocacy groups, such as AAP, KID, PIRG, Consumer Reports, Public Citizen, and CFA, list product features they urge CPSC to consider indicative of a product "designed" for sleep, such as padded sides; excess padding or pillow-like items; soothing sounds, lights, or vibrations; a nest-like appearance; muted color schemes, nighttime themes, and illustrations of sleeping animals or closed eyes; unclear warning labels that fail to warn against infant sleep generally and warn only against specific types of sleep, such as "prolonged," "unattended," or "overnight" sleep"; and no features for another primary purpose, such as feeding or transportation. Several commenters, including AAP, PIRG, Consumer Reports, and CFA, also state that a product is designed for sleep if the purpose is to position an infant at an angle with the intent of leaving the infant in the product unattended during routine sleep, or if the product is intended to relax an infant in a way that it is reasonably expected the infant will fall asleep and be left unattended. These commenters state that if the product is not designed for any other purpose, then a logical conclusion is that the product is designed for sleep. PIRG gave examples of other primary product purposes other than sleep, which are typically designed for supervised use, such as high chairs, which are designed for feeding; car seats, which are designed for travel in a motor vehicle; and strollers, which are designed to contain a child being pushed on a walk.

JPMA states that a "product designed for sleep would be constructed with features that are specifically intended to accommodate an unattended sleeping infant." Iron Mountains states that sleep products generally have "flat, horizontal occupant surfaces with no contour, shaping, or restraint", and are generally larger than "awake time" products. Iron Mountains notes that a product is designed, intended and marketed for sleep if it is visually very similar to a play yard, bassinet, crib, or bedside sleeper, and features include some of or all of the following: vertical side-walls, high side-walls indicating containment, typically a distinct angle between the occupant surface and the side walls, generally large size, flat and horizontal sleep surface with little or no contouring, and lack of a restraint.

Response: Relevant characteristics of sleep products that inform whether they are intended and/or designed for infant sleep may include all of the characteristics suggested by commenters. The preamble to the ISP rule discusses possible characteristics as do the Commission’s FAQs on the ISP rule. 86 Fed. Reg. 33,048, <https://www.cpsc.gov/Business--Manufacturing/Business-Education/Business-Guidance/Infant-Sleep-Products-Business-Guidance-and-Small-Entity-Compliance-Guide>. CPSC staff anticipates that it will consider multi-mode products that have soothing noises and vibrations in some modes, or seats that recline into “couch,” “soother,” or “lounger” mode, “designed for sleep” if they have a mode that includes design characteristics of sleep. Depending on the age range, because of the sleep mode, the product will likely be within the scope of the SSBA.

Issue 5: How should the Commission interpret and implement the terms “marketed” and “intended” as a sleeping accommodation in the SSBA? Should these terms be interpreted and implemented the same as in the ISP Rule?

Comments: JPMA, AAP, PIRG, Consumer Reports, CFA, and KID state that the terms should be interpreted and implemented the same as discussed in the ISP rule. AAP also added that CPSC’s marketing and intent evaluation should include marketing and promotional materials, audience targeting (including algorithms), public and private company communications about a product, and a company’s foreseeable awareness about a product (including images, consumer comments, and discussion on social media and product review pages regarding the use of the product for routine sleep without company intervention). KID adds that while marketed and intended use overlap, together these terms “paint a line between infant products that have other purposes such as play, interaction, transport or feeding and those products that, while some of those might take place on occasion, sleep is clearly an intended purpose.”

Response: The Commission discussed interpretation of “marketed and intended” in the preamble of the ISP rule, stating that infant sleep products “include products that are marketed for ‘napping,’ ‘snoozing,’ ‘dreaming,’ or any other word that implies sleeping, or that are called a ‘bed,’ and items marketed with a picture of a sleeping infant, to be an infant sleep product.” 86 Fed. Reg. 33,063. The preamble also states that “if a product’s packaging, marketing materials, inserts, or instructions indicate that the product is for sleep, or includes pictures of sleeping infants, then CPSC will consider the product to be marketed for sleep.” 86 Fed. Reg. 33,025. In response to a comment on the ISP rule requesting that CPSC remove the word “intended,” staff responded that intent “can be evaluated through stated warning messages, marketing photos, product instructions and other factors, must remain a factor for staff’s consideration.” 86 Fed. Reg. 33,051. In some instances, the manufacturer of a product does not create all marketing materials. A product that the manufacturer does not intend to be used for sleep but is marketed or intended by the importer, distributor, retailer or other party to provide a sleeping accommodation for infants, may be in-scope of the SSBA as well as the ISP rule.

Given the feedback on the way that “marketed and intended” are interpreted and implemented for the ISP rule, staff does not recommend changing how these terms are used when applied to products under the SSBA.

Issue 6: Age Difference for Products in Scope between ISP Rule and SSBA.

Comments: JPMA notes that most sleep products within the scope of the SSBA already fall within the scope of the ISP rule, because they are marketed for children 5 months or younger, and that the

broader age range in the SSBA could prevent “bad actors” from re-marketing products for the 6 month and older age range in an attempt to evade the ISP rule.

AAP and Consumer Reports state important differences exist in the hazards for younger versus older children, informing that significant developmental differences exist between infants who are newborn to 5 months old, as opposed to those between 5 months and one year of age, and advises that these developmental differences necessitate CPSC’s consideration of both how older infants will interact with a product, and what different potential hazards products may pose. Age differences include:

- Older infants have greater arm strength and the ability to roll and change body positions, including from supine to prone;
- Older infants have increased head and neck muscle strength;
- Older infants generally have the ability to lift and hold up their heads;
- As infants age they develop more mature brain development which enables regulation of autonomic nervous functions, including breathing. Older infants in the 9-to-12-month range tend to face more danger from strangulation from straps, restraints, and other loose hazards on sleep products;
- Younger infants are at greater risk of positional asphyxia and the other biomechanical alterations outlined in CPSC’s Mannen report.³

Public Citizen states that hazard patterns may vary by age group and that CPSC should address these differences by making sure products for children up to 1 year of age are included in the scope of the final rule. KID states that the risk to infants over 5 months is important, and that they had commented on the ISP rule NPR to raise the intended age of products in scope. KID maintains that the SSBA will prevent new inclined sleep products marketed for 6 months and up from entering the marketplace, prevent remarketing of existing products, and will provide CPSC with the statutory authority to remove any inclined sleepers marketed for 6 months and up from the marketplace.

CFA advises that infants older than five months should not be sleeping in some of the products covered by the ISP Rule and that all infant sleep products should be covered by a standard. CFA states that although younger and older infants have different developmental needs and behaviors that must be considered for all infant sleep environments, the fact that the SSBA law includes infants up to 1 year is helpful to the CPSC because it broadens the agency’s authority to include inclined sleep products for infants over five months. CFA also notes that the expanded age range prevents suppliers from remarketing infant products to an older age group just to evade the ISP rule, when those products are not suitable for an older child.

Response: Staff agrees that infants differ greatly in their developmental skills in their first year of life. The physical and developmental capabilities of infants render them susceptible to danger from suffocation in certain sleep settings, including inclined sleep surfaces. Infants in the first 4-6 months of life, premature infants, and infants who are born as a set of multiples are particularly vulnerable and are the most at risk due primarily to developmental delays and an immature breathing control system. Physiological abnormalities and delays in the development of vital systems can further hamper an infant’s ability to react to a hazardous sleep setting. This age group is at risk for SIDS, which appears to be related to the development and maturity of the respiratory system. SIDS is thought to occur when an infant with an underlying biological vulnerability, who is at a critical

³ https://www.cpsc.gov/s3fs-public/SupplementalNoticeofProposedRulemakingforInfantSleepProducts_10_16_2019.pdf

development age, is exposed to an external trigger, such as an unsafe sleep setting. The AAP's safe sleep guidance states that infants less than 1 year old should sleep on a firm, flat, surface, such as a crib, bassinet, play yard, or bedside sleeper.

Issue 7: How the SSBA ban of inclined sleepers should affect the ISP Rule

Comments: Commenters largely express general support for the continued implementation and enforcement of the ISP rule, without offering specific suggestions for how SSBA should affect that implementation. JPMA notes that the SSBA bans one class of product that was already in the scope of the ISP rule, so it should have no impact.

The AAP and Consumer Reports state that the SSBA should build upon the successful foundation of the ISP rule to offer clarity on the importance of banning all inclined infant sleep products, such as by including more extensive examination of the marketing, intent, and design of products to ensure that if they are not intended for another purpose (such as travel or eating) and can be used for routine sleep, the products do not have an incline greater than 10 degrees.

Response: The SSBA ban on inclined sleepers for infants overlaps with the ISP rule but covers a broader age range of infants up to one year old. The ISP rule already requires in-scope infant sleep products to have a maximum seat back/sleep surface angle not exceeding 10 degrees. However, the scope of the ISP rule covers flat and inclined infant sleep products intended for infants from 0 to 5 months old, while the SSBA ban applies to inclined sleepers intended for infants up to one year old. Accordingly, the SSBA bans inclined sleep products intended for infants up to one year old, including some of those also covered by the ISP Rule. In addition, the SSBA ban applies to all inclined sleepers for infants sold or distributed after November 12, 2022, regardless of the manufacture date, whereas the ISP rule covers only products manufactured after its effective date.

Issue 8: Testing and Certification To Demonstrate That Inclined Sleep Products Are Out of Scope of the Ban

Comments: Commenters differ on whether testing and certification is needed, and what it would achieve. JPMA opposes testing and certification to demonstrate that inclined sleep products are out of scope of the ban, because they believe that any infant sleep product with an incline of less than 10 degrees would already be within the scope of the ISP rule. Also, JPMA contends that a product with an incline of less than 10 degrees would not meet the definition of an "inclined sleeper for infants" in the SSBA.

Consumer groups support SSBA testing and certification. AAP states that the breadth of the SSBA should preclude the presence of inclined sleep products in the marketplace, but that CPSC should use its authority to require testing and certification to ensure that noncompliant products do not remain on the market. KID and Consumer Reports support testing and certification to demonstrate that products are out of scope of the ban, stating that testing and certification could demonstrate that an inclined sleep product for either older children or with an incline under 10 degrees is not within the scope of the ban. Consumer Reports states that testing and certification would help to eliminate potential loopholes and would help to avoid muddling the longstanding "bare is best" messaging. CFA also supports testing, stating that the ISP rule and the SSBA should effectively ban these products, but if not, urges the CPSC to use all of its authority, including enforcement, testing and certification to protect infant sleep environments.

Response: Staff notes that products intended for sleep for infants up to 5 months old are already subject to testing and certification for CPSC rules for infant sleep products. Staff agrees that testing and certification of all products intended, marketed, or designed as a sleeping accommodation for infants from 0 to 1 year old to demonstrate compliance with the ban may advance consumer safety and reduce the introduction of violative products in the market for those outside of the ISP rule or specific CPSC sleep product rules. Section 14 of the CPSA requires that children's products subject to rules, bans, standards, and regulations be third party tested and certified as compliant to the rules. However, staff recommends considering this testing and certification requirement separately via future rulemaking, to allow additional notice, comment, and related staff work on implementation of such testing and certification.

IV. Other Issues Raised by Commenters, Not Addressing Questions in the NPR Preamble

Issue 9: Products to Restrain Awake, Attended Infants Serve a Necessary Purpose

Comment: Iron Mountains notes that caregivers need products that restrain supervised, awake infants so that they can complete daily tasks. For example, a caregiver cannot safely hold a baby while cooking or doing laundry. Caregivers do not necessarily want to put an awake baby unattended in a sleep product in another room. Swings and other similar products are the only alternative to the couch or other unsafe household surfaces, Iron Mountains states. Playmats, for example, do not contain the infant, Iron Mountains asserts.

Response: Staff agrees that some infant seated products assist with infants' social, visual, and motor development. Newborns typically sleep 16 to 17 total hours a day, 2 to 3 hours at a time. By 8 weeks, they start to sleep longer at night. Between 4 and 6 months of age, infants can sleep 8 to 12 hours during the night with longer durations of fewer naps during the day. During awake time, infants use their sight, hearing, and touch for social and visual development. During these awake times seated products such as bouncers, swings, rockers, strollers, and high chairs are also beneficial to the caregiver, because they allow for completion of daily tasks while providing a safe location for the infant.

Issue 10: The ISP Rule Will Force Parents into Unsafe Sleep Practices

Comment: Iron Mountains states that since "portable bassinets are currently outlawed by the infant sleep rule, it is reasonable to expect to see more unrecommended locations used for infant naps such as couches, adult beds, and infant rockers."

Response: Although comments about the impact of the ISP rule are out of scope of this SSBA rulemaking, staff addresses this comment to note that portable bassinets are not "outlawed."

Issue 11: Inclined Sleep Products Do Not Treat GERD Effectively and Are Not Safe

Comment: The AAP states that infant inclined sleep products pose a substantial risk and are not effective in treating gastroesophageal reflux (GERD) in infants. Although caregivers may seek out inclined sleep products believing them to aid with GERD, research shows that placing infants supine (on their backs) on inclined surfaces is ineffective in reducing GERD and may result in the infant sliding into a position toward the foot of the crib that may compromise breathing.

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An individual commenter (Goodstein) provided information on the history of FDA-approved “sleep positioners,” stating that devices failing to meet FDA approval as a medical device, because manufacturers could not demonstrate that the product benefit outweighed the risk of suffocation and positional asphyxia, are sold to consumers as non-device sleep positioners.

Response: Staff defers to FDA and AAP regarding recommendations for treating GERD. As noted above, sleep positioners and other products such as wedge pillows that are not marketed, intended, or designed as sleeping accommodations are not covered by the SSBA and this rule.

Issue 12: Safe Sleep Outreach

Comment: The AAP provided data that shows SIDS deaths since 2000 in the U.S. have not declined, despite extensive outreach and education campaigns on safe sleep practices for babies. Therefore, AAP comments, the ISP Rule and SSBA Act are needed to remove unsafe inclined sleep products from the marketplace altogether.

The March of Dimes, stating concern with the use of second-hand inclined products, encourages the Commission to “engage in a national public health campaign regarding the danger these products pose to infants following in the footsteps of the highly successful SIDS campaign.”

Many commenters note that consumers incorrectly believe that any product for sale legally in the U.S. has met some kind of safety standard.

Response: Staff agrees that removal of unsafe inclined sleep products from the marketplace is necessary and anticipates that vigorous enforcement of the ISP Rule and SSBA will aid in achieving that goal.

Issue 13: Data from Other Countries on Inclined Sleep, Bedsharing, and Other Factors Addressed by the ISP Rule and SSBA Cause SIDS

Comment: Two individuals (Dr. Shereen Hamadneh and Dr. Jeanine Young) provided peer reviewed research on bedsharing and other unsafe sleep practices in Australia and various countries in the Middle East, and SIDS statistics from those countries. In addition, Dr. Young provided Australian safe sleep guideline documents.

Response: Staff appreciates the sharing of information across countries and acknowledges that safe sleep for infants is not restricted to the United States. Staff assesses that safety organizations benefit when data and safety information is shared and consistent messages for infant safe sleep are developed and shared.

Issue 14: Data from U.S. on extent of SIDS

Comment: Multiple commenters provided data on the extent of SIDS in the U.S. over various time periods. Several commenters referred to an AAP report on SIDS/SUID that estimated 3,500 infant deaths per year. AAP, “Sleep-Related Infant Deaths: Updated 2022 Recommendations for Reducing Infant Deaths in the Sleep Environment” (July 21, 2022), available at: publications.aap.org/pediatrics/article/150/1/e2022057990/188304/Sleep-Related-Infant-Deaths-Updated-2022.

March of Dimes noted that “Rates of preterm birth are increasing, the U.S. is one of the most dangerous places to give birth in the developed world, and there are unacceptable disparities in birth outcomes between women and infants of color and their White peers. An estimated 700 women from complications related to pregnancy each year and more than 22,000 babies die before their first birthday each year. This rate of maternal and infant death is unacceptably high.”

An individual doctor (Schmit) noted that “SIDS/SUID rate declined sharply in the 1990's after the Back to Sleep campaign was implemented. However, since then there has been very little change in this rate and over 3000 babies die every year due to sleep related deaths.” Another doctor (Edwards) noted that “SIDS rates have been cut in half during my career due to safe sleep recommendations from the AAP, and it is painful to watch cases increase again with the increasing popularity of inclined sleepers.”

Response: Staff appreciates and recognizes that SIDS/SUID rates and maternal and infant death rates for American families, particularly families of color, are still at unacceptable levels. Staff contends that removal of unsafe inclined sleep products and promoting safe sleep products of cribs (full and non-full size), bassinets, play yards, and bedside sleepers aid in ensuring safe infant sleep.

Attachment One – Form Letter General Comment

This is the text of the letter in general support of the rule received from 55 commenters. Some commenters slightly modified this letter to indicate they were some other kind of medical professional, or not a member of the AAP.

As a pediatrician and a member of the American Academy of Pediatrics (AAP), I urge you to please approve a comprehensive rule banning inclined sleepers with the soonest possible effective date.

The proposed rule represents a landmark public health achievement to reduce the burden of sleep-related infant deaths. Since inclined sleepers entered the marketplace, pediatricians have expressed concerns about these products.

The AAP has long underscored the importance of the consistent use of safe sleep environments for infants. This includes always placing infants on their back to sleep and doing so on a firm, flat, bare mattress with no soft bedding or crib bumpers, consistent with AAP's safe sleep guidelines. However, merely telling parents and caregivers the elements of a safe sleep environment is woefully insufficient when dangerous infant sleep products are widely available for purchase. I am a resident physician, and I just completed my first year of training, yet, I have personally experienced two preventable infant deaths from unsafe sleep practices.

This is why I was pleased to see the bipartisan Safe Sleep for Babies Act become law, which directs CPSC to ban inclined sleepers and crib bumpers. This overdue reform will protect infants from dangerous sleep products by providing needed clarity to parents and caregivers.

The CPSC has a critical role in implementing the SSBA to protect infants from these dangerous products. I urge you to ensure that the Final Rule is implemented as expeditiously as possible and is sufficiently expansive to ban all infant inclined sleep products. Recognizing the concern that changes to product marketing or categorization could enable the continued sale of dangerous products under dubious auspices, I encourage the CPSC to rigorously apply the letter and spirit of the SSBA to fully clear the marketplace of dangerous inclined sleep products.

In addition, I urge CPSC to engage in robust compliance activities to enforce the Final Rule, extensive public education to further bolster the agency's safe sleep public health campaigns consistent with AAP guidelines, and ongoing surveillance to identify potentially concerning products going forward.

Thank you for your consideration and your work on the Commission.

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