ORAL ARGUMENT NOT YET SCHEDULED
No. 25-1003

In the United States Court of Appeals for the District of Columbia Circuit

HEROES TECHNOLOGY (US) LLC d/b/a SNUGGLE ME ORGANIC,
Petitioner,

v.

UNITED STATES CONSUMER PRODUCT SAFETY COMMISSION,
Respondent.

OPPOSED MOTION FOR STAY PENDING REVIEW

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1(a) and D.C. Circuit Rule 26.1, Heroes Technology (US) LLC states that it is a for-profit, limited liability company organized under the laws of Delaware. It designs, manufactures, and sells the Snuggle Me Infant Loungers and Covers. The Infant Lounger is designed for active engagement, play, and bonding with infants while they are awake. The machine-washable Infant Loungers and Covers are made with organic cotton and the Loungers are filled with polyester fiber.

Heroes Technology (US) LLC's parent company is Heroes Technology Ltd. ("HTL"), a private company limited by shares incorporated and registered in England and Wales under registered number 12620251 whose registered office is at 25 Horsell Road, The Orangery, London N5 1XL, United Kingdom.

No publicly held corporation owns 10 percent or more of Heroes Technology (US) LLC's or HTL's stock.

/s/ Kara M. Rollins
KARA M. ROLLINS

CERTIFICATE OF COMPLIANCE WITH CIRCUIT RULE 18

This motion complies with Circuit Rule 18. On February 6, 2025, Petitioner requested that the Consumer Product Safety Commission stay the effective date of the final rule at issue pending judicial review and asked the Commission to respond by February 28, 2025. A23–36. On February 20, 2025, Petitioner submitted a letter supplementing its February 6 request to the Commission. A19–21. The Commission denied the request on March 6, 2025. A15; A17.

Pursuant to Circuit Rule 18(a)(2), on March 10, 2025, Petitioner notified counsel for Respondent by telephone that it planned to file this motion and sought Respondent's position. On March 11, 2025, Respondent informed Petitioner that it opposed the requested stay.

/s/ Kara M. Rollins
KARA M. ROLLINS

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INTRODUCTION

This is not a case about whether the Consumer Product Safety Commission ("CPSC") should promulgate mandatory consumer product safety standards but how Congress authorized it to do so. Congress limited use of 15 U.S.C. § 2056a's expedited rulemaking process to durable products that are intended for or reasonably expected to be used by children under the age of 5 years. While Congress left the term "durable" undefined, it provided a non-exhaustive list of products to guide CPSC. Those products, including cribs and strollers, are classic examples of durable goods within the term's plain meaning.

In comparison, the products CPSC seeks to regulate in the challenged rule, *Safety Standard for Infant Support Cushions*, 89 Fed. Reg. 87,467 (Nov. 4, 2024) (the "Rule"), are not durable goods. So, CPSC was required to follow the more onerous process and rigorous procedures set forth in §§ 2056 and 2058 before issuing a consumer product safety standard. By relying on its flawed interpretation of the Consumer Product Safety Act ("CPSA"), 15 U.S.C. § 2051 *et seq.*, CPSC exceeded its statutory authority and failed to adhere to its limitations. As a result of its strained reading of § 2056a, CPSC arrogated unlawful power to itself and failed to observe the procedures required by law. The Rule is also arbitrary and capricious.

The meaning of "durable" in § 2056a(f) is a matter of first impression for this Court. A stay pending review is necessary to preserve the status and rights of

Petitioner Heroes Technology (US) LLC d/b/a Snuggle Me Organic ("Heroes Technology" or the "Company"), whose marquee product, the Snuggle Me Infant Lounger and its Cover, is subject to the Rule. A5–6; A10. Absent this Court's intervention, the Company will suffer irreparable, if not existential, harm. A9–13.

Heroes Technology respectfully requests that this Court stay the Rule's effective date pending judicial review.

BACKGROUND

I. CPSA'S RULEMAKING PROCESSES FOR INFANT AND TODDLER PRODUCTS

The CPSA provides two options, relevant here, for issuing product safety standards[1] for infant and toddler products: (1) the process set out in §§ 2056 and 2058, which applies to most consumer products; or (2) the process set out in § 2056a, which only applies to "durable infant or toddler products." There are significant procedural and evidentiary differences between these rulemaking processes. Products regulated under § 2056a are also subject to additional consumer registration and recordkeeping requirements. 15 U.S.C. § 2056a(d).

Under the first option, CPSC must rely upon voluntary safety standards when those standards "eliminate or adequately reduce the risk of injury addressed and it is likely that there will be substantial compliance with such voluntary standards."

[1] Safety standards provide requirements for "performance," "warnings or instructions," or the "form of warnings or instructions." 15 U.S.C. § 2056(a)(1)–(2).

15 U.S.C. § 2056(b)(1). If CPSC determines that a voluntary safety standard will not accomplish those goals, it may promulgate a safety standard under § 2058. *See* 15 U.S.C. § 2058(f)(3)(D).

CPSC must "express … the risk of injury which the standard is designed to eliminate or reduce" and "consider relevant available product data[.]" 15 U.S.C. § 2058(e). It must also "make a host of findings about costs and benefits." *Finnbin, LLC v. CPSC*, 45 F.4th 127, 131 (D.C. Cir. 2022) (citing 15 U.S.C. § 2058(f)).

> Those findings include: (1) "that the rule (including its effective date) is reasonably necessary to eliminate or reduce an unreasonable risk of injury associated with [the] product"; (2) that any voluntary standard is not likely to eliminate or reduce the risk of injury, or that it is "unlikely that there will be substantial compliance" with the voluntary standard; (3) that the rule's benefits "bear a reasonable relationship to its costs"; and (4) that the rule "imposes the least burdensome requirement" to prevent or reduce the risk of injury. 15 U.S.C. § 2058(f)(3)(A), (D), (E), (F).

Window Covering Mfrs. Ass'n v. CPSC, 82 F.4th 1273, 1280 (D.C. Cir. 2023). The findings also require a determination that "the rule is in the public interest." 15 U.S.C. § 2058(f)(3)(B).

Under the second option, CPSC follows § 2056a's expedited process for promulgating safety standards for certain types of children's products.[2] Before it promulgates a safety standard under § 2056a, CPSC must consult with public

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[2] Section 2056a was adopted in 2008 as part of the Consumer Product Safety Improvement Act ("CPSIA"), Pub. L. 110-314.

stakeholders and "examine and assess the effectiveness of any voluntary consumer product safety standards for durable infant or toddler products[.]" 15 U.S.C. § 2056a (b)(1)(A). After participating in that consultative process, CPSC, following 5 U.S.C. § 553's notice-and-comment rulemaking procedures, may promulgate a safety standard that is either "substantially the same as such voluntary standards" or, in certain circumstances, "more stringent than such voluntary standards[.]" 15 U.S.C. § 2056a (b)(1)(B). Thus, under § 2056a, CPSC faces an arguably lower threshold for regulating "durable infant or toddler products" in the first instance because it is not required to defer to voluntary standards or make the findings set out in § 2058. However, later revisions to safety standards promulgated pursuant to § 2056a must follow the process set out in § 2058. *See* 15 U.S.C. § 2056a (b)(4)(B).

The statute defines "durable infant or toddler product[]" as "a durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years[.]" 15 U.S.C. § 2056a (f)(1). While "durable" is not defined by statute, § 2056a (f)(2) provides a non-exhaustive list of twelve infant or toddler products which are included in the definition: "full-size cribs and non-full-size cribs; … toddler beds; … high chairs, booster chairs, and hook-on chairs; … bath seats; … gates and other enclosures for confining a child; … play yards; … stationary activity centers; … infant carriers; … strollers; … walkers; … swings; [and] bassinets and

cradles." Since CPSIA's adoption, CPSC has expanded or modified the list of durable infant or toddler products. *See* 16 C.F.R. § 1130.2(a)(1)–(18).

Products regulated under the durable infant or toddler provision must follow product registration, record keeping, and notification requirements. 15 U.S.C. § 2056a (d).

II. THE INFANT SUPPORT CUSHION RULE

Despite the CPSA's marked preference for voluntary safety standards, CPSC circumvented that process and promulgated the Rule before the voluntary infant lounger safety standard could be completed. A8–9. That standard would have specifically addressed design and use concerns that are unique to infant loungers. *Id.* Instead of allowing that process to run its course—and create a workable voluntary safety standard specific to infant loungers—CPSC rushed out the Rule, opting for a one-size-fits-all approach to numerous unrelated product categories. A9.

In adopting the Rule, CPSC invented an entirely new category of infant products: infant support cushions. They are defined as any

> infant product that is filled with or comprised of resilient material such as foam, fibrous batting, or granular material or with a gel, liquid, or gas, and which is marketed, designed, or intended to support an infant's weight or any portion of an infant while reclining or in a supine, prone, or recumbent position.

89 Fed. Reg. at 87,487. The Rule also "includes any removable covers, or slipcovers, sold on or together with an infant support cushion." *Id.* In-scope products include

some twelve exemplary products, encompassing a broad and incongruent set of purposes and designs. *Id.* at 87,469. CPSC estimated that the Rule is applicable to over 2,000(!) product models. *Id.* at 87,486. The Rule sets out performance standards and testing methods for all in-scope products. *Id.* at 87,488–95. It also establishes marketing, labeling, and instructional requirements. *Id.* at 87,495–498. Finally, because in-scope products are (falsely) deemed "durable infant or toddler products," they are now subject to the registration and recordkeeping requirements set out in 15 U.S.C. § 2056a(d) and its implementing regulations, 16 C.F.R. § 1130.1 *et seq.*

The Rule either eliminates or requires significant and expensive redesigning and testing of thousands of products currently on the market, including the Snuggle Me Infant Lounger. A9–11.

ARGUMENT

Courts may "issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings." 5 U.S.C. § 705. In doing so, they consider "(1) whether the stay applicant has made a strong showing that [it] is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies." *In re NTE Conn., LLC*,

26 F.4th 980, 987–88 (D.C. Cir. 2022) (quoting *Nken v. Holder*, 556 U.S. 418, 434 (2009) (cleaned up)). Heroes Technology makes that showing here.

I. HEROES TECHNOLOGY IS LIKELY TO PREVAIL ON THE MERITS

A. CPSC Exceeded Its Statutory Authority and Conducted This Rulemaking Without the Procedures Required by Law

The Administrative Procedure Act ("APA") permits review of agency actions made reviewable by statute, *see* 5 U.S.C. § 704 and 15 U.S.C. § 2060, and requires courts to "hold unlawful and set aside agency action … found to be … in excess of statutory jurisdiction, authority, or limitations, or short of statutory right" or "without observance of procedure required by law[.]" 5 U.S.C. § 706(2)(C), (D).

CPSC is a "creature[] of statute" and it "accordingly possess[es] only the authority that Congress has provided." *NFIB v. OSHA*, 595 U.S. 109, 117 (2022). Its "powers can be decided only by considering the powers Congress specifically granted it in the light of the statutory language and background." *Nat'l Petro. Refs. Ass'n v. FTC*, 482 F.2d 672, 674 (D.C. Cir. 1973). CPSC "literally has no power to act … unless and until Congress confers power upon it." *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986). Thus, "[t]he question to be answered is 'not what the [Commission] thinks it should do but what Congress has said it can do.'" *Nat'l Petro. Refs. Ass'n.*, 482 F.2d at 674 (citation omitted).

In determining the scope of CPSC's authority, courts "must begin with the words of the statute creating the Commission and delineating its powers." *Id*. Unless

defined, Courts interpret statutes "in accord with the ordinary public meaning of its terms at the time of its enactment." *Bostock v. Clayton Cnty.*, 590 U.S. 644, 654 (2020). An agency's interpretation that "was issued roughly contemporaneously with enactment of the statute and remained consistent over time" may serve as an "interpretive aid[.]" *Loper Bright Enters. v. Raimondo* and *Relentless v. Dep't of Com.*, 603 U.S. 369, 386 (2024). But "[c]ourts must exercise their independent judgment in deciding whether an agency has acted within its statutory authority, as the APA requires." *Id.* at 412. Under the APA, courts "need not" and "may not defer to an agency interpretation of the law simply because a statute is ambiguous." *Id.* at 413. Courts, using traditional tools of statutory construction, "must seek the 'single, best meaning' of a statute, not just permissible interpretations." *Pac. Gas and Elec. Co. v. FERC*, 113 F.4th 943, 949 (D.C. Cir. 2024) (quoting *Loper Bright*, 603 U.S. at 400). An agency's "policy concerns cannot override the text of a statutory provision." *Id.* at 950.

1. Infant Support Cushions Are Not Durable Infant or Toddler Products

CPSC's reliance on § 2056a, as authority for promulgating the Rule, fails for two reasons. *First*, the products regulated by the Rule, including the Snuggle Me Infant Lounger and Cover are not durable goods. *Second*, CPSC's prior contemporaneous interpretation of "durable" is inconsistent with CPSC's current interpretation, even though the statute's text has not changed.

The definition of "durable goods," and its variations, has remained consistent for several decades. *See*, *e.g.*, *Durable Goods*, BLACK'S LAW DICTIONARY (12th ed. 2024) ("Consumer goods that are designed to be used repeatedly over a long period; esp., large things (such as cars, televisions, and furniture) that most people do not buy often."); *Durable Goods*, BLACK'S LAW DICTIONARY (6th ed. 1990) ("Goods which have a reasonably long life and which are generally not consumed in use; *e.g.*, refrigerator."); *Durable Goods*, BLACK'S LAW DICTIONARY (5th ed. 1979) (same). The difference between durable goods and "nondurable goods," "soft goods," or "semidurable goods" is often expressed in terms of the product's perceived lifespan, typically longer than three years as the U.S. Department of Commerce has recognized. *See*, *e.g.*, 76 Fed. Reg. 70,228, 70,287 (Nov. 10, 2011) (collecting sources) (internal citations omitted). Despite having a useful product life of several years or more, a product's reusability has no bearing on whether it is a "durable product." *See* In the Matter of Christina C., CBCA 7750-RELO (July 27, 2023). Consequently, products like textiles and fabric items are not considered durable goods, even if they may be kept for longer than three years. *See* Robert Smith & Zoe Chace, *What Are Durable Goods, Anyway?*, Planet Money, NPR (Mar. 28, 2012, 9:57 AM ET), https://www.npr.org/sections/money/2012/03/28/149523535/what-are-durable-goods-anyway (noting that carpets are not durable goods even though consumers keep them for more than three years); *see also Nondurables*, MERRIAM-

WEBSTER.COM (last visited Mar. 12, 2025), https://www.merriam-webster.com/dictionary/nondurables ("consumer goods (such as textiles, food, clothing, petroleum, and chemical products) that are only able to be used for a relatively short time before deteriorating or that are consumed in a single usage").

In 2008, when Congress adopted CPSIA, the term "durable" was understood to mean a combination of useful product life *and* an ability to withstand significant deterioration over time. *See*, *e.g.*, *Durable Goods*, BLACK'S LAW DICTIONARY (8th ed. 2004) ("[c]onsumer goods that are designed to be used repeatedly over a long period, such as automobiles and personal computers"); *Durable Goods*, MERRIAM-WEBSTER'S ADVANCED LERNER'S ENGLISH DICTIONARY (2008) ("products (such as cars and stoves) that usually last a very long time"); *Consumer Durables*, OXFORD ENGLISH DICTIONARY (Sept. 2024), https://doi.org/10.1093/OED/6922242419 ("Consumer goods which are expected to have a relatively long useful life after purchase[.]").[3] While "durable" was left undefined in § 2056a, the non-exhaustive list of twelve products Congress included share the hallmarks of durable goods, *i.e.*, they are items generally constructed with wood, metal, or plastic. *See* 15 U.S.C. § 2056a (f).

In contrast, the Rule defines "infant support cushions" as any

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[3] This definition was "[o]riginally published as part of the entry for *consumer, n.*" and "was revised in September 2009[.]" *Id.*

> infant product that is filled with or comprised of resilient material such as foam, fibrous batting, or granular material or with a gel, liquid, or gas, and which is marketed, designed, or intended to support an infant's weight or any portion of an infant while reclining or in a supine, prone, or recumbent position.

89 Fed. Reg. at 87,487. It also "includes any removable covers, or slipcovers, sold on or together with an infant support cushion." *Id.* The Rule's definition of in-scope products unmistakably describes textiles. Take for example, the Snuggle Me Infant Lounger and Cover pictured below:

A9.

A13.

Both products are covered by the Rule. A14. The Snuggle Me Infant Lounger is constructed with organic cotton and filled with polyester fiber, and the Infant Lounger Cover is made with organic cotton. A5–6. Both are machine washable. *Id.* These products are intended for use for infants up to 1 year old, *i.e.*, the expected life of the product is up to 1 year. A5. They are nondurable textile products.

While the plain meaning of the statute controls, the Rule cannot be saved by CPSC's recent authority-arrogating interpretation of § 2056a(f) either, as it is neither contemporaneous with the CPSIA's enactment nor consistent over time. A year after CPSIA was adopted, CPSC informed its understanding of "durable" by looking to dictionary definitions of "durable goods" and how the term was understood "[i]n the economic or financial context[.]" 74 Fed. Reg. 30,983, 30,984 (June 29, 2009). It recognized that "clothing, blankets, and such textile products would not be

considered durable infant or toddler products" under the definitions they considered. *Id.* CPSC suggested that "[a]dditional guidance" on the term's meaning could be drawn from the twelve statutory categories. *Id.*; 74 Fed. Reg. 68,668 (Dec. 29, 2009). CPSC also recognized that the statutory definition left "uncertainty," and while "[m]any products may last three or more years … [that] does not necessarily mean that Congress intended them to be considered durable infant or toddler products under this section." 74 Fed. Reg. at 30,985. As recently as 2021, at least some members of the Commission—including now-Acting Chairman Peter Feldman—or its staff, still held the view that "textile products" are not durable goods. A130–31; A27–28.

Despite this contemporaneous and consistent interpretation of § 2056a, CPSC now claims it may regulate textile products that "are filled with cushy foam or soft fibrous batting, covered by flexible fabric" as durable goods. 89 Fed. Reg. at 87,469. It has done so without consulting the statutory product list for guidance and relying instead on factors that have no bearing on whether a product is "durable" within the term's ordinary meaning. *Id.* at 87,480; *but see* A28–29.

CPSC's classification of infant support cushions as durable infant or toddler products cannot overcome the plain meaning of "durable" or CPSC's prior contemporaneous interpretation of § 2056a(f). "[T]he basic nature and meaning of a statute does not change when an agency … has happened to offer its

interpretation[.]" *Loper Bright*, 603 U.S. at 408. And, if an "agency's consistently wrong interpretation cannot rewrite the statute's text to change its meaning[,]" *Missouri v. Trump*, 128 F.4th 979, 994 (8th Cir. 2025), then its inconsistent interpretation cannot either. Infant support cushions, including Snuggle Me Infant Loungers and Covers, are textiles. They are not "durable" products within the meaning of that term as understood in 2008, nor now. CPSC is without power to regulate them under § 2056a, so this Court should stay the Rule pending merits review.

2. CPSC Failed to Observe the Procedures Required by Law When It Promulgated the Rule Under § 2056a

Because CPSC erroneously determined that infant support cushions, including Snuggle Me Infant Loungers and Covers, are "durable," it conducted the rulemaking through the procedural processes outlined in § 2056a, rather than the more rigorous processes required by §§ 2056 and 2058. *See supra* pp. 2–6. CPSC's authority to proceed under option 1, §§ 2056 and 2058, versus option 2, § 2056a, turns on whether the products being regulated are "durable." *Cf. Am. Hosp. Ass'n v. Becerra*, 596 U.S. 724, 735 (2022). CPSC can only exercise option 2 if the products are "durable infant or toddler products." Otherwise, it must regulate, if at all, under option 1. If CPSC chose the wrong process—and it did—then the Rule is unlawful.

CPSA "protects" regulated entities, like Heroes Technology, "by imposing an important procedural prerequisite" before CPSC can promulgate product safety

standards and, under § 2056a, impose mandatory consumer registration and recordkeeping requirements. *Id.* The text and structure of CPSA support the argument that infant support cushions were incorrectly classified as durable products and regulated pursuant to the wrong statutory provision. The question is not whether Heroes Technology's products can be regulated, but how Congress authorized CPSC to regulate them. *See* A31. Here CPSC chose the wrong option and, by doing so, "acted unlawfully" by denying the Company, and other infant support cushion manufacturers, the benefit of §§ 2056 and 2058's more thorough procedural protections. *Cf. Am. Hosp. Ass'n*, 596 U.S. at 736 ("Because HHS did not conduct a survey of hospitals' acquisition costs, HHS acted unlawfully by reducing the reimbursement rates for [certain] hospitals").

B. The Rule Is Arbitrary, Capricious, and Not in Accordance with Law

The Rule also violates the APA's command against arbitrary and capricious agency action. 5 U.S.C. § 706(2)(A). Under the APA, an agency's actions must "be reasonable and reasonably explained." *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021). Agency actions may be reversed or vacated "if the agency has 'entirely failed to consider an important aspect of the problem' or has 'offered an explanation for its decision that runs counter to the evidence before the agency.'" *Saad v. SEC*, 718 F.3d 904, 910–11 (D.C. Cir. 2013) (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

CPSC's 180-day effective date does not reflect "reasoned decisionmaking[.]" Several commentors, including Heroes Technology, raised substantial concerns about manufacturers' ability to adjust to redesign of their products and successfully apply novel and ill-defined testing methods. 89 Fed. Reg. at 87,480; A80–82; A98–100. As the Juvenile Products Manufacturers Association ("JPMA") noted, the Rule "necessitate[s] extensive product redesign and registration card requirements" and noted that in the past CPSC determined that such concerns justified longer effective dates. A138–39.[4] Heroes Technology raised similar concerns, specifically noting that the Rule would necessitate substantial changes to its products not just in terms of redesign and testing, but also in its supply chain and marketing practices. A83; A98–100. Heroes Technology indicated that it required additional time to conduct "the appropriate human factor testing to ensure [it is] producing the safest product possible." A99.

In response to those concerns, CPSC only stated that commentators did not "provide any specific data or information showing that the level of effort to redesign and distribute" compliant in-scope products and concluded that "the rule provides a reasonable effective date that takes into consideration manufacturers burdens and the risk of continued infant injuries and deaths." 89 Fed. Reg. at 87,480. But there is

[4] The Company is a member of JPMA and supported the organization's comments. A79.

no data supporting CPSC's perceived sense of "urgency" beyond the fact that incidents have occurred in the past, with the most recent data being from 2022. *Id.* at 87,470. Nor is there data establishing that the Rule will reduce risks in the future. Nor does it account for risk reduction resulting from CPSC's Infant Sleep Product Rule, 86 Fed. Reg. 33,022, 33,052 (June 23, 2021) (effective June 23, 2022). As Heroes Technology highlighted, the Rule may have the opposite effect on safety and push consumers—who no longer have access to their preferred product choices—to substitute regrettable alternatives in their absence, which may cause increased risk of harm to infants. A95–96.

The Rule suffers from additional infirmities, reinforcing the need for a stay. *First*, the scope of the Rule is incompatible with reasoned decisionmaking. The Rule covers a non-exhaustive list of twelve exemplary product categories (and an estimated 2,000 products currently on the market), each of which serves different consumer needs and is designed for different uses. Instead of regulating these products through the voluntary standards process, CPSC grouped all products that are "filled with cushy foam or soft fibrous batting" and "covered by flexible fabric," 89 Fed. Reg. at 87,469, into a single category and devised one-size-fits-all testing for products which serve different purposes, as reflected in their design and construction. CPSC failed to consider these differences in promulgating the Rule.

Second, CPSC's tests and performance standards are not supported by the record. The novel tests developed to support the Rule make little sense when applied to in-scope products like Snuggle Me Infant Loungers, which are designed and constructed in a way that renders the required tests impracticable or leaves companies to do guesswork to identify placement for the test probe. A88–92. That guesswork, if CPSC later decides a company's placement determination was wrong, opens companies to liability despite the Rule's undefined and vague requirements. A81; A89. Likewise, the firmness test methods are not standardized, and the record lacks any data supporting the replicability of the test methods. A91–92.

Finally, CPSC does not address that the Rule may have the opposite effect than it intends—that it may decrease infant safety. The lower sidewall height is not supported by the record and may lead to more infants rolling out or off in-scope products. A92–95; A104–128. It may also lead to the use of blankets, pillows, and other soft materials—which present known asphyxiation hazards—around in-scope products. A93; A95–96. CPSC studied neither of these foreseeable consequences and cannot reasonably explain how the Rule increases infant safety without doing so.

C. The Rule Conflicts with Executive Orders 14,215 and 14,219

The Rule also conflicts with two recently issued executive orders. Heroes Technology raised the Rule's incompatibility with both executive orders, but CPSC rejected these concerns without comment or analysis. A19–21; A15.

Executive Order 14,215, establishes a policy "to ensure Presidential supervision and control of the entire executive branch[,]" including independent agencies, and sets out various steps independent agencies must take when promulgating rules, including review by the Office of Information and Regulatory Affairs. *See* 90 Fed. Reg. 10,447 (Feb. 24, 2025). Executive Order 14,219 establishes a policy that focuses "enforcement resources on regulations squarely authorized by constitutional Federal statutes[.]" *See* 90 Fed. Reg. 10,583 (Feb. 25, 2025). It also requires agencies to "initiate a process to review all regulations subject to their sole or joint jurisdiction for consistency with law and Administration policy" and identify certain "classes of regulations[.]" *Id.* As relevant here: (1) "regulations that are based on anything other than the best reading of the underlying statutory authority or prohibition;" (2) "regulations that impose significant costs upon private parties that are not outweighed by public benefits;" and, (3) "regulations that impose undue burdens on small business and impede private enterprise and entrepreneurship." *Id.*

CPSC has not indicated that the Rule has gone through the required reviews and consultative processes set out in the new executive orders. A stay of the Rule is warranted to allow those reviews to occur.

II. A STAY IS NECESSARY TO PREVENT IRREPARABLE HARM TO HEROES TECHNOLOGY

Without a stay, Heroes Technology will continue to suffer irreparable harm. The Rule poses an existential threat to Heroes Technology that dramatically affects its operations and staffing. A9–10. The Rule may cause it to cease sales of its marquee product, more than a million of which have been sold since the company was formed in 2007, accounting for the bulk of its revenue. A4–6; A9–10.

Heroes Technology has incurred costs to redesign and test its products to ensure compliance with the Rule. A11. The Company has had to balance compliance with the Rule while also providing a safe, useful, and affordable product that consumers want. A10. Despite its best efforts, Heroes Technology is not prepared to launch its new product by the Rule's May 5 effective date. A11. It estimates that it may take several months until the product can be brought to market. *Id.*

As it warned CPSC in its comment, Heroes Technology incurred significantly higher compliance costs than CPSC estimated. *Compare* A11 *with* 89 Fed. Reg. at 87,489 (estimating "total first year costs of redesign" to be about $16,000). Thus far, Heroes Technology has spent over $97,000 in new direct costs to comply with the Rule. A11. For example, the Company has spent over $43,00 in direct testing,

design, and sampling material costs, and its testing processes are not yet complete. *Id.* The Rule has also caused Heroes Technology to incur significant costs to create new warnings, instructions, and safety collaterals, as well as website and other marketing changes. *Id.* The Company will also lose the goodwill it has accumulated through ratings of its Snuggle Me Infant Lounger. A12. These costs are all related to the development of a single compliant model. A11. Heroes Technology will also be required to change its existing voluntary product registration processes to comply with those set by CPSC. A6–8; A11. As a result of the Rule, a significant portion of Heroes Technology's employees have been allocated to dealing with the effect of the Rule, rather than their sales, client relations, operations, product improvement, and other business roles. To date, Heroes Technology estimates that it has spent over 5,770 hours of professional staff time to comply with the Rule. A11; *compare with* 89 Fed. Reg. at 87,486 (estimating "effort required for a one-time redesign of a product … to be 200 hours of professional staff time"). That estimate is for a single compliant model. A11.

Typically, financial harm, including economic loss, does not constitute irreparable harm. *In re NTE Conn.*, 26 F.4th at 990. However, this Court "has recognized that financial injury can be irreparable where no adequate compensatory or other corrective relief will be available at a later date, in the ordinary course of litigation." *Id.* (cleaned up). As CPSC enjoys sovereign immunity for its actions,

there is no compensatory relief available for economic harms Heroes Technology is suffering because of the unlawful Rule. *See Everglades Harvesting & Hauling, Inc. v. Scalia*, 427 F. Supp. 3d 101, 115 (D.D.C. 2019) ("[W]here economic loss will be unrecoverable, such as in a case against a Government defendant where sovereign immunity will bar recovery, economic loss can be irreparable."). Heroes Technology's economic losses are irreparable harm that cannot be remedied if they succeed on the merits. A stay pending review stay is warranted.

III. THE BALANCE OF EQUITIES AND PUBLIC INTEREST SUPPORT A STAY

Postponing the Rule's effective date will not harm the public or CPSC. *First*, there "is generally no public interest in the perpetuation of unlawful agency action … [t]o the contrary, there is a substantial public interest 'in having governmental agencies abide by the federal laws that govern their existence and operations.'" *League of Women Voters of U.S. v. Newby*, 838 F.3d 1, 12 (D.C. Cir. 2016) (quoting *Washington v. Reno*, 35 F.3d 1093, 1103 (6th Cir. 1994)) (internal citation omitted). Heroes Technology has made a substantial showing that CPSC did not follow the law when it promulgated the Rule, and the public interest cannot lay in such an action.

Second, if the Rule is allowed to take effect, it will harm consumers and businesses. Consumers will face reduced product choices, higher costs, and lower product utility. A11–12. And businesses, including Heroes Technology, will suffer

significant economic harm to develop, redesign, and/or test in-scope products. A11. By CPSC's estimates, the infant support cushion market is large and supported by "[s]everal thousand manufacturers and importers, including hundreds of handcrafters and direct foreign shippers" most of whom are small businesses. 89 Fed. Reg. at 87,469. CPSC has admitted that the Rule may force many small businesses out of the market. *See* 89 Fed. Reg. 2,530, 2,542 (Jan. 16, 2024); *see also* A252–53 (noting that the Rule will place "significant" costs on small businesses).

CPSC has not established that a short stay will cause any risk of harm. While it believes the Rule is urgent, that view is based on years-old incident data that does not account for potential incident-rate reductions because of CPSC's Infant Sleep Product Rule. *See* 86 Fed. Reg. at 33,052. The Rule only applies to products manufactured after May 5, 2025, *see* 89 Fed. Reg. at 87,487, and manufacturers may sell through pre-Rule product stock even after the effective date. Hence, it is unlikely that a short stay, while this Court reviews the merits of the Petition, would cause any harm. Moreover, there is no data establishing that the Rule will reduce risks in the future.

CONCLUSION

This Court should stay the Rule pending review.

Respectfully submitted,

/s/ Kara M. Rollins
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CERTIFICATE OF COMPLIANCE

This motion complies with the type-volume limitation of Fed. R. App. P. 27(d)(2)(A) because it contains 5,196 words excluding the parts of the brief exempted by Fed. R. App. P. 27(a)(2)(B).

This brief complies with the typeface requirements of Rule 32(a)(5) and the type-style requirement of Rule 32(a)(6) because it was prepared in a proportionately spaced typeface using Microsoft Word in Times New Roman 14-point type for text and footnotes.

/s/ Kara M. Rollins
KARA M. ROLLINS

CERTIFICATE OF SERVICE

I hereby certify that on March 13, 2025, I filed the foregoing with the Clerk of Court for the United States Court of Appeals for the District of Columbia Circuit by using the CM/ECF system which will serve all counsel of record.

/s/ Kara M. Rollins
KARA M. ROLLINS

ADDENDUM

ADDENDUM TABLE OF CONTENTS

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

I. PARTIES AND *AMICI*

This case is a petition is a review of final agency action. There were no district court proceedings in this matter. Petitioner is Heroes Technology (US) LLC d/b/a Snuggle Me Organic. Respondent is the United States Consumer Product Safety Commission. To date, there are no parties who have appeared as *amici*.

See Circuit Rule 26.1 disclosure form included above.

II. RULING UNDER REVIEW

Petitioner seeks review of the Consumer Product Safety Commission's final rule entitled Safety Standard for Infant Support Cushions, 89 Fed. Reg. 87,467 (Nov. 4, 2024) (the "Rule").

III. RELATED CASES

The Rule has not previously been before this Court or any other court. Pursuant to Federal Rule of Appellate Procedure 15 and 15 U.S.C. §§ 2056a(b)(3), 2060(g), the deadline for filing petitions seeking review of the Rule was January 3, 2025. To Petitioner's knowledge, no other petitions for review of the Rule have been filed.

EXHIBIT 1

No. 25-1003

In the United States Court of Appeals for the District of Columbia Circuit

HEROES TECHNOLOGY (US) LLC d/b/a SNUGGLE ME ORGANIC,
Petitioner,

v.

UNITED STATES CONSUMER PRODUCT SAFETY COMMISSION,
Respondent.

DECLARATION OF GIANCARLO BRUNI

I, Giancarlo Bruni, hereby declare:

1. Heroes Technology (US) LLC d/b/a Snuggle Me Organic ("Heroes Technology" or the "Company")) is a for-profit, limited liability company organized under the laws of Delaware. Based in White Bear Lake, Minnesota, it designs, manufactures, and sells the Snuggle Me Infant Lounger.

2. I am employed by Heroes Technology Ltd ("HTL") as CFO and I am also a co-founder of HTL. HTL is the parent company of Heroes Technology. I have held this position since 2020. In my role as CFO and co-founder, I regularly consult

with Heroes Technology's design and development, product testing, marketing and sales teams.

3. This declaration has four parts. Part I provides an overview of Heroes Technology and the Snuggle Me Infant Lounger. Part II summarizes the Company's existing compliance and voluntary registration processes. Part III provides an overview of the development of a voluntary standard for infant loungers. Part IV discusses the Company's ongoing efforts to comply with the Infant Support Cushion Rule and explains the irreparable harms that Heroes Technology will suffer because of the Rule.

I. Overview of Heroes Technology's Business and the Snuggle Me Lounger

4. The Snuggle Me Infant Lounger got its start, like many great ideas, with a need—providing place for infants to find comfort when a parent's or caregiver's hands were full.

5. The first lounger was developed by a stay-at-home mom of seven, who made the loungers at her kitchen table.

6. The Company got its start when she began selling the loungers at craft fairs, and finding success there and market need, decided to turn Snuggle Me into a full-time family business.

7. Over 1 million Snuggle Me loungers have been sold since the first one was made 17 years ago.

8. Snuggle Me Infant Loungers are intended for use by infants up to 1 year while engaged awake.[1] The Lounger is "uniquely designed to hug [a] baby's body and create a cozy space to play." It has an unpadded, suspended center sling, which can gently hold an infant in the supine position.

9. An image of a Snuggle Me Infant Lounger is below:

10. Snuggle Me Infant Loungers are made of organic cotton and filled with polyester fiber.

11. Snuggle Me Infant Loungers are machine washable.

[1] https://snugglemeorganic.com/collections/snuggle-me-organic-infant/products/infant-lounger-moss (last visited Mar. 10, 2025).

12. Lounger covers are sold separately.[2] They are designed to fit the product and protect the lounger from spills and leaks. The Infant Lounger Covers are made with 100% organic cotton and are machine washable.

13. An image of the Snuggle Me Infant Lounger Cover is below:

14. On information and belief, both the Snuggle Me Infant Lounger and Lounger Cover fall within the scope of the Infant Support Cushion Rule.

II. Summary of Heroes Technology's Safety, Compliance, and Voluntary Registration Processes

15. The Company has worked tirelessly to stay at the forefront of safety and compliance.

[2] https://snugglemeorganic.com/collections/accessories/products/infant-lounger-cover-moss (last visited Mar. 10, 2025).

16. Since last year, before the Infant Support Cushion Rule mandated it, the Company implemented a voluntary registration process and included registration cards with its products, including the Snuggle Me Infant Lounger.

17. The Company regularly works with its retail partners, including the smallest ones, to make sure they have the most up-to-date safety information on their websites.

18. The Company also provides a QR code with its products and an easy-to-understand landing page that gives parents and caregivers three ways to register their products.[3]

19. The Company has also added a QR code to the packaging for Snuggle Me Infant Loungers so that parents and gift givers can watch its safety video before purchasing or opening its product.[4]

20. All the Company's safety information is also included in the product's User Guide and on its website.[5]

21. The Safety Guidelines website clearly states that

[3] https://snugglemeorganic.com/pages/product-registration?nbt=nb%3Aadwords%3Ax%3A18623326962%3A%3A&nb_adtype=&nb_kwd=&nb_ti=&nb_mi=&nb_pc=&nb_pi=&nb_ppi=&nb_placement=&nb_si={sourceid}&nb_li_ms=&nb_lp_ms=&nb_fii=&nb_ap=&nb_mt=&gad_source=1&gclid=EAIaIQobChMIsNvTuYOAjAMVq2NHAR1pMR9lEAAYASAAEgLUzfD_BwE (last visited Mar. 12, 2025).
[4] https://youtu.be/_RqFp_t7aT8 (last visited Mar. 12, 2025).
[5] https://snugglemeorganic.com/pages/safety (last visited Mar. 12, 2025).

> Snuggle Me products are non-sleep products. They are not designed, marketed or intended for sleep. Sleep includes short naps, cosleeping, and supervised sleep. If a baby falls asleep in a non-sleep product, they should be moved to a safe sleep location immediately. A firm, flat surface (crib or bassinet) is the safest place, and the only place, where infants should be sleeping.

22. The Company's information also provides recommendations for safe use of the Snuggle Me Infant Lounger, a "Safety Checklist," and information about safe infant sleep and safe sleep environments.

23. The Safety Guidelines website also provides a copy of the warning label included on the Snuggle Me Infant Lounger, an image of that label is below:

III. Voluntary Standard for Infant Loungers

24. Heroes Technology by and through its employees has participated in the development of a voluntary product safety standard for infant loungers through ASTM's Infant Loungers Subcommittee. The Company has actively participated in those subcommittee groups both online and in-person for the last three years.

25. While the process was tense at times and parties represented conflicting viewpoints. Heroes Technology participated because it believes that working towards a voluntary safety standard for infant loungers was, and is still, needed.

26. In an October 2024 meeting of the Subcommittee the CPSC submitted a "negative" regarding the draft voluntary standard and asked the Subcommittee to instead match the standard included in the Infant Support Cushion Rule. At that meeting, the Company, as well as others, voiced their concerns with CPSC's request and the standard included in the Infant Support Cushion Rule.

27. Heroes Technology was left with the impression that the CPSC would not approve a voluntary infant lounger standard unless it matched the Infant Support Cushion Rule and that the Commission had no intention to work through the voluntary standards process.

28. The Subcommittee has since voted to discontinue its work.

IV. Compliance with and Irreparable Harms from the Infant Support Cushion Rule

29. The CPSC's Rule will go into effect on May 5, 2025. The Rule imposes immediate and significant, if not existential, harms on Heroes Technology's business. Heroes Technology will be forced to cease production of its marquee product, the Snuggle Me Infant Lounger.

30. Based on current stock and monthly sales, Heroes Technology estimates that it will sell through its pre-Rule Snuggle Me Loungers by the end of 2025, if not sooner.

31. The Company's Snuggle Me Infant Lounger is its marquee product, sales of the Infant Lounger and its Cover accounts for a significant majority of its revenue.

32. The anticipated revenue losses may impact the Company's ability to retain its employees or operate at all.

33. Heroes Technology is also attempting to develop a product that complies with the Rule. This process requires not just CPSC-mandated testing, but additional product research, development, and testing to ensure that a Rule-compliant product is safe, useful, and an affordable product that consumers want.

34. Prior to commenting on the Proposed Rule, Heroes Technology designed and tested a prototype product that attempted to comply with the proposed rule's requirements, including sidewall height. That testing suggested that changing the design of the Snuggle Me Lounger would increase the possibility of infants rolling off of or out of the product, thereby reducing its safety. As that experience shows, complying with a rule's standards and developing a product that is safe or safer than those currently on the market are separate endeavors.

35. To date, Heroes Technology has spent over $97,000 in direct costs to comply with the Rule.

36. To date, these costs include (but are not limited to):

a. Testing costs, which cost at least $7,400.

b. Product design costs, which cost at least $21,000.

c. Legal review and compliance costs, which cost at least $45,000.

d. Sampling and material costs of at least $14,700.

e. Costly changes to mandated registration processes.

f. Over 5,770 hours of professional staff time that has been spent on complying with the Rule.

37. Heroes Technology's processes are not yet completed, and it anticipates incurring further development, compliance, and other costs in the coming months. These costs are all related to the development of a single compliant product model.

38. The process of bringing a new product to market typically takes over a year. And despite Heroes Technology's best efforts, it does not anticipate having a compliant product tested, manufactured, and available for sale for several months.

39. Complying with the Rule also harms Heroes Technology's relationships with its consumers. Consumers purchase Snuggle Me Loungers because they want the product's unique design features. However, under the Rule, as the Company's

efforts have shown, it is not possible to make a compliant product that retains those features.

40. Snuggle Me Infant Loungers are highly sought after and highly rated by parents and caregivers. For example, on Babylist, a popular universal registry provider and retailer, the Snuggle Me Infant Lounger has an average rating of 4.7 out of 5 based on over 1,200 ratings.[6] On Target, the Snuggle Me Infant Lounger has an average rating of 4.9 out of 5 stars based on almost 3,000 reviews, and it has over 2,400 5-star reviews.[7]

41. If Heroes Technology must sell a new product to comply with the Rule, that product will have to start from scratch and will not have the benefit of the years of positive reviews the Snuggle Me Infant Lounger earned.

42. Complying with the Rule also harms Heroes Technology's relationships with its retailers.

43. The Snuggle Me Infant Lounger has been sold through online retailers, big box stores, and boutiques around the country. The Company has developed significant goodwill with its retail partners for providing a highly sought-after

[6] https://www.babylist.com/gp/snuggle-me-organic-infant-lounger/20182/2095801 (last visited Mar. 12, 2025).
[7] https://www.target.com/p/snuggle-me-organic-lounger-natural/-/A-79610426#Reviews (last visited Mar. 12, 2025).

product. Heroes Technology's business-to-business relationships have and will continue to suffer because of the Rule.

44. Although the Rule's effective date is not until May 5, 2025, the Company's relationships are already significantly affected as retailers do not want to purchase products that imminently at risk of non-compliance, scrutiny, and will not continue to be on their shelves in the future, as they would prefer to focus on products that would be sold going forward rather than a "clearance" type item.

45. Insurers place greater scrutiny on products that are soon to be deemed non-compliant as this increases a product's perceived risk profile, in this circumstance, unjustifiably in Heroes Technology's opinion. Heroes Technology will therefore suffer further harm either by way of non-renewal and lacking coverage, or unjustified premium increases.

Pursuant to 28 U.S.C. § 1746(1), I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 12 day of March 2025.

Giancarlo Bruni

EXHIBIT 2

UNITED STATES OF AMERICA CONSUMER
PRODUCT SAFETY COMMISSION

In the Matter of	)
Heroes Technology (US) LLC d/b/a Snuggle Me Organic	)

ORDER DENYING REQUEST TO STAY OR POSTPONE THE EFFECTIVE DATE OF THE SAFETY STANDARD FOR INFANT SUPPORT CUSHIONS

On February 6, 2025 counsel for Heroes Technology (US) LLC d/b/a Snuggle Me Organic ("Heroes Technology") submitted a request to the Commission to postpone the effective date of the Safety Standard for Infant Support Cushions. On February 20, 2025 counsel for Hereos Technology supplemented the request.

WHEREAS the Commission has reviewed and considered Heroes Technology's request,

IT IS HEREBY ORDERED THAT Heroes Technology's request for a stay or postponement of the effective date of the Safety Standard for Infant Support Cushions is DENIED. CPSC staff is directed to notify Heroes Technology of the Commission's decision.

SO ORDERED this 6th day of March, 2025.

BY THE COMMISSION,

Alberta E. Mills
Secretary
Consumer Product Safety Commission

EXHIBIT 3

United States
Consumer Product Safety Commission

Record of Commission Action
Commissioners Voting by Ballot*

Commissioners Voting: Acting Chairman Feldman
Commissioner Alexander Hoehn-Saric
Commissioner Richard Trumka Jr.
Commissioner Mary T. Boyle
Commissioner Douglas Dziak

ITEM:

Request by Heroes Technology (US) LLC d/b/a Snuggle Me Organic to Postpone the Effective Date of Infant Support Cushions Rule

(Ballot vote package dated February 26, 2025, OS No. 0359A)

DECISION:

The Commission voted unanimously (5-0) to deny Heroes Technology's Request and direct the Secretary to notify Heroes Technology of the Commission's decision by issuing the draft Order denying the request.

For the Commission:

Alberta E. Mills

Alberta Mills
Secretary

*Ballot vote due March 5, 2025.

Acting Chairman Feldman voted on March 5, 2025
Commissioner Hoehn-Saric voted on March 5, 2025
Commissioner Trumka voted on March 5, 2025
Commissioner Boyle voted on March 5, 2025
Commissioner Dziak voted on March 5, 2025

EXHIBIT 4

New Civil Liberties Alliance

February 20, 2025

VIA EMAIL

Alberta E. Mills
Secretary of the Commission
U.S. Consumer Product Safety Commission
4330 East West Highway
Washington, DC 20207
AMills@cpsc.gov

Re: **Supplemental Request to Postpone the Effective Date of *Safety Standard for Infant Support Cushions*, 89 Fed. Reg. 87,467 (Nov. 4, 2024)**

Dear Secretary Mills,

On February 6, 2025, Heroes Technology (US) LLC d/b/a Snuggle Me Organic ("Heroes Technology") wrote to the U.S. Consumer Product Safety Commission's ("CPSC") requesting that the Commission stay the effective date of its rule entitled *Safety Standard for Infant Support Cushions*, 89 Fed. Reg. 87,467 (Nov. 4, 2024) (the "Rule"). Since submitting its request, President Trump has issued two Executive Orders that Heroes Technology believes bear on the Commission's consideration of its stay request.

First, on February 18, 2025, President Trump issued an Executive Order entitled *Ensuring Accountability for All Agencies*.[1] This Executive Order reflects the President's understanding that "[t]he Constitution vests all executive power in the President and charges him with faithfully executing the laws" and that "independent" regulatory agencies like the CPSC "exercise substantial executive authority without sufficient accountability to the President" and ultimately "to the American people."[2] In furtherance of that understanding, the President established that "it shall be the policy of the executive branch to ensure Presidential supervision and control of the

[1] https://www.whitehouse.gov/presidential-actions/2025/02/ensuring-accountability-for-all-agencies/.

[2] *Id.* at § 1.

entire executive branch."[3] Critically here, Section 7 of the Executive Order restricts the Commission from "advance[ing] an interpretation of the law as the position of the United States that contravenes the President or the Attorney General's opinion on a matter of law, including but not limited to the issuance of regulations, guidance, and positions advanced in litigation, unless authorized to do so by the President or in writing by the Attorney General."[4] Given that the Rule was promulgated before the President took office, no review of it occurred for consistency with the President's interpretation. As discussed in its initial letter, the Rule relies on the Commission's interpretation of 15 U.S.C. § 2056a. Thus, the *Ensuring Accountability for All Agencies* Executive Order provides additional basis for postponing the Rule's effective date, so that the Rule may be reviewed in conformity with the Executive Order.

Second, on February 20, 2025, President Trump issued an Executive Order entitled *Ensuring Lawful Governance and Implementing the President's "Department of Government Efficiency" Deregulatory Initiative*.[5] This Executive Order establishes that it is the policy of the Trump Administration "to focus the executive branch's limited enforcement resources on regulations squarely authorized by constitutional Federal statutes, and to commence the deconstruction of the overbearing and burdensome administrative state."[6] Pursuant to this Executive Order, agencies must "initiate a process to review all regulations subject to their sole or joint jurisdiction for consistency with law and Administration policy."[7] They are required to identify certain classes of regulations in consultation with the Attorney General.[8] As evidenced in its initial request, Heroes Technology believes that the Rule implicates three classes identified in the Executive Order: (1) "regulations that are based on anything other than the best reading of the underlying statutory authority or prohibition[;]" (2) "regulations that impose significant costs upon private parties that are not outweighed by public benefits[;]" and, (3) "regulations that impose undue burdens on small business and impede private enterprise and entrepreneurship."[9] The Rule should be postponed so that the required review and consultation with the Director of the Office of Management and Budget, Administrator of the Office of Information and Regulatory Affairs, and the Attorney General may occur.

* * *

[3] *Id.*
[4] *Id.* at § 1.
[5] https://www.whitehouse.gov/presidential-actions/2025/02/ensuring-lawful-governance-and-implementing-the-presidents-department-of-government-efficiency-regulatory-initiative/.
[6] *Id.* at § 1.
[7] *Id.* at § 2.
[8] *Id.*
[9] *Id.*

For the foregoing additional reasons, Heroes Technology requests that the CPSC stay the Rule's May 5, 2025 effective date.

Respectfully,

/s/ Kara M. Rollins
KARA MCKENNA ROLLINS*
Litigation Counsel
JOHN J. VECCHIONE
Senior Litigation Counsel
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Counsel for Heroes Technology (US) LLC d/b/a Snuggle Me Organic

** Not licensed in Virginia; admitted to practice in New Jersey, New York, D.C., and select federal jurisdictions*

CC:

Kelsey Fraser via email (kelsey.g.fraser@usdoj.gov)
Gerard Sinzdak via email (gerard.j.sinzdak@usdoj.gov)

EXHIBIT 5

New Civil Liberties Alliance

February 6, 2025

VIA EMAIL

Alberta E. Mills
Secretary of the Commission
U.S. Consumer Product Safety Commission
4330 East West Highway
Washington, DC 20207
AMills@cpsc.gov

Re: **Request to Postpone the Effective Date of *Safety Standard for Infant Support Cushions*, 89 Fed. Reg. 87,467 (Nov. 4, 2024)**

Dear Secretary Mills,

Heroes Technology (US) LLC d/b/a Snuggle Me Organic ("Heroes Technology") has petitioned the D.C. Circuit for judicial review of the U.S. Consumer Product Safety Commission's ("CPSC") *Safety Standard for Infant Support Cushions*, 89 Fed. Reg. 87,467 (Nov. 4, 2024) (the "Rule"). Pursuant to 5 U.S.C. § 705 and Federal Rule of Appellate Procedure 18(a)(1), Heroes Technology requests that the CPSC stay the effective date of the Rule, which establishes an arbitrary and ineffective safety standard, including testing requirements, for infant support cushions, and amends certain registration and notice requirements to apply to such products. *See* 89 Fed. Reg. 87,467.

In the alternative, Heroes Technology requests postponement and reconsideration of the rule pursuant to President Trump's *Regulatory Freeze Pending Review* Executive Memorandum.[1]

Please respond to this request by February 28, 2025, so that Heroes Technology may seek a stay from the D.C. Circuit if necessary.

[1] 90 Fed. Reg. 8,249 (Jan. 28, 2025) (issued on Jan. 20, 2025).

ARGUMENT

Heroes Technology designs, manufactures, and sells the Snuggle Me Infant Lounger. The lounger is unlike any other product on the market.[2] It has an unpadded, suspended center sling, which can gently hold an infant in the supine position.[3] The loungers are made of organic cotton and filled with polyester fiber.[4] They are machine washable.[5] For all intents and purposes Snuggle Me Loungers are textiles, which are not considered durable goods. Yet, despite this fact, the Commission's in-scope product description and examples provided in the Rule likely include products like the Snuggle Me Infant Lounger and similar soft products that have by long agency practice and interpretation been considered nondurable goods.

Under 5 U.S.C. § 705, the Commission is permitted to "postpone the effective date of action taken by it, pending judicial review" if it finds that "justice so requires[.]" In considering a request under section 705, agencies consider the same requirements that apply to motions for stay pending appeal before the courts.[6] Those familiar factors require the agency to consider "(1) whether the stay applicant has made a strong showing that [it] is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies."[7]

Heroes Technology easily makes that showing here and the Commission should postpone the effective date of the Rule while the petition for review is pending.

I. HEROES TECHNOLOGY IS LIKELY TO PREVAIL ON THE MERITS

A. The CPSC Exceeded Its Statutory Authority and, in Doing so, Conducted This Rulemaking Without the Procedures Required by Law

The Administrative Procedure Act ("APA") provides for review of "final" agency actions, 5 U.S.C. § 704, and requires courts to "hold unlawful and set aside agency action … found to be ... in excess of statutory jurisdiction, authority, or limitations, or short of statutory right" or "without observance of procedure required by law[.]"[8]

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[2] Letter from Alessio Bruni to Alberta Mills at 5 (Mar. 18, 2024), https://www.regulations.gov/comment/CPSC-2023-0047-0017.

[3] *Id.*

[4] https://snugglemeorganic.com/collections/snuggle-me-organic-infant/products/infant-lounger-natural.

[5] *Id.*

[6] *Sierra Club v. Jackson*, 833 F. Supp. 2d 11, 29–30 (D.D.C. 2012) ("[T]he standard for a stay at the agency level is the same as the standard for a stay of agency action by a court.").

[7] *In re NTE Connecticut, LLC*, 26 F.4th 980, 987–88 (D.C. Cir. 2022) (quoting *Nken v. Holder*, 556 U.S. 418, 434 (2009) (cleaned up)).

[8] 5 U.S.C. § 706(2)(C), (D).

CPSC, like all administrative agencies, is a "creature[] of statute."[9] CPSC "accordingly possess[es] only the authority that Congress has provided."[10] The Commission's "powers can be decided only by considering the powers Congress specifically granted it in the light of the statutory language and background."[11] CPSC "literally has no power to act … unless and until Congress confers power upon it."[12] Thus, "[t]he question to be answered is 'not what the [Commission] thinks it should do but what Congress has said it can do.'"[13]

1. Infant Support Cushions Are Not Durable Infant or Toddler Products

The contours of the CPSC's powers are determined by statute, for infant and toddler products usually 15 U.S.C. §§ 2056 and 2058, or § 2056a.[14] As to certain infant or toddler products, Congress has said that CPSC may regulate under § 2056a if the products are "durable product[s] intended for use, or that may be reasonably expected to be used, by children under the age of 5 years[.]"[15] "Durable product" is not defined in the statute. The critical question then is: what is a "durable product" for purposes of § 2056a?

To determine the scope of the CPSC's authority, courts "must begin with the words of the statute creating the Commission and delineating its powers."[16] And they "must interpret statutory language, unless otherwise defined, 'in accord with the ordinary public meaning of its terms at the time of its enactment.'"[17] An agency's interpretation that "was issued roughly contemporaneously with enactment of the statute and remained consistent over time" may serve as an "interpretative aid[.]"[18] But "[c]ourts must exercise their independent judgment in deciding whether an agency has acted within its statutory authority, as the APA requires."[19]And "courts need not and under the APA may not defer to an agency interpretation of the law simply because a statute is ambiguous."[20]

A "durable product," often referred to as a "durable good," "durables," or "hard goods," are **"**[c]onsumer goods that are designed to be used repeatedly over a long period; esp., large things

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[9] *NFIB v. OSHA*, 595 U.S. 109, 117 (2022).
[10] *Id.*
[11] *Nat'l Petroleum Refiners Ass'n v. FTC.*, 482 F.2d 672, 674 (D.C. Cir. 1973).
[12] *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986).
[13] *Nat'l Petroleum Refiners Ass'n.*, 482 F.2d at 674 (quoting *CAB v. Delta Air Lines*, 367 U.S. 316, 322 (1961)).
[14] While there are specific provisions governing how certain products are regulated, *e.g.*, toys, Snuggle Me believes that its products that fall within the scope of the Rule are not subject to those other provisions.
[15] 15 U.S.C. § 2056a(f).
[16] *Nat'l Petroleum Refiners Ass'n.*, 482 F.2d at 674; *see also Tanzin v. Tanvir*, 592 U.S. 43, 46 (2020) ("[Courts] start with the statutory text.").
[17] *Secular Student Alliance v. U.S. Dep't of Education*, No. CV 21-0169 (ABJ), 2025 WL 105843, at *5 (D.D.C. Jan. 15, 2025) (quoting *Bostock v. Clayton Cnty.*, 590 U.S. 644, 654 (2020))
[18] *Loper Bright Enters. v. Raimondo* and *Relentless v. Dep't of Com.*, 603 U.S. 369, 386 (2024).
[19] *Id.* at 412.
[20] *Id.* at 413.

(such as cars, televisions, and furniture) that most people do not buy often."[21] The definition of "durable goods," and its variations, has remained consistent over the course of several decades. A review of various dictionaries also shows that there is a consistent substantive understanding of the term. The Oxford English Dictionary defines "consumer durables" as "[c]onsumer goods which are expected to have a relatively long useful life after purchase[.]"[22] Merriam-Webster defines "durables" as "consumer goods (such as vehicles and household appliances) that are typically used repeatedly over a period of years[.]"[23] And the American Heritage Dictionary defines "durable" as "[a] good or product made to withstand repeated use over a relatively long period, usually several years or more[.]"[24]

Sometimes the difference between durable goods and "nondurable goods," "soft goods," or "semidurable goods" is expressed in terms of the product's perceived lifespan, typically longer than three years.[25] A product's reusability has no bearing on whether it is a "durable product."[26]

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[21] *Durable Goods*, Black's Law Dictionary (12th ed. 2024); *see also Durable Goods*, Black's Law Dictionary (8th ed. 2004) ("[c]onsumer goods that are designed to be used repeatedly over a long period, such as automobiles and personal computers"); *Durable Goods*, Black's Law Dictionary (6th ed. 1990) ("Goods which have a reasonably long life and which are generally not consumed in use; *e.g.* refrigerator."); *Durable Goods*, Black's Law Dictionary (5th ed. 1979) (same).

[22] *Consumer Durables*, Oxford English Dictionary (Sept. 2024), https://doi.org/10.1093/OED/6922242419 (definition was "[o]riginally published as part of the entry for *consumer, n.*" and "was revised in September 2009").

[23] *Durables*, Merriam-Webster.com (last accessed Feb. 6, 2025), https://www.merriam-webster.com/dictionary/durable%20goods; *see also Durable*, Merriam-Webster.com (last accessed Feb. 6, 2025), https://www.merriam-webster.com/dictionary/durable ("able to exist for a long time without significant deterioration in quality or value"); *see also Durable Goods*, Merriam-Webster's Advanced Lerner's English Dictionary (2008) ("products (such as cars or stoves) that usually last a very long time").

[24] *Durable*, American Heritage Dictionary of the English Language (5th Ed. 2022), https://ahdictionary.com/word/search.html?q=durable.

[25] *See* 76 Fed. Reg. 70,228, 70,287 (Nov. 10, 2011) (collecting sources) (internal citations omitted) ("The United States Department of Commerce uses a durability standard of 3 years for consumer durable goods for National Income and Accounts estimates. Furthermore, economics dictionaries, various encyclopedias, and economics textbooks define durable goods as goods that are expected to last longer than 3 years."); *see also* Environmental Protection Agency, *Frequent Questions regarding EPA's Facts and Figures about Materials, Waste and Recycling* (last accessed Feb. 4, 2025), https://www.epa.gov/facts-and-figures-about-materials-waste-and-recycling/frequent-questions-regarding-epas-facts-and#Difference ("Durable goods last three years or more" and "[n]ondurable goods generally last less than three years[.]"); *Durable goods*, Bureau of Economic Analysis, *Glossary* (last accessed Feb. 4, 2025), https://www.bea.gov/help/glossary?title_1=All&title=durable ("Tangible products that can be stored or inventoried and that have an average life of at least three years.").

[26] *See* In the Matter of Christina C., CBCA 7750-RELO, 23-1 BCA ¶ 38,397 (finding that a manufacturer's description of a product as "reusable" does not overcome the definition of "durable goods").

Consequently, certain products, like textiles and fabric items are not considered durable goods, even if they may be kept for longer than three years.[27]

Indeed, contemporaneous with § 2056a's adoption, the Commission's prior understanding of "durable" looked at both dictionary definitions of "durable goods" as well as how the term was understood "[i]n the economic or financial context[.]"[28] It recognized that "clothing, blankets, and such textile products would not be considered durable infant or toddler products" under the definitions they considered.[29] The Commission also suggested that "[a]dditional guidance" on the term's meaning could be drawn from the twelve statutory categories.[30] As the Commission noted, "[t]he statutory definition leaves uncertainty about which products would be considered durable infant or toddler products."[31] The Commission also recognized that while "[m]any products may last three or more years … does not necessarily mean that Congress intended them to be considered durable infant or toddler products under this section."[32] As recently as 2021, at least some members of the Commission, or its staff, still held the view that "textile products" were not considered durable goods.[33] For example, now-Acting Chair Peter A. Feldman questioned the viability of

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[27] *See* Robert Smith & Zoe Chace, *What Are Durable Goods, Anyway?*, Planet Money, NPR (Mar. 28, 2012 9:57 AM ET), https://www.npr.org/sections/money/2012/03/28/149523535/what-are-durable-goods-anyway (noting that carpets are not durable goods even though consumers keep them for more than three years); *see also Nondurables*, Merriam-Webster.com (last accessed Feb. 4, 2025), https://www.merriam-webster.com/dictionary/nondurables ("consumer goods (such as textiles, food, clothing, petroleum, and chemical products) that are only able to be used for a relatively short time before deteriorating or that are consumed in a single usage").

[28] *Requirements for Consumer Registration of Durable Infant or Toddler Products*, 74 Fed. Reg. 30,983, 30,984 (June 29, 2009).

[29] *Id.*

[30] *Id.*; 15 U.S.C. § 2056a(f)(2) (durable infant or toddler goods includes "(A) full-size cribs and nonfull-size cribs; (B) toddler beds; (C) high chairs, booster chairs, and hook-on chairs; (D) bath seats; (E) gates and other enclosures for confining a child; (F) play yards; (G) stationary activity centers; (H) infant carriers; (I) strollers; (J) walkers; (K) swings; and (L) bassinets and cradles."); *see also Requirements for Consumer Registration of Durable Infant or Toddler Products; Final Rule*, 74 Fed. Reg. 68,668 (Dec. 29, 2009).

[31] 74 Fed. Reg. at 30,985.

[32] *Id.*

[33] Letter from Comm'r Peter A. Feldman to Sen. Maria Cantwell and Roger Wicker (Apr. 28, 2021) (attached as Exhibit 1 to Letter from Samuel S. Sykes, II to the CPSC (Mar. 18, 2024)), https://www.regulations.gov/comment/CPSC-2023-0047-0014; *see also* Mem. from Gregory B. Rodgrs Assoc. Exec. Dir., Directorate for Economic Analysis, to Timothy Smith, Project Manager, Crib Bumper Project, Directorate for Engineering Sciences, at 26–30 (Sept. 9, 2016), https://www.cpsc.gov/s3fs-public/StaffResponsetotheRecordofCommissionActiononCribBumper.pdf.

regulating crib bumpers under § 2056a because they are "textiles."[34] As Commission Staff articulated in 2016:

> [C]rib bumpers probably would not be considered "durable products" by existing economic and commercial definitions. Bumpers, along with apparel and other textile consumer goods, generally are classified in government statistics as non-durable goods with a useful life of less than 3 years. Although bumpers might be passed down among infants and could last more than 3 years with light use or repair, the expected life of bumpers in regular use is likely to be less than 3 years. If crib bumpers are not "durable infant or toddler products," rulemaking under section 104 of the CPSIA is not a viable option.[35]

While the Commission has previously indicated that the term "durable goods" is "blurry at its edges"[36] this is not an "edge" case. In any event, "blurriness" does not permit the Commission to interpret the statute in such a way that it rewrites the English language, particularly when that interpretation bears on whether the Commission has acted within its statutory authority.

The Commission's classification of infant support cushions as durable infant or toddler products cannot overcome the plain meaning of "durable goods" or its prior contemporaneous understanding of § 2056a(f). The Rule describes in-scope products as "products that support an infant for lounging, meaning reclining in a supine, prone, or recumbent position."[37] It also recognized that "[m]ost infant support cushions currently on the market are filled with cushy foam or soft fibrous batting, covered by flexible fabric."[38] In other words, most infant support cushions on the market and the subject of the Rule are textiles. But textiles are not durable goods. Snuggle Me Loungers are undoubtedly textiles.

The Commission attempts to support its determination by noting several of its reasons for deciding that infant support cushions are durable infant or toddler products, including that they are (1) "not disposable; (2) "have a useful life of up to several years and are often used by multiple children in succession;" (3) "are similar to other soft durable infant and children's products such as crib mattresses and sling carriers[;]" (4) "are resold and widely available on secondary marketplaces[.]"[39] The Commission is wrong on each of these points and offers no explanation for why it now considers infant support cushions, which are textiles, to be durable infant or toddler products.

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[34] Mem. from Gregory B. Rodgers Assoc. Exec. Dir., Directorate for Economic Analysis, to Timothy Smith, Project Manager, Crib Bumper Project, Directorate for Engineering Sciences, at 27.

[35] *Id.*

[36] Mem. from Gregory B. Rodgers Assoc. Exec. Dir., Directorate for Economic Analysis, to Timothy Smith, Project Manager, Crib Bumper Project, Directorate for Engineering Sciences, Tab B at II (June 1, 2016).

[37] 89 Fed. Reg. at 87,469.

[38] *Id.*

[39] 89 Fed. Reg. at 87,480.

First, disposable products are not durable goods, but, as noted above, the fact that a product can be reused, or used by multiple children in succession, does not make a product a "durable good." Carpets and other textiles, like children's clothing, cloth diapers, and blankets, are reused, and sometimes used by multiple children in succession, but are not classified as "durable goods." *Second*, the useful life of a product is only one consideration in determining whether it is a durable good. Products that are used repeatedly over long periods of time without degrading are durable goods. Thus, it is the combination of useful life of the product and its ability to withstand significant deterioration that guides whether a product is durable. *Third*, that CPSC has determined that crib mattresses and sling carriers are "soft" durable infant or toddler products does that mean that infant support cushions are. The Commission's *ipse dixit* cannot overcome the plain and ordinary meaning of the statute. Moreover, that the Commission's classifications of those products were not challenged does not mean that the CPSC's interpretation was correct then, or applicable here. *Fourth*, the ability of a product to be resold or made available in a secondary marketplace has no bearing on whether it is a durable product. Again, if that were the case, children's clothing, cloth diapers, and blankets would all be "durable goods," but they are not because they are textiles.

Critically, the Commission did not reference § 2056a(f)(2)'s statutory product list for guidance, as it had previously done. The products in that list—adopted by Congress—tend to be made from hard and rigid materials like plastic, wood, and metal and/or fit into traditional categories of durable goods like furniture, *e.g.*, cribs, toddler beds, and high chairs.[40] In comparison, the Rule's in-scope products, like Snuggle Me Loungers, are textiles and have no analogous statutory product category. Nor does the Commission suggest that such exists. Instead, CPSC relies on its determinations that infant sling carriers and crib mattresses are "soft" durable infant and children's products—a category that is not prescribed by statute.[41] As to "infant slings[,]" the Commission determined that they are durable infant or toddler products because the products "are similar to infant or child carriers which are explicitly covered" by § 2056a(f)(2).[42] In 2022, nearly twelve years after § 2056a(f) was adopted, CPSC issued its Safety Standard for Crib Mattresses final rule.[43] In that rule, the Commission noted how crib mattresses are "similar to" and used "in conjunction with" with the products listed in § 2056a(f)(2).[44] But CPSC provides no such analysis here and provides no reason for disregarding its long-held interpretive methods.[45]

[40] *Cf.* Mem. from Gregory B. Rodgers Assoc. Exec. Dir., Directorate for Economic Analysis, to Timothy Smith, Project Manager, Crib Bumper Project, Directorate for Engineering Sciences, Tab B at II. ("CPSC staff has considered consumer product durability based, in part, on a product's metal, wood, or plastic content.").

[41] 89 Fed. Reg. at 87,480.

[42] 74 Fed. Reg. at 68,673.

[43] 87 Fed. Reg. 8,640 (Feb. 15, 2022).

[44] *Id.* at 8,641.

[45] Such interpretative methods, if contemporaneous with § 2056a's adoption and remaining consistent over time, would at best provide an interpretative aid. *See Loper Bright* and *Relentless*, 603 U.S. at 386. But the Commission appears to have abandoned such interpretive rationales.

2. By Proceeding under § 2056a the Commission Failed to Observe the Procedures Required by §§ 2056 and 2058

The Rule falters at the start. By CPSC's own description and examples of in-scope products, it is obvious that the products described are likely, if not exclusively, nondurable products more akin to textiles and soft goods than to cribs or other products provided for by statute. Certainly, that is the case for Snuggle Me Loungers.

Proceeding under § 2056 versus § 2056a requires an initial determination about the nature of the products to be regulated, *i.e.*, whether they are durable infant or toddler products. From there, the law's various procedural requirements flow. If a product is a durable infant or toddler product, the Commission may promulgate safety standards pursuant to § 2056a and require manufacturers of such products to follow the CPSC's consumer registration requirements. 15 U.S.C. § 2056a(b), (d), (f). If a product is not a durable infant or toddler product, then the Commission must follow the procedures set forth in §§ 2056 and 2058, which vary significantly from § 2056a's procedures.

Among other things, the § 2056 process requires the Commission to "rely upon voluntary consumer product safety standards[,]" rather than promulgating mandatory standards, "whenever compliance with such voluntary standards would eliminate or adequately reduce the risk of injury addressed and it is likely that there will be substantial compliance with such voluntary standards." 15 U.S.C. § 2056(b). Safety standards promulgated under § 2056 are subject to the procedural requirements set out in § 2058. Before the Commission can issue a mandatory safety standard under those sections it must first consider whether there is a voluntary standard, and if that voluntary standard eliminates or adequately reduces the risk of injury associated with the to-be-regulated product.[46] If a proposed rule is published, the Commission must provide a "preliminary regulatory analysis containing" certain information including a cost-benefit analysis, reasons why a voluntary standard would not be developed within a reasonable amount of time, and consideration of reasonable alternatives.[47] And before promulgating a final rule, the Commission must also make certain findings regarding, for example, the "degree and nature of the risk of injury the rule is designed to eliminate or reduce" and quantify how many products are affected.[48] The Commission may not promulgate a consumer product safety rule unless it makes a series of findings, including "the benefits expected from the rule bear a reasonable relationship to its costs" and "that the rule imposes the least burdensome requirement which prevents or adequately reduces the risk of injury for which the rule is being promulgated."[49]

In comparison, rulemaking pursuant to § 2056a requires none of these heightened rulemaking procedures.[50] Thus, when as here, the Commission incorrectly claims a product

[46] 15 U.S.C. § 2058(a), (b)
[47] 15 U.S.C. § 2058(c).
[48] 15 U.S.C. § 2058(f)(1).
[49] 15 U.S.C. § 2058(f)(3); *see also* 15 U.S.C. § 2058(f)(2) (requiring "a final regulatory analysis").
[50] *See* 15 U.S.C. § 2056a(b)(1)(B), 5 U.S.C. § 553; *see also* 89 Fed. Reg. at 87,480 (identifying analyses that "are not required" under § 2056a); 87 Fed. Reg. at 8,665 ("[T]he

category is a durable infant or toddler product, it bypasses the heightened procedural requirements of § 2058. In doing so, the Commission acted both "in excess of [its] statutory jurisdiction, authority, or limitations, or short of statutory right" and "without observance of procedure required by law."[51]

To be clear, it is not Heroes Technology's position that the in-scope products cannot be regulated, rather it is its view that the Commission has relied on the wrong statutory authority and rulemaking procedures to do so.

B. The Rule is Arbitrary, Capricious, and Not in Accordance with Law

Even if the Rule was properly promulgated under § 2056a, the Rule still violates the APA, which requires courts to "hold unlawful and set aside agency action … found to be ... arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law[.]"[52] Under the APA, an agency's actions must "be reasonable and reasonably explained."[53] "[A]n agency must 'articulate a satisfactory explanation for its action including a "rational connection between the facts found and the choice made."'"[54] And agency actions may be reversed or vacated "if the agency has 'entirely failed to consider an important aspect of the problem' or has 'offered an explanation for its decision that runs counter to the evidence before the agency.'"[55]

The Commission's 180-day effective date does not reflect "reasoned decisionmaking[.]" Three commentors, including Heroes Technology, raised substantial concerns about manufacturers' ability to adjust to redesign of their products and successfully apply novel and ill-defined testing methods.[56] As the Juvenile Products Manufacturers Association ("JPMA") noted, the Rule "necessitate[s] extensive product redesign and registration card requirements" and noted that in the past the CPSC determined that such concerns justified longer effective dates.[57] Heroes Technology raised similar concerns specifically noting that the Rule would necessitate substantial

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rulemaking procedure described in [§ 2058] … is inapplicable to rules issued under [§ 2056a]. Section [§ 2056a] contains a different rulemaking authority and different rulemaking procedures. For example, 15 U.S.C. 2058(c) … also requires a preliminary regulatory analysis that is inapplicable to rules issued under [§ 2056a]").

[51] 5 U.S.C. § 706(2)(C), (D).

[52] 5 U.S.C. § 706(2)(A); to the extent that the agency's interpretation of "durable" raises a question of whether the Rule was consistent with statutory authorization and is cognizable under § 706(2)(A), the CPSC's determination, for the reasons articulated above, does not constitute the "best reading" of the statute. *See Loper Bright* and *Relentless*, 603 U.S. at 395–96.

[53] *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021).

[54] *Window Covering Mfrs. Ass'n v. CPSC*, 82 F.4th 1273, 1286 (D.C. Cir. 2023) (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) and *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962)).

[55] *Saad v. SEC*, 718 F.3d 904, 910–11 (D.C. Cir. 2013) (quoting *State Farm*, 463 U.S. at 43).

[56] 89 Fed. Reg. at 87,480; *see also* Letter from Alessio Bruni to Alberta Mills at 20–22.

[57] Letter from Lisa Trofe to Alberta Mills at 6–7 (Mar. 18, 2023), https://www.regulations.gov/comment/CPSC-2023-0047-0018.

changes to its products not just in terms of redesign and testing, but also in its supply chain and marketing practices.[58] It also noted that Heroes Technology would require additional time to conduct "the appropriate human factor testing to ensure [it is] producing the safest product possible."[59]

In response to those concerns, the Commission only stated that those commentators did not "provide any specific data or information showing that the level of effort to redesign and distribute" compliant in-scope products.[60] The Commission simply concluded that "the rule provides a reasonable effective date that takes into consideration manufacturers burdens and the risk of continued infant injuries and deaths."[61] But there is no data supporting the Commission's perceived sense of "urgency" beyond the fact that incidents have occurred in the past, with the most recent data being from 2022.[62] And there is no data establishing that the Rule will actually reduce risks in the future. Moreover, as Heroes Technology previously raised with the Commission, the Rule may have the opposite effect on safety and push consumers—who no longer have access to their preferred product choices—to adopt regrettable substitutions in their absence, which may cause increased risk of harm to infants.[63]

While the foregoing reasons are sufficient to warrant of a stay of the effective date of the Rule, the Rule suffers from additional infirmities, which reinforce the need for a stay. *First*, the scope of the Rule is incompatible with reasoned decisionmaking. The Rule covers a non-exhaustive list of twelve exemplary product categories (and an estimated 2,000 products currently on the market), each of which serves different consumer needs and are designed for different uses. Instead of regulating these products through the voluntary standards process, the Commission grouped all products that are "filled with cushy foam or soft fibrous batting" and "covered by flexible fabric"[64] into a single category and devised one-size-fits-all testing for products which serve very different purposes, as often reflected in their design and construction. The Commission failed to consider these differences in promulgating the Rule. *Second*, CPSC's tests and performance standards are not supported by the record. The novel tests developed to support the Rule make little sense when applied to in-scope products like Snuggle Me Loungers, which are designed and constructed in such a way that the required tests are either impracticable or leave companies to do guesswork to identify placement for the test probe. That guesswork, if CPSC later decides a company's placement determination was wrong, opens companies to liability despite the Rule's undefined and vague requirements. Likewise, the firmness test methods are not standardized and the record lacks any data supporting the replicability of the test methods. *Finally*,

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[58] Letter from Alessio Bruni to Alberta Mills at 21.
[59] *Id.*
[60] 89 Fed. Reg. at 87,480
[61] *Id.*
[62] The incident data included incidents reported to have occurred between January 1, 2010 and December 31, 2022. The data does not account for potential reductions in incident rates as a direct result of the Commission's Infant Sleep Product Rule, 86 Fed. Reg. 33,052 (June 23, 2021) (effective June 23, 2022); *see also Window Covering Mfrs. Ass'n*, 82 F.4th at 1292 (finding that 180-day effective date was "not supported by substantial evidence").
[63] Letter from Alessio Bruni to Alberta Mills at 17–18.
[64] 89 Fed. Reg. at 87,469

the CPSC does not address the fact that the Rule may have the opposite effect it intends—that the Rule may actually decrease infant safety. The lower sidewall height is not supported by the record and may lead to more infants rolling out or off of in-scope products. It may also lead to the use of blankets, pillows, and other soft materials—which present known asphyxiation hazards—around in-scope products. The Commission studied neither of these foreseeable consequences and cannot reasonably explain how the Rule increases infant safety without doing so.

II. HEROES TECHNOLOGY HAS AND WILL CONTINUE TO SUFFER IRREPARABLE HARM IF THE CPSC DOES NOT POSTPONE THE RULE'S EFFECTIVE DATE

As indicated in its March 18, 2024 comment, Heroes Technology is a small company, and sales of its infant loungers represent a significant portion of its total revenues.[65] As a result of the Rule's pending effective date, Heroes Technology has incurred costs to redesign and test its products to ensure that they comply with the Rule. As highlighted in its comment, after the Rule was promulgated it has had to balance compliance with the Rule while also providing a safe, useful, affordable product that is wanted in the marketplace. While Heroes Technology is a privately held Minnesota company whose sales and revenue data are confidential, given its experience to date, the costs outlined in the Rule are significantly higher than the CPSC's estimates. Thus far, Heroes Technology has spent over $90,000 in new direct costs to comply with the Rule. For example, the company has spent over $9,000 in direct testing costs, and its testing processes are not yet complete. By way of comparison, the CPSC estimated the cost of third-party testing to be between $600–1,100.[66] The Commission's estimates are off by at least a factor of 10.

The Rule will also require Heroes Technology to incur significant costs to create new warnings, instructions, and safety collaterals, as well as website and other marketing changes. Heroes Technology will also be required to change its existing voluntary product registration processes to comply with those set by the Commission. As a result of the Rule, a significant portion of Heroes Technology's employees have been allocated to dealing with the effect of the Rule, rather than their sales, client relations, operations, product improvement, and other business roles.

The Rule is an existential threat to Heroes Technology that dramatically affects its operations and staffing, and may cause it to cease sales of its marquee product, more than a million of which have been sold since the company was formed in 2007.

III. THE BALANCE OF EQUITIES AND PUBLIC INTEREST SUPPORT POSTPONING THE RULE'S EFFECTIVE DATE

Postponing the Rule's effective date will not harm the public or the Commission. There "is generally no public interest in the perpetuation of unlawful agency action … [t]o the contrary, there is a substantial public interest 'in having governmental agencies abide by the federal laws

[65] Letter from Alessio Bruni to Alberta Mills at 22.
[66] 89 Fed. Reg. at 87,486.

that govern their existence and operations.'"[67] And Heroes Technology has made a substantial showing that the Commission did not follow the law when it promulgated the Rule.

The Commission also has not shown how delaying the rule will cause any risk of harm if it is stayed pending judicial review. As discussed above, it ignored significant concerns from manufacturers regarding their ability to redesign, successfully test, and market compliant products within the time allowed, as well as meeting the Rule's registration card requirements because they were not, in the Commission's view, specific enough. The Commission also relied on its view that the Rule was urgent, based on historical incident data, but it provided no reasoning for why or how a short delay would reduce the risks the Rule seeks to address and there is no data establishing that the Rule will actually reduce risks in the future.

But if the Rule is allowed to take effect it will harm consumers through reduced product choices, higher costs, and lower product utility. Further businesses, including Snuggle Me, will suffer significant economic harm to develop, redesign, and/or test in-scope products. As the Commission observed, in-scope products are sold both online and in-store at general retailers, "big box" retailers, baby products stores, specialty shops, and through marketplaces for hand-crafted items.[68] While CPSC does not quantify the market in terms of gross sales, either monetarily or by units sold, it does recognize that the infant support cushion market is large and supported by "[s]everal thousand manufacturers and importers, including hundreds of handcrafters and direct foreign shippers" most of whom are small businesses.[69] Given that the product category is new (*i.e.*, the term "infant support cushions" was developed by CPSC for purposes of the Rule), the Rule includes some twelve exemplary products, and the standard is broadly applicable across incongruent products it comes as little surprise that the Rule requires an estimated 2,000 product models to be redesigned at significant cost.[70] The Commission has also admitted some manufacturers suppliers may be forced out of the market.[71] It is obvious from the scope of the Rule, that compliance with the Rule cannot be accomplished within the 180-day period.

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[67] *League of Women Voters of United States v. Newby*, 838 F.3d 1, 12 (D.C. Cir. 2016) (internal citation omitted).

[68] 89 Fed. Reg. at 87,469.

[69] *Id.*; *see also* Memorandum from Daniel R. Vice, Assistant General Counsel, and Elizabeth Layton, Attorney, to CPSC and Alberta E. Mills, Secretary, at 34 (Nov. 8, 2023)https://www.cpsc.gov/s3fs-public/Briefing-Package-Notice-of-Proposed-Rulemaking-Safety-Standard-for-Infant-Support-Cushions.pdf?VersionId=rA60lesWHddS1.wrk_EvV00xeX75dsFc (identifying "more than 2,000 suppliers of infant support cushions"); 89 Fed. Reg. 2,530, 2,543 (Jan. 16, 2024).

[70] *See id.* 89 Fed. Reg. at 2,542; 89 Fed. Reg. at 87,486.

[71] 89 Fed. Reg. at 2,542.

IV. THE *REGULATORY FREEZE PENDING REVIEW* EXECUTIVE MEMORANDUM REQUIRES CPSC TO CONSIDER POSTPONING THE INFANT SUPPORT CUSHION RULE TO CONDUCT ADDITIONAL REVIEW

In his first day in office, President Trump issued the *Regulatory Freeze Pending Review* Executive Memorandum.[72] That Executive Memorandum requires "all executive departments and agencies" to take certain steps with regard to pending regulations.[73] Regarding regulations like the Rule, those that were promulgated but "have not taken effect[,]" agencies should "consider postponing for 60 days from [January 20, 2025] the effective date … for the purpose of reviewing any questions of fact, law, and policy that the rules may raise."[74] The Executive Memorandum commands agencies to "consider opening a comment period to allow interested parties to provide comments about issues of fact, law, and policy raised by the rules postponed under this memorandum, and consider reevaluating pending petitions involving such rules."[75] The Executive Memorandum contemplates further delays of such rules "where necessary to continue to review these questions of fact, law, and policy[.]"[76] And, where, as here, a rule "raise[s] substantial questions of fact, law, or policy, agencies should notify and take further appropriate action in consultation with the OMB Director."[77]

As discussed above, the Rule raises a substantial question of law regarding the meaning of "durable infant or toddler product." Heroes Technology's products, and potentially the entire class of infant support cushions, are not durable goods with the ordinary meaning of that term. Thus, the Commission erred by regulating such products under § 2056a. Heroes Technology has also raised substantial questions regarding the procedures used to adopt the rule and the facts and data the Commission relied on. The Commission should postpone the rule and notify the OMB Director pursuant to the *Regulatory Freeze Pending Review* Executive Memorandum.

CONCLUSION

For the foregoing reasons, Snuggle Me requests that the CPSC stay the Rule's May 5, 2025 effective date pending the D.C. Circuit's review, or, in the alternative, postpone the Rule pursuant to the *Regulatory Freeze Pending Review* Executive Memorandum.

Respectfully,

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[72] 90 Fed. Reg. 8,249.
[73] *Id.*
[74] *Id.*
[75] *Id.*
[76] *Id.*
[77] *Id.*

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CC:

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EXHIBIT 6

43°22′14″ N, long. 72°22″6 W) for Claremont Municipal Airport contained a typographical error. This action corrects the error by correcting the coordinates (lat. 43°22′14″ N, long. 72°22′06″ W) for Claremont Municipal Airport.

Correction to the Final Rule

Pursuant to the authority delegated to me, the amendment of Class E airspace extending upward from 700 feet above the surface for Claremont Municipal Airport, Claremont, NH, in Docket No. FAA–2024–1650, as published in the **Federal Register** on October 3, 2024 (89 FR 80382), is corrected as follows:

§ 71.1 [Corrected]

■ On page 80383, in the first column, replace the Claremont Municipal Airport coordinates (Lat. 43°22′14″ N, long. 72°22″6 W) with the corrected coordinates (lat. 43°22′14″ N, long. 72°22′06″ W).

Issued in College Park, Georgia, on October 28, 2024.

Patrick Young,

Manager, Airspace & Procedures Team North, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2024–25456 Filed 11–1–24; 8:45 am]

BILLING CODE 4910–13–P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1112, 1130, and 1243

[CPSC Docket No. 2023–0047]

Safety Standard for Infant Support Cushions

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: The Danny Keysar Child Product Safety Notification Act, section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), requires the U.S. Consumer Product Safety Commission (Commission or CPSC) to promulgate consumer product safety standards for durable infant or toddler products. Under this statutory authority, the Commission is issuing a safety standard for infant support cushions. The Commission is also amending CPSC's consumer registration requirements to identify infant support cushions as durable infant or toddler products and amending CPSC's list of notices of requirements (NORs) to include infant support cushions.

DATES: The rule is effective on May 5, 2025. The incorporation by reference of the publication listed in this rule is approved by the Director of the Federal Register as of May 5, 2025.

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:

I. Background and Statutory Authority

A. Background

Infant support cushions are filled with or comprised of resilient material such as foam, fibrous batting, or granular material or with a gel, liquid, or gas, and are marketed, designed, or intended to support an infant's weight or any portion of an infant while reclining or in a supine, prone, or recumbent position. CPSC is aware of at least 79 reported fatalities involving infant support cushions from January 1, 2010, through December 31, 2022, as well as 124 nonfatal incidents or reports involving these products within the same time period. There were 17 deaths in 2020, and a minimum of 17 more in 2021.[1] More than 80 percent of the known fatalities associated with these products involve infants three months old or younger. In more than 60 percent of the fatalities, the official cause of death was asphyxia or probable asphyxia. These incidents typically involved the use of an infant support cushion placed in or on a sleep-related consumer product such as an adult bed, futon, crib, bassinet, play yard, or couch. For the nonfatal incidents, the most common circumstances involved an infant falling from an infant support cushion placed on a raised surface such as a bed or a sofa, or a threat of asphyxia or entrapment.

In 1992, pursuant to authority under the Federal Hazardous Substances Act (FHSA), 15 U.S.C. 1261–1278, the Commission issued a ban on certain infant cushions and pillows filled with foam, plastic beads, or other granular material. 57 FR 27912 (June 23, 1992). That ban prohibits infant cushions, infant pillows, and similar articles that are:

- made with a flexible fabric covering;
- loosely filled with granular material, including, but not limited to, polystyrene beads or pellets;
- easily flattened;
- capable of conforming to the body or face of an infant; and
- intended or promoted for use by children under one year of age.

See 16 CFR 1500.18(a)(16). This final rule for infant support cushions does not change the existing FHSA ban. That ban was limited to products with the specific hazard presented by loosely filled granular material such as polystyrene beads or pellets, and those products will continue to be banned under the FHSA. Infant support cushions that are not subject to the ban are within the scope of this rule and are required to comply with the performance and labeling requirements of this rule.[2]

B. Statutory Authority

Section 104(b)(1)(A) of the CPSIA requires the Commission to (1) examine and assess the effectiveness of voluntary consumer product safety standards for durable infant or toddler products, in consultation with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts and (2) promulgate consumer product safety standards for durable infant and toddler products. *See* 15 U.S.C. 2056a(b)(1)(A). The Commission must continue to promulgate standards for all categories of durable infant or toddler products until the Commission has promulgated standards for all such product categories. *See* 15 U.S.C. 2056a(b)(2).

Consistent with section 104(b)(1)(A) of the CPSIA, CPSC consulted with manufacturers, retailers, trade organizations, laboratories, consumer advocacy groups, consultants, and the public to develop this rule, including through participation in the juvenile products subcommittee meetings of ASTM.[3] However, currently no voluntary or mandatory safety standard for infant support cushions exists to

[1] Due to reporting delays, fatality data reported to the CPSC is not considered complete until three years later; thus, the 2021 fatality data were not yet considered complete when the analysis was conducted in 2023.

[2] An exemption to the infant pillow ban applies to Boston Billow nursing pillows and substantially similar nursing pillows that are designed to be used only as nursing aids for breastfeeding mothers. 16 CFR 1500.86(a)(9). The exemption applies specifically to the FHSA ban and is not applicable to this rule or to the final rule for nursing pillows. 89 FR 85388 (October 25, 2024).

[3] CPSC formally began the consultation process for this rulemaking in December 2021, via a letter from staff requesting that ASTM form a working group to develop a voluntary standard to reduce the risk of death and injury from hazards associated with infant pillow products, including nursing pillows. In response, ASTM formed two subcommittees intended to develop two separate voluntary standards: the F15.16 Infant Feeding Supports subcommittee, intended to develop a standard for nursing pillows; and the F15.21 Infant Loungers subcommittee. Staff has been actively participating in both ASTM subcommittees to develop voluntary standards that address hazards associated with these products.

address the hazards posed by these products.

Infant support cushions are durable infant or toddler products under section 104(f) of the CPSIA. Section 104(f)(1) defines the term durable infant or toddler product as a durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years. *See* 15 U.S.C. 2056a(f)(1). Section 104(f)(2) of the CPSIA provides a non-exhaustive list of product categories within the definition of durable infant or toddler products. Although infant support cushions are not specifically listed in section 104(f)(2), they are durable infant or toddler products because (as explained in Part II, below) they: are not disposable; have a useful life of up to several years during which they are often used by multiple children successively; are similar to other soft durable infant and children's products such as crib mattresses and sling carriers (which the Commission has issued rules for under section 104); are resold and widely available on secondary marketplaces; and are primarily intended to be used by children five years old or younger.

Section 104(d) of the CPSIA requires manufacturers of durable infant or toddler products to establish a product registration program and comply with CPSC's rule for product registration cards, 16 CFR part 1130. The final rule amends part 1130 to include infant support cushions in the list of durable infant or toddler products that must comply with these product registration requirements. *See* 16 CFR 1130.2(a).

Manufacturers of children's products must also comply with the testing and certification requirements for children's products that are codified in 16 CFR parts 1107 and 1109. Section 14(a)(3) of the Consumer Product Safety Act (CPSA) requires the Commission to publish an NOR for the accreditation of third party conformity assessment bodies (test laboratories) to assess conformity with a children's product safety rule to which a children's product is subject. The final rule is a children's product safety rule that requires issuance of an NOR.

C. Notice of Proposed Rulemaking (NPR)

On January 16, 2024, the Commission published an NPR under section 104 of the CPSIA that proposed a mandatory consumer product safety standard for infant support cushions to address the risk of death and injury associated with these products. 89 FR 2530. The proposed rule addressed the suffocation, entrapment, and fall hazards associated with infant support cushions by including performance, testing, labeling, and instructional literature requirements. The proposed requirements in the NPR were based on staff's analysis of the hazards presented by infant support cushions as well as incident, injury and fatality data. The proposed requirements also considered the recommendations in the June 30, 2022, Pillows Product Characterization and Testing, Boise State University Report (BSU Final Report).[4] CPSC awarded a contract to Boise State University (BSU) for infant biomechanics and suffocation research and consultancy services. This research included an analysis of the risk of injury or death to infants associated with the use of nursing pillows and infant support cushions during activities such as feeding, nursing, sleeping, propping, and lounging. The BSU Final Report provided recommendations and conclusions related to the performance and design of infant support cushions, including recommendations regarding firmness testing, airflow testing, and sagittal-plane testing. Tab C of Staff's NPR Briefing Package summarizes how the requirements of the NPR relate to the conclusions and recommendations of the BSU Final Report. The Commission received 18 comments in response to the NPR.

On April 23, 2024, CPSC published a notice of availability (NOA) in the **Federal Register** that announced the availability of the incident data relied upon for the infant support cushions NPR and sought comments from the public. 89 FR 30295. The Commission received one comment in response to the NOA.

D. Final Rule Overview

Pursuant to section 104 of the CPSIA, 15 U.S.C. 2056a, the Commission is issuing a mandatory standard for infant support cushions based on the proposed requirements in the NPR, with certain modifications in response to public comments, which are discussed in detail in Sections VI and VII of the preamble.[5] The final rule defines an infant support cushion as an infant product that is filled with or comprised of resilient material such as foam, fibrous batting, or granular material or with a gel, liquid, or gas, and which is marketed, designed, or intended to support an infant's weight or any portion of an infant while reclining or in a supine, prone, or recumbent position. This definition includes any removable covers, or slipcovers, sold on or together with an infant support cushion. This includes infant pillows, infant loungers, nursing pillows with a lounging function, infant props or cushions used to support an infant for activities such as tummy time, and other similar products. The final rule addresses the risk of death and injury associated with infant support cushions primarily due to suffocation, entrapment, and fall hazards. It addresses positional asphyxiation hazards by requiring that all surfaces be sufficiently firm that they are unlikely to conform to an infant's face and occlude the airways,[6] and by setting a maximum incline angle that would prevent hazardous positioning of an infant's head and neck along the surfaces of the product. The final rule sets a side angle requirement that addresses the risk of entrapment between the sidewall and the occupant support surface. It addresses fall hazards by effectively limiting sidewall height to discourage caregivers from mistakenly believing these products to be safe for unsupervised infants. Finally, the final rule requires a strongly worded, conspicuous, and permanent on-product warning label.

Based on comments received on the NPR, the following changes have been made in the final rule:

- For clarity, the definition of infant lounger in § 1243.2 has been revised to change the term infant product to infant support cushion.
- For clarity, the definition of infant support cushion in § 1243.2. has been revised to add the sentence ''This definition includes any removable covers, or slipcovers, sold on or together with an infant support cushion'' at the end of the definition.
- To avoid ambiguity, a new definition of the term sidewall has been added in § 1243.2 which is defined as any wall at the edge of the occupant support surface.

[4] Erin M. Mannen et al; Consumer Prod. Safety Comm'n. Pillows Product Characterization and Testing (2022). *www.cpsc.gov/content/Pillows-Product-Characterization-and-Testing.*

[5] On October 16, 2024, the Commission voted (5–0) to publish this final rule with changes. Chair Hoehn-Saric issued a statement in connection with his vote, available at: *www.cpsc.gov/About-CPSC/Chairman/Alexander-Hoehn-Saric/Statement/Statement-of-Chair-Alexander-Hoehn-Saric-on-Commission-Approval-of-a-Final-Rule-Establishing-a-Safety-Standard-for-Infant-Support-Cushions.*

[6] Airways occlusion means to block the passage of air from the nose and mouth into the lungs, so that inhaled air cannot reach the lungs. In this case, the airway occlusion is caused by a soft product that covers the nose and mouth. Once an infant's airflow is compromised, decreased levels of oxygen in the blood can further impair the ability of the infant to respond to the situation. If an infant cannot respond, a feedback loop of decreased heart and respiration rate develops that can eventually lead to cessation of breathing and may become fatal if uninterrupted.

• For accuracy and consistency, a reference to infant pillow in § 1243.3(d) has been changed to infant support cushion.

• The final rule removes proposed § 1243.3(e) regarding side height as this requirement is redundant with the maximum incline angle limits in the rule. The final rule renumbers the paragraphs following proposed § 1243.3(e) to reflect this change. The rule also removes the corresponding test in § 1243.5(d)(8) for consistency. To reflect this change, all numbers after § 1243.5(d)(7) have been renumbered in the final rule.

• The performance requirements in § 1243.4(e)(2) and (3) and (f) as well as the corresponding test methods in §§ 1243.5(g) and 1243.4(h) and (i) have been revised to clarify that the performance requirements and test methods apply only to products that contain a sidewall with language stating, for products with a sidewall.

• The test method in § 1243.5(f) has been clarified to explain that products sold with a slipcover on or together with the product are to be tested as assembled, with the slipcover on the product. The test method in § 1243.5(f) has also been clarified to explain that all products, including products one inch or less in thickness, shall be tested.

• Figure 2 (for products without a tummy time feature) to paragraph (d)(7) in § 1243.6 has been revised and a new figure 3 (for products with a tummy time feature) has been added to reflect changes in warning content made in response to public comments. These changes include adding a statement to address prone use during tummy time, removing references to ''an awake baby,'' separating the sleep and suffocating-relating warning content to provide clarity, adding a warning to address soft bedding both in and outside of the product, and deleting some of the statements to reduce length and increase clarity. Additionally, § 1243.6(d)(7) clarifies that all infant support cushions are required to contain a warning with the content and format depicted in this section as figure 2 (for products without tummy time) or figure 3 (if the product has a tummy time feature) to paragraph (d)(7), as applicable.

• Section 1243.6(e) has been revised to clarify that slipcovers sold on or together with the product shall contain the warning statement shown in figures 2 and 3 to paragraph (d)(7), as applicable.

II. The Product Category

A. Infant Support Cushions

Infant support cushions are products that support an infant for lounging, meaning reclining in a supine, prone, or recumbent position. Infant products within this category may or may not have perimeter sidewalls. Most infant support cushions currently on the market are filled with cushy foam or soft fibrous batting, covered by flexible fabric. Some infant support cushions are marketed for use in a crib or other infant sleep product, notwithstanding warnings from the Commission and other institutions, including the American Academy of Pediatrics (AAP), that soft objects, such as pillows and excess bedding, should not be placed in an infant's sleep environment.[7]

Illustrative pictures of infant support cushions can be found in Tab C of Staff's NPR Briefing Package.[8] A non-exhaustive list of examples of infant support cushions includes:

• head positioner pillows;
• flat baby loungers;
• crib pillows;
• wedge pillows for infants;
• infant sleep positioners, unless regulated as medical devices by the Food and Drug Administration (FDA);
• stuffed toys marketed for use as an infant support cushion;
• infant tummy time or lounging pillows, whether flat or inclined;
• multi-purpose pillows marketed for both nursing and lounging;
• anti-rollover pillows with or without straps that fasten the pillow to the infant;
• infant self-feeding pillows that hold a bottle in front of the face of a reclining or lying infant;
• pads and mats; and
• accessory pillows and other padded accessories, often marketed for use with an infant car seat, stroller, or bouncer, but not sold with that product and therefore not included in the mandatory safety standard for those products.

These in-scope products must meet the requirements of the rule. However, to avoid potentially duplicative or conflicting obligations, the scope of products that would be subject to this rule does not include durable infant products that are already regulated by the Commission and included in the list of products at 16 CFR 1130.2(a).

The following products are NOT infant support cushions within the scope of this rule:

• pillows not marketed, designed, or intended for use by infants, such as adult bed and throw pillows;
• nursing pillows if subject to the Commission's final rule for nursing pillows (89 FR 85388 (October 25, 2024)), unless they are also marketed for lounging;
• crib and play yard mattresses that are regulated under the play yard standard (16 CFR part 1221) and crib mattress standard (16 CFR part 1241);
• purely decorative nursery pillows, such as those personalized with a baby's name and birthdate, that are not marketed, designed, or intended for infant use;
• stuffed toys (unless they meet the definition of an infant support cushion in this rule);
• padded seat liners that are sold with a rocker, stroller, car seat, infant carrier, swing, highchair, or bouncer that are specifically designed to fit that product;
• padded seat liners and inserts for a rocker, stroller, car seat, infant carrier, swing, highchair, or bouncer that are sold separately by the manufacturer as a replacement part and specifically designed to fit that product; and
• sleeping accommodations that are regulated under the Commission's infant sleep product rule at 16 CFR part 1236.

B. Market Description

Most types of new infant support cushions are sold online, including from general online retailers, online sites for ''big box'' stores, online baby products sites, and online marketplaces for hand-crafted items. Some types of infant support cushions, particularly crib pillows and baby loungers, are also available from brick-and-mortar baby specialty stores and general retail stores. Prices for new infant support cushions average roughly $30 and range from less than $15 for a simple head positioner pillow or crib pillow to more than $250 for a lounger with a removable cover or a large stuffed toy marketed for use while an infant sleeps. Several thousand manufacturers and importers, including hundreds of handcrafters and direct foreign shippers, supply infant support cushions to the U.S. market. *See* Tab E of Staff's NPR Briefing Package.[9]

[7] Rachel Y. Moon, Rebecca F. Carlin, Ivan Hand, *The Task Force On Sudden Infant Death Syndrome And The Committee On Fetus And Newborn,* 150(1) American Academy of Pediatrics: Evidence Base for 2022 Updated Recommendations for a Safe Infant Sleeping Environment to Reduce the Risk of Sleep-Related Infant Deaths (2022).

[8] Staff's NPR Briefing Package, available at: *www.cpsc.gov/s3fs-public/Briefing-Package-Notice-of-Proposed-Rulemaking-Safety-Standard-for-Infant-Support-Cushions.pdf?VersionId=rA60lesWHddS1.wrk_EvV00xeX75dsFc.*

[9] Staff's NPR Briefing Package, available at: *www.cpsc.gov/s3fs-public/Briefing-Package-Notice-*

Continued

Infant support cushions may be re-used for multiple children or resold for use after an infant outgrows the product. For example, in June 2023, staff found listings on Mercari for used changing pads, large stuffed toys marketed for infant sleep, crib wedge pillows, baby neck pillows, baby sleep positioners, baby loungers, baby sleep mats, baby pillow chairs, infant self-feeding pillows, baby/toddler bean bag chairs, and crib pillows. Similar listings were identified on eBay.

III. Incident Data and Hazard Patterns

Staff searched the Consumer Product Safety Risk Management System (CPSRMS) [10] and National Electronic Injury Surveillance System (NEISS) [11] databases for fatalities, incidents, and concerns associated with infant support cushions and involving infants up to 12 months old, reported to have occurred between January 1, 2010, and December 31, 2022. Staff identified 79 fatal incidents and 124 nonfatal incidents and consumer concerns reported to CPSC from 2010–2022. Of the 124 [12] non-fatal reports, 22 consisted of emergency-department-treated injuries, three involved hospital admissions, 45 involved no injury, and for 54 the disposition was either unknown or unspecified. The incident data and hazard patterns cited in support of the NPR support this final rule and are unchanged from the NPR. For further discussion of the incident data and hazard patterns, see the NPR and Tab A of Staff's NPR Briefing Package, which describe the incident and hazard patterns associated with infant support cushions,[13] and the NOA, which describes the incident data and hazard patterns relied on for the rulemaking.[14]

IV. International and Voluntary Standards for Infant Support Cushions

A. International Standards for Infant Support Cushions

The Commission is aware of two British standards that contain performance requirements addressing suffocation and asphyxiation hazards associated with infant pillows: BS 1877–8:1974, Specification for Domestic bedding—Part 8: Pillows and bolsters for domestic use (excluding cellular rubber pillows and bolsters) (BS 1877–8:1974) and BS 4578:1970, Specification for Methods of test for hardness of, and for air flow through, infants' pillows (BS 4578:1970). The scope of BS 1877–8:1974 includes both adult and cot pillows (infant pillows) and recommends that cot pillows be filled firmly enough to prevent infants' heads from sinking into the products and that the pillow covering not be loose enough to be drawn into an infant's mouth. BS 1877–8:1974 has requirements for cot pillow size, filling, and covering. Under that standard, cot pillows must be 58 x 38 cm (23 x 15 inches) and their covering must be of open construction to allow air permeability. Both the filling and covering must meet performance requirements described in BS 4578:1970 for hardness (*i.e.,* firmness) and air permeability.

The hardness test in BS 4578:1970 requires that a 100 mm diameter probe be placed in the center of the product with 10 newtons (N) of force for one minute. BS 1877–8:1974 requires that displacement of the pillow when the force is applied shall not exceed 25 percent of the thickness. The proportional approach used in this standard allows thicker pillows to have a greater displacement than thinner pillows, which staff assesses does not sufficiently protect against the suffocation and asphyxia hazards associated with infant support cushions because that greater displacement could allow the product to obstruct the infant's airway.

B. ASTM Voluntary Standards Work

Currently, there are no published U.S. voluntary standards for infant support cushions. ASTM is working on a voluntary standard for infant loungers under the Subcommittee F15.21 on Infant Carriers, Bouncers, and Baby Swings.[15] On March 25, 2024, ASTM issued ballot F15.21 (24–01), which included the latest draft of the infant lounger's voluntary standard. The ballot closed on April 29, 2024, and received eight negative votes and other comments including a comment from staff.[16] On September 16, 2024, ASTM issued ballot F15 (24–18), Item #1 which addressed the negative comments and other comments on the draft standard for infant loungers included in ballot F15 (24–01). That ballot closed on October 16, 2024.[17]

In the ASTM draft voluntary standard, infant loungers would be products with a raised perimeter, a recess, or other area that is intended to be placed on the floor and to provide a place for an infant to sit, lie, recline, or rest, while supervised by an adult, but are not intended or marketed for sleep. The draft definition would apply to only a subset of the products covered by this rule, which includes infant positioners, nursing pillows with dual use for lounging, infant cushions, and other infant pillow-like products, as well as the infant loungers being considered by the ASTM draft standard. ASTM's draft voluntary standard for infant loungers includes general requirements typically found in other ASTM juvenile product standards, such as requirements addressing lead content, small parts, hazardous sharp edges or points, resistance to collapse and disassembly, openings, protective components, permanency of labels and warnings, and toy accessories that are attached to, removable from, or sold with the products. The ASTM draft standard also specifies that if the lounger can be converted to another product, it shall comply with the applicable requirements of the converted product's standard. The general requirements of the ASTM draft infant lounger standard also state that the sidewall height of the

of-Proposed-Rulemaking-Safety-Standard-for-Infant-Support-Cushions.pdf?VersionId=rA60lesWHddS1.wrk_EvV00xeX75dsFc.

[10] CPSRMS is the epidemiological database that houses all anecdotal reports of incidents received by CPSC, ''external cause''-based death certificates purchased by CPSC, all in-depth investigations of these anecdotal reports, as well as investigations of select NEISS injuries. CPSRMS documents include hotline reports, online reports, news reports, medical examiner's reports, death certificates, retailer/manufacturer reports, and documents sent by state and local authorities, among others.

[11] NEISS is a statistically valid surveillance system for collecting injury data. NEISS is based on a nationally representative probability sample of hospitals in the U.S. and its territories. Each participating NEISS hospital reports patient information for every emergency department visit associated with a consumer product or a poisoning to a child younger than five years of age. The total number of product-related hospital emergency department visits nationwide can be estimated from the sample of cases reported in the NEISS. *See www.cpsc.gov/Research—Statistics/NEISS-Injury-Data.*

[12] The NPR listed 125 nonfatal incidents, but one of those incidents was a duplicate.

[13] Staff's NPR Briefing Package, available at: *www.cpsc.gov/s3fs-public/Briefing-Package-Notice-of-Proposed-Rulemaking-Safety-Standard-for-Infant-Support-Cushions.pdf?VersionId=rA60lesWHddS1.wrk_EvV00xeX75dsFc.*

[14] Notice of Availability and Request for Comment: Data Regarding Incidents Associated With Infant Support Cushions, 89 FR 30295 (April 23, 2024), available at: *www.federalregister.gov/d/2024–08605.*

[15] *See* Tab B of Staff's NPR Briefing Package, available at: *www.cpsc.gov/s3fs-public/Briefing-Package-Notice-of-Proposed-Rulemaking-Safety-Standard-for-Infant-Support-Cushions.pdf?VersionId=rA60lesWHddS1.wrk_EvV00xeX75dsFc.* This ASTM standard is still in draft form and has not completed the full consensus process to become an approved standard, and thus the draft standard is subject to change.

[16] CPSC Staff Comment to Ballot ASTM F15.21 on Infant Loungers, available at: *www.cpsc.gov/s3fs-public/CPSCStaffCommenttoBallotASTMF1521onInfantLoungers.pdf?VersionId=tGM05rvyA6WCUzQxHFCDkVHVxRLbtQLv.*

[17] CPSC Staff Comment to Ballot ASTM F15.21 on Infant Loungers, available at: *www.cpsc.gov/s3fs-public/staff-comment-to-ballot-ASTM–F15–21-on-infant-loungers.pdf?VersionId=oMjqKOhKBI0lEWiQliiCJ3u3OP2XcB7n.*

product shall be less than two inches on both the interior and exterior sides of the sidewall when measured according to the sidewall height measurement test method specified in the draft standard. The ASTM draft voluntary standard includes performance requirements that address stability, restraints, occupant support surface angle, fabric/mesh integrity, bounded openings, occupant support surface firmness, sidewall firmness, side angle measurements, and deflection at the occupant support surface and sidewall intersection. Finally, the ASTM draft voluntary standard for loungers also includes marking, labeling, and instructional literature requirements, such as warning the consumer about not using the product for sleep or naps, only using the product when the occupant baby is supervised, only using the product on the floor, keeping soft bedding out of the product, not using the product on raised surfaces, and not using the product to carry or move an infant.

As previously noted, the ASTM draft standard for infant loungers primarily differs from the final rule regarding the scope of products subject to the standard. Specifically, the final rule includes all types of infant support cushions such as infant positioners, infant loungers, and other types of infant mats and pads, while the scope of the ASTM draft standard would apply only to infant loungers. Given that the ASTM draft standard for loungers has not been finalized and published and would not cover the same scope of products as the final rule, the Commission finds that no voluntary standard currently exists or will likely exist in the foreseeable future that would adequately address the hazards presented by infant support cushions. This rule is required under section 104 of the CPSIA to address the identified hazards presented by infant support cushions. 15 U.S.C. 2056a.

VI. Response to Public Comments

CPSC received 18 public comments during the NPR comment period, and one comment during the NOA comment period. The comments are available on: *www.regulations.gov,* by searching under docket number CPSC–2023–0047. This section describes the significant issues raised in the comments and CPSC's responses to them.

A. Scope of the Final Rule

Comment: The Boppy Company, LLC (Boppy), Best Practice Quality LLC (BPQ), Heroes Technology (US) LLC d/b/a Snuggle Me Organic (Heroes Technology), and Juvenile Products Manufacturers Association (JPMA) object to the broad scope of the proposed rule and argue that the proposed rule does not take into consideration that it is difficult to develop specific standards because of the wide range of infant support cushion designs.

Response: We disagree that performance requirements and warning and labeling requirements for a wide range of infant support cushions cannot be comprehensively developed to mitigate the hazards posed to infants from infant support cushions. Although infant support cushions include many different types of products, incident data relied upon to support the rule indicate that infants are at risk from falls and suffocations, and that the hazard patterns are similar for all types of infant support cushions. As indicated in the incident data, caregivers use infant support cushions, which are not intended for sleep, in infant sleep settings and infants tend to fall asleep in these products. Thus, it is reasonably foreseeable that caregivers will use infant support cushions in infant sleep settings, which poses a suffocation hazard. Therefore, the performance requirements and warnings in the rule are designed to reduce the fall and suffocation hazards that these products pose.

Comment: JPMA argues that a rule for infant support cushions is unnecessary because CPSC has a safety standard for infant sleep products, codified at 16 CFR part 1236, addressing infant support cushions that are primarily intended or marketed for sleep.

Response: The scope of this rule includes products that are not subject to the infant sleep products rule, but that still present a risk of injury or death to infants. Infant support cushions do not meet the definition of infant sleep products because they are not marketed or intended to provide sleeping accommodations. Therefore, this rule is necessary to addresses the hazards posed by infant support cushions because the infant sleep products rule does not apply to infant support cushions.

1. Scope Age

Comment: BPQ asserts that the in-scope age range in the rule should be changed to align with the ASTM Lounger standard in development, which BPQ states covers infants 0–6 months.

Response: Since publication of the NPR, the ASTM F15.21 Infant Loungers Scope Task Group changed the scope of its draft safety standard to include infants up to 12 months of age.[18] Incident data, as outlined in the incident data and hazard pattern section of the NPR and Tab A of Staff's NPR Briefing Package,[19] indicate that incidents associated with infant support cushions occur with infants up to 12 months old (*i.e.,* 365 days). Based on the incident data and hazard pattern analysis, the performance requirements and warnings were developed to mitigate the hazards associated with infant support cushions for infants up to 12 months old. The Commission declines to limit the scope of the final rule with a specific age limitation. The Commission's approach mitigates the hazards associated with infant support cushions for all infants, regardless of age, and discourages manufacturers from making age-based marketing claims specifically to attempt to remove their products from being subject to the rule.

2. Tummy Time Pillows

Comment: BPQ, the Toy Association (TA), Boppy, and Graco Children's Products Inc (Graco) argue that the rule should exempt tummy time pillows.

Response: We disagree that tummy time pillows should be exempted from the rule. Tummy time pillows, which are pillow products on which infants may be propped, present the same suffocation and fall hazards as other types of infant support cushions, as indicated in the incident data discussed above. Infants can suffocate when tummy time pillows conform to an infant's face and occlude the airways; further, infants can roll from a tummy time pillow, creating a fall risk if the tummy time pillow is placed on an elevated surface. Therefore, tummy time pillows are subject to the requirements of the rule because allowing an exemption for tummy time pillows would allow those products to present the same suffocation and fall hazards to infants that this rule is intended to address. We note that AAP and National Institute of Child Health and Human Development (NICHD), while endorsing tummy time, do not specifically

[18] ASTM F15.21 Infant Loungers Scope Task Group—MeetingLog, available at: *www.cpsc.gov/content/ASTM–F1521-Infant-Loungers-Scope-Task-Group-Meeting%E2%80%AFLog-1.*

[19] Staff's NPR Briefing Package available at: *www.cpsc.gov/s3fs-public/Briefing-Package-Notice-of-Proposed-Rulemaking-Safety-Standard-for-Infant-Support-Cushions.pdf?VersionId=rA60lesWHddS1.wrk_EvV00xeX75dsFc.*

recommend tummy time pillows for that activity.[20] [21]

3. Dual Use Products

Comment: AAP supports the scope of the proposed rule and specifically asserts that dual use products marketed for both nursing and lounging should be within the scope of the rule. BPQ and Boppy state that the rule should exempt dual use products. Boppy asserts that there are distinct differences between nursing pillows and infant support cushions; it further states that the intent of the nursing pillows rule is to limit nursing pillow use to solely breast feeding and bottle feeding, obviating the need to cover nursing pillows of any type, including dual use, in this rule. BPQ further argues that because the draft ASTM nursing pillows standard, at the time of the comment, specifically states that nursing pillows may not be marketed for multipurpose use, nursing pillows should be exempt from this rule even if they otherwise would meet the definition of an infant lounger.

Response: We disagree that the rule should exempt dual use products marketed for both nursing and lounging. A nursing pillow that is also marketed for lounging is an infant support cushion subject to this rule. The new nursing pillow standard, ASTM F3669–24, published on September 10, 2024, specifies that if a nursing pillow can be converted into another product or has use features for which a consumer safety specification exists, the product shall comply with the requirements of all applicable voluntary standards. On October 25, 2024, the Commission final rule for nursing pillows published (89 FR 85388), which does not have a requirement for convertible products. Nursing pillows that meet the definition of infant lounger in § 1243.2 must also meet the requirements of this rule because the two rules are intended to address different hazard patterns. While the nursing pillow performance requirements and warnings discourage lounging, the infant support cushion rule requirements are intended to mitigate suffocation hazard while lounging. It is common for multiple CPSC mandatory safety regulations to apply to a single children's product, such as the existing regulations for small parts, phthalates, and lead content.

Comment: BPQ recommends the following statement should be added to the rule: If the infant lounger can be converted into another product for which a consumer safety specification exists, the product shall comply with the applicable requirements of that standard.

Response: The commenter's requested statement is unnecessary because § 1243.3(g) of the rule regarding convertible products already states that if the infant support cushion can be converted into another product for which a consumer product safety standard exists, the product also shall comply with the applicable requirements of that standard.

4. Playmats

Comments: Bureau Veritas (BV) requests clarification regarding whether playmats are intended to be classified as infant support cushions. Dorel Juvenile Group, Inc. asserts that playmat products subject to the requirements for toys in ASTM F963 and 16 CFR part 1250 and whose base ''pad or mat'' is a flat layer no greater than one inch in thickness should be exempt from the rule. TA and Graco also assert that playmats that are subject to ASTM F963 and 16 CFR part 1250 should be exempt from the rule.

Response: We disagree that the rule should exempt playmats. While playmats must meet the requirements of ASTM F963 and 16 CFR part 1250, those requirements do not address the infant suffocation hazards presented by playmats. Additionally, a playmat could have a flat layer no greater than one inch in thickness but still have greater than 1-inch sides or borders presenting a potential suffocation hazard. Finally, not providing the requested exemption is consistent with the ASTM draft voluntary standard for infant loungers, which currently also does not contain an exemption for playmats.

5. Accessory Pillows and Other Padded Accessories

Comment: BV requests clarification on the scope of the final rule regarding accessory pillows and other padded accessories sold with a juvenile product, or accessories sold separately from a juvenile product but intended to be used on a juvenile product. Boppy and Graco assert that the rule should exempt accessory pillows and other padded accessories for durable nursery products that are sold separately. Boppy additionally states that infants are seated while in contact with these pillows and padded accessories, so they do not meet the definition of an infant support cushion. Dorel Juvenile Group argues that the rule should exempt padded seat liners and inserts included with a car seat. BPQ argues that products that are used to keep an infant's head positioned in an infant carrier should be out of scope of this rule.

Response: Padded seat liners that are sold with a rocker, stroller, car seat, infant carrier, swing, highchair, or bouncer and are specifically designed to fit that product are not subject to the rule. However, we agree with BV, Boppy, Graco, and Dorel Juvenile Group that replacement padded seat liners and inserts for these products that are sold separately by the manufacturer as a replacement part and specifically designed to fit a rocker, stroller, car seat, infant carrier, swing, highchair, or bouncer would meet the rule's definition of an infant support cushion, even though they would be subject to the rules for those specific products as well. To avoid this unintended result, we have added these products to the list of products not within the scope of the rule because they are subject to the specific safety standard for those products discussed in section II.A of the preamble. Under § 1243.1, products subject to another standard listed in 16 CFR 1130.2(a) are exempt from the rule.

Aftermarket accessory pillows and other padded accessories, often marketed for use with a rocker, stroller, infant car seat, infant carrier, swing, highchair, or bouncer, but not sold with that specific product or as a replacement part, are subject to this rule, and thus must meet the requirements of the rule. This can include products that are used to keep an infant's head positioned in an infant carrier, unless they are sold with that product or as a manufacturer's replacement part. Such portable products can be used for purposes other than their intended use, including as an infant sleep product. Therefore, we disagree with BPQ that products that are used to keep an infant's head positioned in an infant carrier should be outside the scope of this rule. We also disagree with Boppy that accessory pillows and other padded accessories, used with seated products, should be excluded from the scope of the rule. These accessories present a suffocation hazard to infants because they are highly portable, and therefore can be used not only in the product for which they were intended but also in a variety of other products in which infants sleep, such as cribs, bassinets, and play yards. Because infants sleep for a majority of the day and tend to fall asleep in products intended for lounging, it is reasonably

[20] Benefits of Tummy Time | Safe to Sleep® (nih.gov), available at: *https://safetosleep.nichd.nih.gov/reduce-risk/tummy-time#:~:text=Babies%20benefit%20from%20having%20two,of%20total%20tummy%20time%20daily* .

[21] American Academy of Pediatrics (2017). Back to sleep, tummy to play. Retrieved August 28, 2018, from *www.healthychildren.org/English/ages-stages/baby/sleep/Pages/Back-to-Sleep-Tummy-to-Play.aspx.*

foreseeable that caregivers will use these accessory products in an infant sleep environment or that infants will fall asleep on them. Therefore, the rule has requirements and warnings to reduce the suffocation hazard presented by infant support cushions.

6. Infant Sleep Positioners, Anti-Rollover Pillows, and Wedge Pillows for Infants

Comment: BPQ and Boppy argue that the rule should exempt infant sleep positioners and anti-rollover pillows. Boppy states that the rule should exempt wedge pillows for infants. Boppy and Graco additionally state infant wedge pillows, infant sleep positioners, and anti-rollover pillows are all sleep products and thus should be subject to the infant sleep products rule, not this rule. BPQ additionally states that there is precedent to have discrete standards for each product category.

Response: We disagree with the commenters' assertion that infant wedge pillows, infant sleep positioners, and anti-rollover pillows should be outside the scope of the rule because all of these products are sleep products.[22] Infant wedge pillows, infant sleep positioners, and anti-rollover pillows do not meet the definition of infant sleep products in 16 CFR part 1236 because they are not marketed or intended to provide sleeping accommodations. Nevertheless, it is reasonably foreseeable that caregivers will use these products in an infant sleep environment. CPSC and FDA have warned against using infant positioning products in an infant sleep environment because they pose suffocation hazards.[23] [24] The incident data, which includes both fatal and nonfatal incidents, show that infants can suffocate when wedges, sleep positioners, and anti-rollover pillows conform to an infant's face. Therefore, the performance requirements and warnings of the rule are intended to mitigate the suffocation hazard posed by these products. Because the incident data hazard patterns associated with these products are the same and show that all infant support cushions are used for lounging, we disagree that it is necessary to develop separate standards specifically for these products.

7. Pads and Mats

Comments: An anonymous commenter requests clarification on the type of pads and mats subject to the rule because they assert that the term is generic and could apply to products beyond those on which a child could sleep.

Response: Pads and mats that are marketed, designed, or intended to support an infant's weight or any portion of an infant while reclining or in a supine, prone, or recumbent position are subject to the rule. These pads and mats pose a suffocation hazard because they can be used in a variety of products in which infants sleep such as cribs, bassinets, and play yards. In addition, because infants sleep for a majority of the day and tend to fall asleep in products intended for lounging, it is reasonably foreseeable that infants will fall asleep on pads and mats. Pads and mats are associated with both fatal and nonfatal incidents in the incident data, and the performance requirements of the final rule are intended to mitigate the suffocation hazard to infants from these products.

8. Framed Seating Products

Comment: Graco argues that framed seating products should be exempt from the rule because these types of framed products do not present the same hazards as soft cushioned infant pillow products and because the NPR did not specifically address hazards associated with seated infant products that have rigid frame containment.

Response: We agree with the commenter that framed seating products, including infant floor seats, rockers, strollers, car seats, infant carriers, swings, highchairs, bouncers, or other infant products with rigid components are not infant support cushions as defined in § 1243.2 of the rule. Thus, an exemption is unnecessary because these products are not subject to the requirements of the final rule.

B. Definitions

Comment: TA requests the term ''infant pillow'' used in § 1243.3(d), but nowhere else in the proposed rule, be amended to reference the defined term of infant support cushion for consistency. Alternatively, TA argues that ''infant pillow'' could be included as a discrete term in § 1243.2.

Response: For consistency and clarity, the reference to infant pillow in § 1243.3(d) of the proposed rule has been changed to infant support cushion in the final rule.

Comment: Graco requests that the definition of infant lounger be modified by to substitute the term infant support cushion for infant product. Graco also requests that the phrase ''infant loungers do not include seated infant products with a rigid frame used as containment'' be added to the definition of an infant lounger.

Response: We agree with the commenter's recommended change to the definition of infant lounger in § 1243.2 and have replaced the phrase infant product with infant support cushion in the final rule. We disagree that it is necessary to specify that infant loungers do not include seated products with a rigid frame used as containment as these products are not within the scope of infant support cushions and thus are not subject to the requirements of the rule.

Comment: JPMA asserts that the definitions used in the rule should align with the ASTM standard, in development, for infant loungers.

Response: The draft ASTM standard for infant loungers is in draft form and subject to change as part of the consensus process. Therefore, we decline to align the definitions in the final rule with the ASTM standard in development. Additionally, the final rule's definition of infant support cushion addresses the hazards presented by different types of infant support cushions, not just the infant loungers under consideration by the ASTM draft standard.

Comment: Heroes Technology argues that many of the products within the scope of the rule do not have an occupant support surface and the rule does not address how to test products without an occupant support surface.

Response: All infant support cushions contain an occupant support surface, which is defined in § 1243.2 as the area that holds up and bears the infant or any portion of the infant to support the infant's weight or any portion of the infant while reclining or in a supine, prone, or recumbent position. By definition, every infant support cushion subject to the rule contains an occupant support surface, and thus is required to meet the performance requirements of the rule that involve testing the occupant support surface.

Comment: Boppy notes that the proposed rule does not define the term sidewall.

Response: The Commission agrees that a definition of the term sidewall is needed for clarity. Thus, a new definition for sidewall, which means any wall at the edge of the occupant support surface, has been added to § 1243.2 of the final rule.

[22] *See* Safety Standard for Infant Sleep Products, 86 FR 33022 (June 23, 2021), available at: *www.federalregister.gov/d/2021–12723.*

[23] Recommendations for Parents/Caregivers About the Use of Baby Products | FDA, available at: *www.fda.gov/medical-devices/baby-products-sids-prevention-claims/recommendations-parentscaregivers-about-use-baby-products.*

[24] Deaths prompt CPSC, FDA warning on infant sleep positioners | CPSC.gov, available at: *www.cpsc.gov/Newsroom/News-Releases/2010/Deaths-prompt-CPSC–FDA-warning-on-infant-sleep-positioners.*

C. Use of Substitute Products

Comment: Boppy, Heroes Technology and JPMA raised a concern about the potential for consumers to use substitute products such as adult pillows or blankets, instead of infant support cushions. The commenters note that such products would fall outside the scope of the rule but could pose similar suffocation and fall hazards to infants.

Response: None of the commenters provide data to support the claim that the requirements in the proposed rule would lead consumers to use substitute products. The rule is intended to ensure that consumers have access to infant support cushions that do not present the same risks of death or injury as some current products, and this rule should not cause consumers to seek out alternative products. The rule also contains warnings that explain why soft surfaces, blankets, and other soft items present a hazard when placed in and around the product, which can further educate consumers on the risks posed by substitute products with soft surfaces.

Comment: Boppy questions whether the performance requirements in the proposed rule could negatively impact tummy time rates.

Response: The rule is not likely to reduce beneficial tummy time. Regarding tummy time, AAP and NICHD, while endorsing tummy time, do not recommend specifically using tummy time pillows. Additionally, this rule would allow the manufacture and sale of tummy time products as long as those products meet the requirements of the rule. Therefore, tummy time guidance is not likely to change based on this rule.

D. Product Misuse and Education

Comment: BPQ recommends CPSC develop educational campaigns to address the unsafe sleep settings and misuse of products not intended for infant sleep exhibited in the incident data. Commenter Julian Dreest asks what strategies are currently in place to educate consumers about the proper use of infant support cushions.

Response: The use of infant support cushions for sleep, or in an infant sleep setting, is not appropriate. Consumer education campaigns about safe sleep and the safe use of infant support cushions are useful and necessary to assist new parents and older generations of caregivers about safe sleep practices. CPSC actively promotes safe sleep outreach and education throughout the year to reach parents, grandparents, and caregivers on our website [25] and by engaging in targeted safe sleep messaging during Baby Safety month (September).

However, education campaigns alone are not enough to address the hazards associated with infant support cushions. Data generally indicate that consumers believe if an infant product is on the market, it must be safe for use with infants—an assumption that is not always true. Therefore, this final rule for infant support cushions, paired with educational campaigns, is needed to better ensure safe uses of these products.

Comment: Julian Dreest, BPQ, and Heroes Technology assert that educational strategies should reflect the new requirement for a maximum incline angle of 10 degrees or less, which limits the side height of the product to approximately 1.9 inches. The commenters assert this new requirement will invite some caregivers to improvise or modify the product to achieve the containment level they desire, increase consumer complacency, and provide a false sense of security leading to less supervision. Therefore, they argue, the rule will increase falls from elevated surfaces and the likelihood of roll-out from the product into an unsafe setting. AAP and the Joint Consumer Advocate Commenters strongly support the maximum incline angle requirement of 10 degrees or less in the proposed rule.

Response: We disagree that limiting the maximum incline angle to 10 degrees or less will lead to increased falls or suffocations due to decreased supervision. As discussed in Tab D of Staff's NPR Briefing Package,[26] a cushioned sidewall with a height of up to four inches may give caregivers the false perception that the product can safely contain a child without supervision, regardless of what the product warnings might say. The presence of a distinct, raised perimeter surrounding the occupant support surface, as observed in various products on the market, provides a visual cue to consumers that the infant is safely contained in the product. Infant support cushions currently marketed for sale often display images of infants sleeping or resting in such products, and thus convey the appearance of effective containment of infants. The incident data shows that parents may mistakenly believe that products with cushioned sidewalls greater than two inches surrounding the infant would make them safe on elevated surfaces, that the infant can be left alone on the product, and that the product will safety contain their infant. The incident data further shows that infants suffer falls from products with cushioned sidewalls that are higher than 2 inches surrounding the occupant. Specifically, infants roll out of products with cushioned sidewalls greater than two inches into hazardous settings. With infant support cushions with cushioned sidewalls less than 2 inches, parents can see their infant is not secure in the product, that the product does not contain their infant, and that the infant should not be left alone on the product, particularly on elevated surfaces. Furthermore, the accompanying warnings alert users to the risks of leaving infants unattended or allowing use of the products for sleep or using on elevated surfaces. We note that AAP and the Joint Consumer Advocate Commenters strongly support the maximum incline angle requirement of 10 degrees or less in the proposed rule.

Comment: Graco states that in addition to the current infant pillows that are already banned under 16 CFR 1500.18, the CPSC had considered an ''Infant Pillow Ban'' in former operating plans that would take these dangerous products off the market, but instead has pivoted to allow the very same types of products in the NPR, without sufficient requirements that would address the inherent misuse and hazards.

Response: The Commission finds that the requirements in this rule will mitigate the suffocation and fall hazards to infants posed by infant support cushions. Therefore, the Commission concludes, that this rule will better address the known hazards posed by infant support cushions rather than just merely expanding the existing infant pillow ban, while still providing consumers with the utility of infant support cushions for supervised infant use.

Comment: JPMA asserts that improper use of infant support cushions has contributed to the majority of incidents associated with these products since 2010. JPMA also contends that the majority of the products in the scope of this rule are not marketed or intended for sleep and have recognized utility for parents who need a safe product in which to place their child during awake time interaction, play, and engagement.

Response: The incident data clearly indicate a pattern of use of infant support cushions in infant sleep settings and for sleep. The designs of infant

[25] Safe Sleep—Cribs and Infant Products, available at: *www.cpsc.gov/SafeSleep.*

[26] *See* Tab D of Staff's NPR Briefing Package, available at: *www.cpsc.gov/s3fs-public/Briefing-Package-Notice-of-Proposed-Rulemaking-Safety-Standard-for-Infant-Support-Cushions.pdf?VersionId=rA60lesWHddS1.wrk_EvV00xeX75dsFc.*

support cushions currently on the market encourage the use of these products for sleep. These products are often used for sleep because of the false perception that the soft, pillow-like design, with high borders/sides, are appropriate for infant sleep and will safely contain an infant, including on elevated surfaces. Further, staff is aware of infant support cushions that are or have previously been marketed and promoted as sleep products. Changing only the marketing of the product, without changing the design of the product, will not adequately discourage the behavior of caregivers allowing infants to sleep on infant support cushions unsupervised. We agree that infant support cushions have utility for parents to place their infant when actively supervised.

E. Incident Data

Comment: BPQ, Boppy, Heroes Technology, and JPMA state that the percentages of incidents by product category are not provided in the NPR and Tab A of Staff's NPR Briefing Package. BPQ also argues that the two largest nonfatal hazard patterns, falls and threatened asphyxia, are not broken down by age.

Response: The Commission published an NOA announcing the availability of incident data relied upon for the NPR and seeking comment. The data in the NOA released for public comment shows that for fatal incidents, 63 incidents were associated with loungers, 10 incidents were associated with sleep positioners, four incidents were associated with pads/mats, one incident was associated with an infant wedge, and one incident was associated with a tummy time pillow. For nonfatal incidents, 104 incidents were associated with loungers, 13 incidents were associated with sleep positioners, three incidents were associated with infant wedges, two incidents were associated with pads/mats, one incident was associated with a tummy time pillow, and one incident was associated with a small infant pillow. As described above, the hazard patterns throughout these incidents are consistent with the risks of suffocation and falls presented by infant support cushions. Based on the data made available to commenters in the NOA, for incidents involving threatened asphyxia, 21 victims were up to 4 months old, two were 4–6 months old, and in three incidents the age was unreported. For incidents involving falls, 15 victims were up to 4 months old, nine were 4–6 months old, four were over 6 months old, and in one incident the age was unreported.

Comment: Boppy argues in a comment on the NPR that CPSC provided insufficient data to support that all products proposed to be covered by the rule, and specifically tummy time pillows, need regulation with a mandatory rule. Boppy also argues in a comment on the NOA that there are zero reported incidents related to tummy time pillows, so there is no justification for any inclusion of tummy time pillows within the scope of this proposed rule.

Response: The Commission disagrees that tummy time pillows should be excluded from the scope of the rule. Tummy time pillows are products on which infants may be propped, and therefore they must meet the requirements of this rule. Tummy time pillows were associated with one fatal incident and one nonfatal incident as reflected in the incident data and present the same hazards as other infant support cushions. So, allowing a tummy time pillow for infants to be exempted from this regulation is contrary to the regulation's intent and would allow manufacturers to remarket other types of infant support cushions as tummy time pillows to avoid regulation. We note AAP and NICHD, while endorsing tummy time, do not specifically recommend pillows for tummy time.

F. General Requirements

Comments: Consumer Federation of America, Consumer Reports, Kids In Danger, National Center for Health Research, Public Citizen, U.S. Public Interest Research Group (Joint Consumer Advocate Commenters), and Safe Infant Sleep recommend that the rule prohibit any type of electronics used inside or attached to an infant support cushion. The commenters also recommend prohibiting battery powered features, including vibration and white noise that can encourage sleep or may overheat presenting a burn risk, or features that contain cords which present a strangulation risk.

Response: Some vibrations and music/sounds may lull infants to sleep. However, other music and sounds may engage infants during awake time. Staff has not identified any products in the incident data where an electronic component caused an injury or a death through fire, heat, or otherwise. Because no such products were identified in the incident data as presenting a hazard, this rule does not include a requirement related to electronics.

G. Performance Requirements

Comment: Heroes Technology requests that CPSC conduct round robin studies of the performance requirements and test methods involving multiple laboratories and multiple exemplar products in each category, with a view to reproposing and ultimately adopting test methods and performance requirements.

Response: The Commission considers the performance requirements and test methods in this rule to adequately address the hazards associated with infant support cushions without a need for the type of round robin process suggested by Heroes Technology, which could take years to complete while injuries and deaths continue to occur. The Commission concludes that the urgency of addressing the hazards associated with infant support cushions, and the requirement in CPSIA section 104 to promulgate safety standards, supports the Commission's promulgation of this rule. The factual and scientific basis for the performance requirements and test methods in the rule are described in Tab C of Staff's NPR Briefing Package.[27]

1. Restraint

Comments: Graco asserts that the presence of a restraint system on an infant support cushion or lounger would further deter consumers from using them for sleep because the safety standards for sleep products do not allow restraint systems or cords or straps in the occupant area. On this basis, Graco suggests that the rule's prohibition on restraints could indicate to caregivers that infant support cushions are intended for sleep.

Response: The Commission's yearly report of injuries and deaths associated with nursery products demonstrates that consumers use infant products, both with and without restraints, for infant sleep.[28] In addition, restraints indicate to consumers that the infant is secure in the product and will not move, and thus the caregiver can leave the infant unsupervised. Because fall-related incidents have involved unattended infants who were left propped or lounging in the product, consumers are likely to interpret the presence of an infant restraint as meaning that unattended use is acceptable when an infant is restrained. Additionally, as is the case with several other children's product areas, loops, cords, or strings

[27] Staff's NPR Briefing Package, available at: *www.cpsc.gov/s3fs-public/Briefing-Package-Notice-of-Proposed-Rulemaking-Safety-Standard-for-Infant-Support-Cushions.pdf?VersionId=rA60lesWHddS1.wrk_EvV00xeX75dsFc.*

[28] Injuries and Deaths Associated with Nursery Products Among Children Younger than Age Five, August 2023, available at: *www.cpsc.gov/content/Injuries-and-Deaths-Associated-with-Nursery-Products-Among-Children-Younger-than-Age-Five-12.*

that enter into the occupant space can create an entanglement hazard, as seen in the incident data. Infant support cushions should be used with constant adult supervision, so prohibiting restraints in the rule is appropriate.

2. Maximum Incline Angle

Comment: Heroes Technology argues that it is not clear in the rule what ''approximately 1.9 inches'' means and asserts that this is an arbitrary value. Graco argues that figure 6 in the text of the proposed rule alludes to a side height measurement, without criteria stipulated for the side height.

Response: The rule does not include a side height performance requirement or a side height test method. Instead, the maximum incline angle performance requirement of 10 degrees or less in the rule effectively limits the height of the product to approximately 1.9 inches, which reduces the hazard from falls and suffocation when the product could otherwise give the false perception of containment to a caregiver that the product will safely contain the infant. The maximum incline angle test in the rule, as compared to a side height test, can more effectively be applied to all the different types of infant support cushions subject to the rule, which include infant support cushion products other than loungers and even products without a sidewall. Some products subject to the rule contain occupant support surfaces that allow an infant to be placed in various locations on the product. The maximum incline angle requirement applies to all the manufacturer's recommended use positions, and also to all other infant support cushion surfaces that can feasibly support an infant's head (occupant support surface-head), including the angle from the sidewall (if present) to the occupant support surface, or from the occupant support surface-head to the floor when no elevated sidewall is present, or from the sidewall to the floor when an elevated sidewall is present. Staff calculated that the side height for very firm products which meet the 10-degree angle requirements would likely be approximately 1.9 inches (4.8 cm) or less based on the geometry of the newborn hinged weight gauge. The side height was not recommended arbitrarily, and is not itself a requirement, but rather describes the geometric calculations of the likely height of a product just meeting the required incline angle of 10 degrees.

Comment: BPQ recommends the sidewall height should be set at 2 inches, as in the draft ASTM infant loungers standard, and not 1.9 inches. BPQ contends that if the height of the product is set at 1.9 inches, then there would be no need to measure the incline angle. The commenter also recommends that the inclined angle of 10 degrees or less should be applied on the support surface of the base and only if the side height is greater than 2 inches.

Response: The Commission disagrees that a maximum sidewall height of 2 inches should be required. The NPR did not propose a maximum side height requirement but instead proposed a maximum incline angle performance requirement. As discussed in the response to the previous comment, the maximum incline angle performance requirement in the rule is based on the varying designs of products and is expected to geometrically result in the height of the product being no more than 1.9 inches in order to comply with the incline angle requirement.

Comment: Graco argues that subjecting infant support cushions to a maximum incline angle requirement for products that are not intended for sleep would incorrectly result in them sharing a critical characteristic of infant sleep products, that are also required to have a sleep surface of 10 degrees or less.

Response: Infant support cushions are not sleep products, but infants fall asleep in many types of products other than sleep products, including infant support cushions. The maximum incline angle requirement in the rule addresses the suffocation hazard that could result if an infant sleeps in an infant support cushion. Section 1243.5(d) of the rule requires infant support cushions to have an incline angle of 10 degrees or less in order to reduce the hazard of suffocation if an infant falls asleep in the product.

Comment: Heroes Technology argues that if there is no incline in the manufacturer's recommended use location for the product, and other use locations represent misuse, then the product should not be subject to a maximum incline angle requirement.

Response: We disagree that products with no incline in the manufacturer's recommended use location should not be subject to the maximum incline angle requirement of the rule. Some products subject to the rule contain occupant support surfaces that allow a variety of use modes, so the infant may be placed in various locations on the product, while some products do not have sidewalls. With other products, infants may move, roll, or be placed in various positions on the product. To address known hazard patterns, the rule appropriately includes a maximum 10-degree incline angle requirement that applies to any foreseeable use position on the infant support cushion's occupant support surface or sidewall that supports the head for reclining, to mitigate suffocation and fall hazards. The maximum incline angle requirement applies to all manufacturer's recommended use positions, as well as to all other infant support cushion surfaces that can feasibly support an infant's head (occupant support surface-head). This includes the angle from the sidewall (if present) to the occupant support surface or from the occupant support surface-head to the floor when no elevated sidewall is present or from sidewall to floor when an elevated sidewall is present.

Comment: Heroes Technology notes that an example of a ''feasible location'' is provided in the proposed rule, but the term is not defined. The comment also notes that a ''location likely to fail'' is also not defined in the rule, nor is any guidance provided as to how such a location should be determined.

Response: A ''feasible location'' is language commonly used in ASTM standards and is typically followed by an example of such a location in the requirement. Section 1243.5(d)(8) is the only place in the rule where the term feasible location is used. This section represents the intent for a feasible location by providing an explicit example ''such as perpendicular to the recommended use location(s)'' without limiting the potential to test any area that is applicable with a discrete definition.

The language a ''location likely to fail'' is language commonly used in ASTM standards and longstanding CPSC safety standards that incorporate these ASTM standards. While a location most likely to fail cannot be determined by the use of a single test, not all locations on the product need to be evaluated. For example, with respect to the maximum incline angle requirement, any extremity with respect to the overall height of the sidewall or occupant support surface should be considered areas likely to fail. Therefore, we disagree that ''feasible location'' or ''location most likely to fail'' needs to be defined in the rule.

Comment: Graco argues that it is unclear if a two-inch height would prevent infants from rolling out of a product into a dangerous environment. Dony Ly suggests CPSC should recommend a side height that will best mitigate falls, while accounting for the wide range of infant age and ability but did not provide any recommendation as to that height. Julian Dreest proposes revising the sidewall height limitation

to a minimum of four inches to mitigate the risk of falls; he also asks if there has been a risk assessment analysis comparing the incidence of falls from products with different sidewall heights, while also taking into account the age of the infant. Heroes Technology asserts that CPSC failed to consider that a shorter sidewall height will increase the fall hazard.

Response: As seen in the incident data and proposed in the NPR, a maximum incline angle requirement of 10 degrees or less mathematically limits the side height of the product to less than 2 inches to address potential asphyxiation hazards. The incident data also indicated that caregivers placed infant support cushions into infant sleep settings for unsupervised sleep or on elevated surfaces. Higher sidewall heights give the false perception to the caregiver that the product will safely contain their infant. At the same time, the incident data show that higher sidewall heights do not adequately contain infants or prevent falls and that infants roll out from and fall out of products with a side height of 4 inches or higher. The incident data also indicates that infants can turn over or roll without warning and are at risk of falling when infant support cushions are placed on an elevated surface.

In contrast to products with higher side heights, products with side heights of approximately 2 inches or less are less likely to give the false perception to the caregiver that the product will safely contain their infant. Therefore, caregivers are less likely to leave infants unattended in a product with a less than 2-inch side height or to place the product on an elevated surface. When the side height is limited to less than 2 inches it provides a visual cue to caregivers that the product will NOT safely contain their infant which encourages caregivers to place the product on the floor, thus mitigating the fall hazard posed to infants from products placed on elevated surfaces. Furthermore, there is no evidence that a maximum sidewall height of about 2 inches would increase the risk of injury from a fall or lead to different consequences than a higher sidewall because, as reflected in the incident data, infant support cushions with higher side heights do not safely contain infants and infants already roll out of these products. Additionally, products with side heights of more than 2 inches would exceed the maximum incline angle requirement in the final rule and poses a suffocation or positional asphyxiation hazard. Also, the commenter's proposal to require 4-inch-high sidewalls would not allow for products such as flat playmats or other infant support cushion products that do not contain sidewalls. Staff's analysis of incident data did not identify the need for a sidewall requirement and thus the final rule has no requirements for a minimum side height. Therefore, the Commission is not adopting the commenters' recommendations to require higher sidewalls because higher sidewalls encourage unsafe placement of infants on elevated surfaces, while also failing to adequately contain infants or prevent falls. Finally, staff is unaware of a risk assessment analysis specifically comparing the incidence of falls from infant support cushions of different product heights, while also taking into account the age of the infant.

Comment: Heroes Technology asserts that CPSC failed to consider that with reduced side heights consumers will use blankets and towels to create a bumper.

Response: Although this rule only regulates infant support cushions, it does contain specific warnings about the serious risks posed by soft bedding and other soft items in and around infant support cushions. Regardless of the side height of a product, some caregivers may use other products such as blankets and pillows to create a barrier around an infant, whether the infant is on an infant support cushion or not. CPSC will continue providing information and education campaigns for safe infant care regarding the hazards associated with soft bedding and soft items in sleep settings.

3. Firmness

Comment: Boppy argues that the test requirements and procedures in the proposed rule do not consider products that do not have a sidewall. The performance requirements do not specify if the sidewall firmness and angle requirements only apply to products with a sidewall, and the testing procedures for sidewalls do not include language such as ''if applicable'' or ''for products with a sidewall.''

Response: We agree that the rule should clarify whether the performance requirements and test methods apply to products that do not contain a sidewall. Therefore, the final rule adds ''For products with a sidewall'' to the beginning of the sentence regarding the performance requirements in § 1243.4(e)(2) and (3) and (f) and also adds ''For products with a sidewall'' to the beginning of the sentence before ''perform'' in the test methods in §§ 1243.5(g) and 1243.4(h) and (i).

Comment: Boppy notes that the rule does not specify how testing is to be performed on products with an occupant support surface of one inch or less.

Response: We agree that clarification on how testing is to be performed on products with an occupant support surface of one inch or less is necessary in the final rule. Therefore, § 1243.5(f) of the final rule adds the language ''All products, including products one inch or less in thickness, are required to be tested'' to clarify how testing is to be performed on products with an occupant support surface of one inch or less. The rule requires all in-scope products, including those with an occupant support surface of one inch or less, to be tested to all of the performance requirements to ensure that they meet the standard. As discussed above, no exception is provided for products of one inch or less in thickness.

Comment: Safe Infant Sleep proposes that CPSC should consider a requirement that would not allow covers to have extra padding or cushioning, since such extra padding or cushioning may introduce an additional suffocation hazard.

Response: The Commission agrees that slipcovers with extra padding or cushioning may introduce a suffocation hazard that would not be addressed by testing only the firmness of the infant support cushion without the slipcover installed on the product during testing. The Commission also agrees that testing should be performed with slipcovers installed as part of the as assembled product and the product and slipcover, if sold on or together with the product, must meet the test requirements because extra padding or cushioning on a slipcover may introduce an additional suffocation hazard that is not addressed if the product is tested without the slipcover installed. In order to make clear that infant support cushions sold with a slipcover, on or together with the product, are subject to the rule and must be tested as assembled, the definition of infant support cushion in § 1243.2 has been revised to add a new sentence at the end of the definition stating ''This definition includes any removable covers, or slipcovers, sold on or together with an infant support cushion.'' However, aftermarket slipcovers not sold with the product do not meet the definition of an infant support cushion and thus would not be within scope of this rule. Finally, § 1243.5(f) adds the language ''for products sold with a slipcover on or together with the product, products shall be tested as assembled with the slipcover on the product'' to the final rule to clarify that slipcovers, sold on or together with the

product, need to be installed on the product during testing.

Comment: Graco argues that infant support cushions should not be tested on a solid or firm testing surface.

Response: We disagree. Infant support cushions should be tested on a solid or firm testing surface as the product relies on the underlying surface it is placed upon for support and shape. In order to accurately measure the firmness of the foam, filling, padding, or supporting material in an infant support cushion, the testing surface cannot move in response to the applied force (*i.e.,* displace, shift, bend, deviate, compress, deflect, translate or otherwise), because any movement of the testing surface in response to the applied load would contribute to an under-measured value for the firmness measurement and thus would not provide repeatable results.

Comment: Graco argues that the minimum value for acceptable firmness for the firmness test cannot be directly correlated to the firmness values used in other safety standards for children's products. Graco recommends that all data underlying the performance requirements be published to permit an independent assessment. Graco also argues that the performance requirements are not substantiated by reliable test results.

Response: The Commission considered the recommendations of the BSU Final Report when developing the proposed requirements in the rule.[29] Additionally, the requirements in the rule reflect staff's testing of a variety of infant support cushions, as well as an analysis of hazard patterns obtained from incident data associated with infant support cushions. The Commission made this incident data available for public review and comment as described in the NOA. This information was used to develop the specific performance requirements, and labeling and instructional literature requirements that address the suffocation and fall hazards associated with infant support cushions. The development of the firmness test method and test results are discussed in further detail in Tab C of the Staff's NPR Briefing Package.[30]

Comment: Heroes Technology argues that the firmness testing described in the rule regarding the intersection of the occupant support surface and sidewalls is ambiguous and that the term ''location most likely to fail'' is similarly vague.

Response: The firmness test for the intersection of the sidewall and occupant support surface is intended to address suffocation hazards from infant support cushion products due to the presence of a sidewall adjacent to an occupant support surface. The rule provides instructions and guidance to measure firmness at the intersection of the sidewall and occupant support surface. Specifically, firmness is measured at the intersection of sidewall and occupant support surface as the force to deflect the surface 1.0 in (2.54 cm) using the 3-inch hemispherical probe oriented at an angle, determined according to the test method in § 1243.5(h), *Intersection of sidewall and occupant support surface firmness.* Section 1243.5(h) requires a force greater than 10.0 N (2.24 lbs) to address the suffocation hazard due to soft surfaces. The terms ''most likely to fail'' or ''likely to fail'' are standard language commonly used in ASTM standards and longstanding CPSC rules that incorporate these ASTM standards. However, areas where the sidewall appears to be vertical or slanted inward immediately over top of the occupant support surface, even while satisfying the angle requirement for the side as a whole, would be considered areas ''likely to fail.'' Therefore, the Commission disagrees that ''location most likely to fail'' needs to be defined in the rule.

4. Sidewall Angle

Comment: Heroes Technology argues that the proposed sidewall angle requirement cannot be conducted effectively on the firm's Snuggle Me infant lounger due to the lounger's unique design features.

Response: The sidewall angle requirement is intended to address the risk of entrapment between the sidewall and the occupant support surface that is not fully addressed by the firmness requirements alone. While the Snuggle Me infant lounger may possess unique design features, such as an unpadded occupant support surface, the product can still be evaluated to the sidewall angle requirement in the rule. The unpadded surface, and the firm flat surface the rule requires the units be tested on, would be considered the occupant support surface for the evaluation and the sidewall angle should be taken with respect to that surface.

Comment: Heroes Technology argues that the rule provides no instructions or guidance to locate the intersection of the sidewall and occupant support surface.

Response: In § 1243.5(i), *Sidewall angle determination,* the rule provides instructions and guidance regarding the test procedure to locate the intersection of the sidewall and occupant support surface.

H. Marking and Labeling

Comment: Boppy, AAP, BPQ, the Joint Consumer Advocate Commenters, Safe Infant Sleep, and JPMA all recommend an additional warning for the tummy time infant support cushion subcategory to provide clarity and resolve confusion surrounding the warning ''use only on floor, with baby face up on back'' when it is used on a product that is also a tummy time pillow.

Response: We agree that some infant support cushion products, such as tummy time pillows, may have features that require the infant to be on their stomach while using the product and that different statements are appropriate for products designed for tummy time. Because prone positioning is a risk factor for infants that can lead to suffocation when the mouth and nose are occluded, the final rule adds a new figure 3 in § 1243.6 to accommodate products with multi-use positions. Specifically, the following statement ''Put baby on back after Tummy Time'' has been added to the warning label after the phrase ''use only on the floor with baby on back, face up'' in new figure 3. Figure 3 is only required for products that have a tummy time feature because only products that have a tummy time feature should allow prone positioning. Tummy time pillow manufacturers may also omit the word ''only'' from the statement ''use only on floor with baby on back, face up'' to accommodate the multi-use positioning of the product which is indicated in new figure 3. This entire warning statement bullet point was also moved up within the warning statement in figures 2 and 3 to reflect the serious hazard to infants from prone positioning. Products without a tummy time feature are required to use figure 2.

Comment: The Joint Consumer Advocate Commenters propose requiring the product warning label on replacement covers for infant support cushions.

Response: The Commission agrees that warning labels should be included on slipcovers that are sold on or together with infant support cushions. As discussed above regarding slipcovers sold on or together with the product that

[29] Erin M. Mannen et al; Consumer Prod. Safety Comm'n. *Pillows Product Characterization and Testing* (2022). *www.cpsc.gov/content/Pillows-Product-Characterization-and-Testing.*

[30] Staff's NPR Briefing Package, available at: *www.cpsc.gov/s3fs-public/Briefing-Package-Notice-of-Proposed-Rulemaking-Safety-Standard-for-Infant-Support-Cushions.pdf?VersionId=rA60lesWHddS1.wrk_EvV00xeX75dsFc.*

must be tested with the slipcover installed on the product, the definition of infant support cushion in § 1243.2 has been revised to add a new sentence at the end of the definition, ''This definition includes any removable covers, or slipcovers, sold on or together with an infant support cushion,'' to make clear that slipcovers sold on or together with the product are subject to the requirements of the rule. However, aftermarket slipcovers or third-party covers are considered accessories that are not part of the product and thus not subject to the rule. Finally, in response to this comment, § 1243.6(e) of the final rule has been revised to require warning labels on slipcovers that are sold on or together with an infant support cushion.

Comment: Safe Infant Sleep recommends laundering/cleaning instructions to mitigate a mold hazard.

Response: Incident data do not indicate there is a mold hazard that would require infant support cushions to have laundering/cleaning instructions as part of this rulemaking. Therefore, the Commission assesses at this time no requirement is needed to address laundering/cleaning. However, if this information is provided, it should not be placed on a warning label because warning labels that have too much information that is not urgent for the user of the product dilute all messages on the label.

Comment: The Joint Consumer Advocate Commenters suggest that CPSC should consider more ways to clearly emphasize in the warning label that infant support cushions should not be used for sleep.

Response: The Commission assesses that no change to the rule is needed to clearly emphasize the warning against using infant support cushions for sleep because this message is already strongly communicated through the initial sentence of the warning about the deadly consequences of using the product for sleep or naps.

Comment: Safe Infant Sleep objects to using the statement ''using this product for sleep or naps can kill'' because this statement implies that naps are different than sleep and this can be damaging to safe sleep education. The commenter instead recommends ''using this product for ANY duration of sleep, even when supervised can kill.''

Response: Consumers have indicated that ''sleep'' and ''naps'' may mean different things for infants and have indicated that infants ''nap'' anywhere but should be in a specific sleep product when they are put to ''sleep.'' [31] Therefore, the rule retains the requirement for the warning label to contain the statement ''using this product for sleep or naps can kill'' to reinforce that the products are unsafe for all types of sleep. However, the final rule revises the warning labels in figure 2 and new figure 3 of § 1243.6 by separating ''stay near and watch baby during use'' from ''if a baby falls asleep, move baby to infant sleep product, such as a crib or bassinet.'' These changes, which provide clearer instruction on what a caregiver should do if their baby falls asleep, have been made to figure 2 and new figure 3 of § 1243.6.

Comment: Graco notes that the warning ''use only with an awake baby'' is a new type of warning and it is not clear if parents understand what level of awake their baby should be.

Response: The Commission agrees that the phrase ''use only with an awake baby'' from the warning statement should be removed because the safety messaging to not use infant support cushions with sleeping infants or in an infant sleep setting is already strongly communicated through the initial sentence of the warning about the deadly consequences of using the product for sleep or lounging. Therefore, the final rule removes ''use only with an awake baby'' from the warning labels in figure 2 and new figure 3 of § 1243.6.

Comment: Heroes Technology recommends changing the proposed warning ''USING THIS PRODUCT FOR SLEEP OR NAPS CAN KILL'' to ''USING THIS PRODUCT FOR INFANT SLEEP OR NAPS CAN LEAD TO SERIOUS INJURIES OR DEATH.''

Response: We disagree with the commenter's recommended change to the warning label. First, the warning label statement ''can kill'' is an accurate and concise statement of the consequences of infants sleeping or napping on infant support cushions. Warning messages on many infant products are often too long, resulting in consumers not reading and heeding the messages. The commenter's recommended statement ''can lead to serious injuries or death'' is much less impactful than ''can kill'' and thus would not be as effective in warning caregivers about the serious suffocation hazard to infants from using these products for sleep or naps.

Comment: Heroes Technology suggests stronger warning language surrounding the use of soft bedding in and around infant support cushions.

Response: Incident data indicate that infant deaths occurred when soft bedding was placed in an infant support cushion. Infant deaths also occurred when the product was used on soft bedding and the infant rolled out of the product into a hazardous setting containing soft bedding around the product. The Commission accordingly agrees that the rule should have stronger warning language regarding the use of soft bedding in and around infant support cushions. Therefore, the warning labels in figure 2 and new figure 3 of § 1243.6 have been revised to add ''Do not use on soft surfaces or in sleep products like cribs or bassinets. Keep blankets and other soft items out of and away from product.'' to warn against the hazard presented by soft bedding in and around infant support cushions. Additionally, this revision to figure 2 and new figure 3 of § 1243.6 in the final rule separates this warning statement into a separate bullet point to emphasize the risk to infants from soft bedding.

Comment: Heroes Technology suggests stronger and more impactful language surrounding the fall risk from placing the product on elevated surfaces, and warning consumers that infants may roll unexpectedly.

Response: We disagree that the warning label in the rule requires stronger and more impactful language regarding the fall risk from placing infant support cushions on elevated surfaces and warning consumers that their infants may roll unexpectedly is necessary. These messages are already presented concisely on the warning labels in figure 2 and new figure 3 of § 1243.6.

Comment: Graco states that the warning statements were not provided in the proposed regulatory text and were only provided in figure 2 of the NPR.

Response: The proposed rule characterized the warning label in figure 2 as an example. Thus, it was unclear if the exact content and format for the warning label depicted in proposed figure 2 in § 1243.6(d)(7) is required. The final rule clarifies that the required content and format of the warning labels in figure 2 and new figure 3 are to be used exactly as written, as applicable. Additionally, in § 1243.6(d)(7), the word example was removed from the figure 2 and new figure 3 captions.

Comment: Graco recommends adding the following statement to the warning label of the infant support cushion rule: ''For babies with medical conditions, developmental delay, or complications relating to premature birth, consult a doctor before use.''

[31] Fors Marsh Group's, 2022 ''Consumer Product Safety Commission (CPSC): Sleep Warnings Final Report'', available at: *www.cpsc.gov/s3fs-public/Consumer-Product-Safety-Commission%E2%80%93Sleep-Warnings-Final-Report.pdf?VersionId=MfJcAAip4YNWVf.RllvXQtwNN7chjHyt.*

Response: The Commission disagrees with requiring this information to be placed on the warning label because not all helpful information needs to be included on the warning label in the rule. The warning label in § 1243.6 of the rule includes messaging focused on the serious suffocation and fall hazards posed by infant support cushions.

I. Comparative Analysis

Comment: JPMA argues that CPSC has not provided a risk/benefit analysis, risk/hazard analysis, or a consumer choice analysis regarding the proposed rule.

Response: The types of analysis described by the commenter that would quantify the hazard reduction benefits versus the costs of compliance are not required by section 104 of the CPSIA. A consumer choice model would require detailed consumer demand data that commenters did not provide and would involve quantifying consumer demand for theoretical product alternatives not specified by the commenter and not required by section 104 of the CPSIA. The Initial Regulatory Flexibility Analysis (IRFA) [32] did provide a specific numerical estimate of the cost of compliance, and the staff analysis of incidents found multiple deaths each year associated with these products—17 deaths per year in 2021 and at least 17 in 2022.[33]

J. Effective Date

Comments: Boppy, Heroes Technology, and JPMA contend that a 180-day effective date is insufficient for compliance and argue that a one-year effective date would be appropriate to limit the burdens on manufacturers.

Response: While the commenters assert that 180 days is insufficient time to comply with the rule without burdening manufacturers, they do not provide any specific data or information showing that the level of effort to redesign and distribute an infant support cushion would require a one-year compliance period. Furthermore, JPMA typically allows 180 days for products in their certification program to implement a new voluntary standard such that juvenile product manufacturers are accustomed to adjusting to new standards within this time frame. Therefore, the rule provides a reasonable effective date that takes into consideration manufacturers burdens and the risk of continued infant injuries and deaths. Based on the urgency of addressing the hazards associated with infant support cushions, the 180-day effective date proposed in the NPR is appropriate and is being finalized as proposed.

K. Stockpiling

Comments: AAP and the Joint Consumer Advocate Commenters request that CPSC take action to prevent manufacturers from increasing production of, or stockpiling, noncompliant infant support cushions and to prevent sellers from putting on the market large quantities of products that are noncompliant.

Response: The Commission notes the commenters' recommendations to include a stockpiling provision in the final rule. Commenters provided no evidence that manufacturers or importers are likely to increase significantly their manufacture or importation of infant support cushions before the rule's effective date. In addition, the 180-day effective date should serve to limit the stockpiling of noncompliant products so as to prevent such manufacturers from circumventing the purpose of the rule. Therefore, the final rule does not include a stockpiling provision.

L. Regulatory Procedure

Comment: BPQ requests that CPSC revise the NPR and reissue it for public comment to reflect recent revisions to ASTM's draft infant lounger voluntary standard.

Response: As of the date of the publication of the final rule, there is no voluntary standard addressing the suffocation and fall hazards of infant support cushions on which a mandatory rule could be based. Additionally, the draft ASTM standard is in draft form and subject to change as part of the consensus process. Section 104 of the CPSIA does not require an existing voluntary standard in order for the Commission to promulgate a safety standard for a durable infant or toddler product. *See* 15 U.S.C. 2056a(b)(2); *Finnbin, LLC* v. *Consumer Prod. Safety Comm'n,* 45 F.4th 127, 134 (D.C. Cir. 2022).

Comment: Boppy and Heroes Technology argue that this rule cannot be promulgated under section 104 of the CPSIA without a preexisting voluntary standard for infant support cushions.

Response: Section 104 of the CPSIA does not require an existing voluntary standard in order for the Commission to promulgate a safety standard for a durable infant or toddler product. *See* 15 U.S.C. 2056a(b)(2); *Finnbin, LLC* v. *CPSC,* 45 F.4th 127, 134 (D.C. Cir. 2022). In *Finnbin,* the court explained that CPSC has an express statutory command to regulate all categories of durable infant or toddler products and must do so for products not covered by voluntary standards. Furthermore, by the terms of 15 U.S.C. 2056a(b)(1), the requirement to examine and assess the effectiveness of any voluntary standards only applies if a voluntary standard exists. Because no voluntary standards currently address the suffocation and fall hazards posed by infant support cushions, the procedural requirements in section 104(b) of the CPSIA, to develop a rule with reference to an existing standard, do not apply to this rule.

Comment: Boppy argues that infant support cushions are not durable nursery products because infant support cushions are ''pillow-like'' and pillows are soft, textile products that are in no way comparable to cribs, strollers, bathtubs, or bed rails. Boppy additionally argues that there are no products in either the original twelve, or additional six product categories of durable goods that can be rationally compared to ''pillows.''

Response: Infant support cushions meet the statutory requirement for durable infant or toddler products in section 104(f)(1) of the CPSIA because they are intended for use, and may be reasonably expected to be used, by children under the age of 5 years and routinely have a life span of several years. They are not disposable; have a useful life of up to several years and are often used by multiple children in succession; are similar to other soft durable infant and children's products such as crib mattresses and sling carriers (which the Commission has issued rules for under section 104); are resold and widely available on secondary marketplaces; and are primarily intended to be used by children five years old or younger. Therefore, although infant support cushions are not specifically listed in section 104(f)(2) of the CPSIA, the Commission may reasonably treat them as ''durable infant or toddler products.''

The Commission has previously added to the statutory list of durable infant or toddler products by including other products for young infants, such as changing products and infant bouncers, that also have a market for secondary use. As the Commission explained in 2009, ''[b]ecause the statute has a broad definition of a durable infant or toddler product but

[32] *See* Tab E of Staff's NPR Briefing Package, available at: *www.cpsc.gov/s3fs-public/Briefing-Package-Notice-of-Proposed-Rulemaking-Safety-Standard-for-Infant-Support-Cushions.pdf?VersionId=rA60lesWHddS1.wrk_EvV00xeX75dsFc.*

[33] *See* Tab A of Staff's NPR Briefing Package, available at: *www.cpsc.gov/s3fs-public/Briefing-Package-Notice-of-Proposed-Rulemaking-Safety-Standard-for-Infant-Support-Cushions.pdf?VersionId=rA60lesWHddS1.wrk_EvV00xeX75dsFc.*

also includes 12 specific product categories, additional items can and should be included in the definition.'' Requirements for Consumer Registration of Durable Infant or Toddler Products, 74 FR 68668, 68669 (December 29, 2009).

Comments: Boppy contends the proposed rule is unconstitutional because it violates the non-delegation doctrine and the Separation of Powers and Appointments Clause of the U.S. Constitution.

Response: The rule is being promulgated under the Danny Keysar Child Product Safety Notification Act, section 104 of the CPSIA, which directs the Commission to promulgate consumer product safety standards for durable infant or toddler products. CPSC is an independent agency and the Commissioners do not exercise Executive power, consistent with the Supreme Court's holding in *Humphrey's Executor* v. *United States,* 295 U.S. 602 (1935). Several Federal Courts of Appeals have recently rejected similar Constitutional arguments about CPSC. *Consumers' Rsch.* v. *CPSC,* 91 F.4th 342 (2024), petition for cert. filed, *(Consumers' Rsch.* v. *CPSC,* No. 23–1323 (petition for cert. filed on July 18, 2024)), and *Leachco, Inc.* v. *CPSC,* 103 F4th 748 (10th Cir. 2024), petition for cert. pending, No. 22–7060 (filed Aug. 9, 2024)).

VII. Description of the Final Rule for Infant Support Cushions

As section 104 of the CPSIA requires, to address the risks of death and injury associated with infant suffocations, entrapments, and falls, the Commission is issuing this rule to establish mandatory performance and labeling requirements for infant support cushions. The requirements of the rule are based on an evaluation of incident data and the hazard patterns associated with infant support cushions, and the recommendations of the BSU Final Report. The final rule is summarized below, and the rule is being finalized as proposed in the NPR except as noted.

A. Section 1243.1 Scope, Purpose, Applications, and Exemptions

Section 1243.1 explains that the rule applies to infant support cushions, including infant positioners, nursing pillows with a dual use for lounging, infant loungers, infant props, or cushions used to support an infant for activities such as tummy time, and other infant pillow-like products. It excludes products already regulated by other Commission mandatory standards for durable infant products, which are listed in 16 CFR 1130.2(a). The rule applies to all infant support cushions manufactured after the effective date of the rule. Section 1243.1 is being finalized without changes as proposed in the NPR.

B. Section 1243.2 Definitions

Section 1243.2 provides definitions for the following terms used in the rule: conspicuous, infant lounger, infant positioner, infant support cushion, occupant support surface, seat bight line, and sidewall. The definitions in § 1243.2 are being finalized as proposed in the NPR except as discussed below. In response to a comment from Graco and for clarity, the definition of infant lounger has been revised to change the proposed words ''infant product'' to ''infant support cushion'' in the final rule. Also, in response to comments from Safe Infant Sleep and The Joint Consumer Advocate Commenters, the definition of infant support cushion has been revised to add a new sentence at the end of the definition ''This definition includes any removable covers, or slipcovers, sold on or together with an infant support cushion''. Finally, in response to a comment from Boppy, a new definition for the term ''sidewall,'' which is defined as ''any wall at the edge of the occupant support surface'', has been added to the final rule to provide clarity regarding the meaning of that term.

C. Section 1243.3 General Requirements

Section 1243.3 provides general requirements for infant support cushions, including requirements addressing hazardous sharp edges or points (§ 1243.3(a)), small parts (§ 1243.3(b), lead in paints (§ 1243.3(c)), toys (§ 1243.3(d)), the removal of components (§ 1243.3(e)), the permanency of labels and warnings (§ 1243.3(f)), and convertible products (§ 1243.3(g)). Section 1243.3 is being finalized as proposed in the NPR except that the reference to ''infant pillow'' in § 1243.3(d) has been changed in the final rule to ''infant support cushion'' for accuracy and consistency based on a comment from TA. The final rule also removes proposed § 1243.3(e) regarding side height. Measuring the height of the product is unnecessary and thus duplicative because the maximum incline angle test in § 1243.5(d)(7) already accounts for the height of the product remaining under 2 inches. The final rule renumbers the paragraphs following § 1243.3(d) to reflect this change.

D. Section 1243.4 Performance Requirements

Section 1243.4 provides performance requirements for infant support cushions for restraints (§ 1243.4(a)), seam strength (§ 1243.4(b)), bounded openings (§ 1243.4(c)), maximum incline angle (§ 1243.4(d)), firmness (§ 1243.4(e)), and sidewall angle (§ 1243.4(f)). Section 1243.4 is being finalized as proposed in the NPR except as discussed below. In response to a comment from Boppy, two changes have been made in paragraph (e) of § 1243.4 that establishes requirements for firmness. In § 1243.4(e)(2) and (3), ''For products with a sidewall'' has been added to the beginning of the sentence because the proposed rule did not make clear whether the performance requirements are applicable to products without sidewalls. Additionally, in response to a comment from Boppy, the same change has been made to § 1243.4(f) that establishes requirements for side angles because the proposed rule did not clarify the applicability of performance requirements for products without sidewalls.

E. Section 1243.5 Test Methods

Section 1243.5 provides the test methods to be used to test for compliance with the requirements of the rule. Section 1243.5 includes test methods for test conditions (§ 1243.5(a)), test for permanence of labeling and markings (§ 1243.5(b)), head entrapment test (§ 1243.5(c)), maximum incline test (§ 1243.5(d)), firmness test setup (§ 1243.5(e), occupant support surface firmness test method (§ 1243.5(f)), sidewall firmness test method (§ 1243.5(g)), test method for the intersection of sidewall and occupant support surface firmness (§ 1243.5(h)), test method for sidewall angle determination (§ 1243.5(i)), seam strength test method (§ 1243.5(j)), and removal of components test method (§ 1243.5(k)). Section 1243.5 is being finalized as proposed in the NPR except as discussed below.

For the same reason discussed above for the removal of proposed § 1243.3(e) regarding side height, the final rule removes the corresponding test in § 1243.5(d)(8) for consistency. To reflect this change, all numbers after § 1243.5(d)(7) have been renumbered.

In response to a comment from Safe Infant Sleep, the following language has been added after the first sentence of § 1243.5(f): ''For products sold with a slipcover on or together with the product, products shall be tested as assembled with the slipcover on the product.'' This language has been added

to the final rule because slipcovers with extra padding or cushioning may introduce suffocation hazards that would not be addressed if slipcovers sold on or together with an infant support cushion were not required to be tested as assembled with the slipcover on the product. In response to a comment from Boppy, right after the new sentence added above, the following language has been added to § 1243.5(f) of the final rule: ''All products, including products one inch or less in thickness, are required to be tested.'' This language has been added to the final rule because a product could either vary in thickness or be so close to 1 inch in thickness that it would be difficult to determine thickness without testing. In response to another comment from Boppy, § 1243.5(g) of the final rule adds in the first sentence ''products with a sidewall'' between ''For'' and ''perform'' because the proposed rule did not specifically clarify the applicability of test methods for products without sidewalls. The Boppy comment also resulted in changes to § 1243.5(h) and (i) at the beginning of the first sentence, adding ''For products with a sidewall,'' before ''perform,'' to state directly that products with sidewalls must be tested according to the test methods.

F. Section 1243.6 Marking and Labeling

Section 1243.6 provides the marking and labeling requirements for infant support cushions, including general markings (§ 1243.6(a)), permanency (§ 1243.6(b)), upholstery labeling (§ 1243.6(c)), warning design for product (§ 1243.6(d)), and warning statements (§ 1243.6(e)). Section 1243.6 is being finalized as proposed in the NPR except as discussed below.

Several changes have been made to figure 2 in § 1243.6(d)(7) as described below. We also add a new figure 3, Warning for Tummy Time Product, in § 1243.6(d)(7), as described below.

- In response to a comment from Graco, the phrase ''use only with an awake baby'' has been removed from the warning label in figure 2 and new figure 3 because the safety messaging to not use infant support cushions with sleeping infants or in an infant sleep setting is already strongly communicated through the initial sentence of the warning about the deadly consequences of using the product for sleep or naps, and limiting the amount of text on warning labels makes the material being presented more prominent.
- The rule clarifies that figure 2 in § 1243.6(d)(7) is required for all infant support cushions that do not have a tummy time feature.
- In response to comments from Boppy, AAP, BPQ, the Joint Consumer Advocate Commenters, Safe Infant Sleep, and JPMA, the Commission is adding a new figure 3 in § 1243.6(d)(7) for products with a tummy time feature. The statement bullet point was also moved up within the warning statement to reflect the serious hazard to infants presented by prone positioning. In new figure 3, the statement ''Put baby on back after Tummy Time'' is added to the warning label after the phrase ''Use only on the floor with baby on back, face up,'' to accommodate multi-use positions of some infant support cushion products, such as tummy time pillows that may have features that require the infant to be on their stomach while using the product. Figure 3 additionally omits the word ''only'' from ''use only on the floor with baby on back, face up''. Figure 3 is required only for products that have a tummy time feature because only those products that have a tummy time feature should allow for prone positioning.
- In response to a comment from Safe Infant Sleep the warning labels have been revised with more concise wording and clarity to provide instruction for what a caregiver should do if their baby falls asleep by separating ''stay near and watch baby during use'' from ''if a baby falls asleep, move baby to infant sleep product, such as a crib or bassinet''.
- In response to a comment from Heroes Technology, the warning labels for figure 2 and new figure 3 now includes the statement ''Do not use on soft surfaces or in sleep products like cribs or bassinets. Keep blankets and other soft items out of and away from product'' to discourage soft bedding use in and around the product. This revision also separates these warning statements into a separate bullet point to emphasize the risk to infants from soft bedding placed both in and around the product.
- In response to a comment from Graco, the word ''example'' was removed from the captions on figure 2 and new figure 3 because it was unclear if the exact content and format for the warning labels in § 1243.6(d)(7) is required as depicted in proposed figure 2 and new figure 3. Additionally, the final rule clarifies in § 1243.6(d)(7) that the content and format as depicted in figure 2 and new figure 3 as applicable, are required.
- Note 4 to proposed § 1243.6(e) has been removed from the rule as unnecessary because the final rule clarifies that the required content and format of the warning labels in figure 2 and new figure 3, as applicable, are to be used as written.
- A new note 4 to § 1243.6(d)(6) has been added below figure 1 for paragraph (d)(6), which was originally the language above figure 1 for paragraph (d)(6), with the new note 4 providing the original text indicating that the depicted warnings are filler text, known as lorem ipsum, commonly used to demonstrate graphic elements.
- In figure 2 and new figure 3, a black line has been inserted between the suffocation warnings and the fall warnings to distinguish between the messages.

The changes described above are depicted below in the revised figure 2, Warning for Product Without Tummy Time, and new figure 3, Warning for Tummy Time Product, from § 1243.6 of the final rule.

Warning for Product Without Tummy Time

⚠WARNING

USING THIS PRODUCT FOR SLEEP OR NAPS CAN KILL.

Babies can turn over or roll out without warning and CAN SUFFOCATE in only a few minutes.

- **Only use on the floor with baby on back, face-up.**
- **Stay near and watch baby during use.**
- **Do not use on soft surfaces or in sleep products** like cribs or bassinets. Keep blankets and other soft items out of and away from product.
- If baby falls asleep, move baby to infant sleep product, such as a crib or bassinet.

Babies have been injured from FALLS.

- Do not use on beds, sofas, or other raised surfaces.
- Never carry or move product with baby in it.

Warning for Tummy Time Product

⚠WARNING

USING THIS PRODUCT FOR SLEEP OR NAPS CAN KILL.

Babies can turn over or roll out without warning and CAN SUFFOCATE in only a few minutes.

- **Use on the floor with baby on back, face-up.** Put baby on back after Tummy Time.
- **Stay near and watch baby during use.**
- **Do not use on soft surfaces or in sleep products** like cribs or bassinets. Keep blankets and other soft items out of and away from product.
- If baby falls asleep, move baby to infant sleep product, such as a crib or bassinet.

Babies have been injured from FALLS.

- Do not use on beds, sofas, or other raised surfaces.
- Never carry or move product with baby in it.

Additionally, in response to a comment from the Joint Consumer Advocate Commenters, the final rule adds language at the end of § 1243.6(e) stating that slipcovers, sold on or together with the product, are required to contain a warning with the content and format depicted in figure 2 or 3, as applicable, to paragraph (d)(7). This language is being added because when an infant support cushion is sold with a slipcover, it is expected that slipcover will hide the warning label that should be visible to a caregiver while placing an infant onto or into the product, when the product is in the manufacturer's recommended use position. Therefore, the warning label should be conspicuously located on the slipcover as is required for an infant support cushion that does not come with a slipcover.

G. Section 1243.7 Instructional Literature

Section 1243.7 provides requirements for instructional literature for infant

support cushions, including requiring instructional literature be provided with the product, as well as requirements as to what such information must include. Section 1243.7 also requires that instructional literature meet the requirements of the National Electrical Manufacturers Association's (NEMA's) ANSI Z535.4–2011(R2017), *American National Standard for Product Safety Signs and Labels* (ANSI Z535.4–2011). The final rule specifically requires the warning format requirements in sections 6.1–6.4, 7.2–7.6.3, and 8.1 of ANSI Z535.4–2011(R20217). Finally, under § 1243.7 any instructions provided in addition to those required by § 1243.7 shall not contradict or confuse the meaning of the required information or be otherwise misleading to the consumer. Section 1243.7 is being finalized as proposed in the NPR.

H. Section 1243.8 Incorporation by Reference

Section 1243.8 incorporates by reference ANSI Z535.4–2011(R20217), *American National Standard for Product Safety Signs and Labels,* and ASTM D3359–23, *Standard Test Methods for Rating Adhesion by Tape Test,* and provides information on where those standards are available. ANSI Z535.4–2011 includes requirements related to safety alert symbol use; signal word selection; warning panel format, arrangement, and shape; color requirements for each panel; letter style; to identify and warn against specific hazards; and to provide information to avoid personal injury. ASTM D3359–23 covers procedures for assessing the adhesion of relatively ductile coating films to metallic substrates by applying and removing pressure-sensitive tape over cuts made in the film.

VIII. Amendment to 16 CFR Part 1112 To Include NOR for Infant Support Cushions

Products subject to a consumer product safety rule under the CPSA, or to a similar rule, ban, standard, or regulation under any other act enforced by the Commission, must be certified as complying with all applicable CPSC-enforced requirements. 15 U.S.C. 2063(a). Certification of children's products subject to a children's product safety rule must be based on testing conducted by a CPSC-accepted third-party conformity assessment body. 15 U.S.C. 2063(a)(2). The Commission must publish an NOR for the accreditation of testing laboratories as third party conformity assessment bodies to assess conformity with a children's product safety rule. 15 U.S.C. 2063(a)(3). The infant support cushions rule is a children's product safety rule that requires the issuance of an NOR.

The Commission's rules, at 16 CFR part 1112, establish requirements for accreditation of third party conformity assessment bodies to test for conformance with a children's product safety rule in accordance with section 14(a)(2) of the CPSA. Part 1112 also lists the NORs that the CPSC has published. In the NPR the Commission proposed to amend part 1112 to include the Safety Standard for Infant Support Cushions in the list of children's product safety rules for which the CPSC has issued NORs. Section 1112.15(a)(57) is being finalized as proposed in the NPR.

Laboratories applying for acceptance as a CPSC-accepted third party conformity assessment body to test to the new Safety Standard for Infant Support Cushions standard are required to meet the third party conformity assessment body accreditation requirements in part 1112. When a laboratory meets the requirements as a CPSC-accepted third party conformity assessment body, the laboratory can apply to the CPSC to have the Safety Standard for Infant Support Cushions included in its scope of accreditation as reflected on the CPSC website at *www.cpsc.gov/labsearch*.

IX. Amendment to 16 CFR Part 1130 To Include Infant Support Cushions

Infant support cushions are a category of ''durable infant or toddler product'' for purposes of CPSIA section 104 because they: are intended for use, and may be reasonably expected to be used, by children under the age of five years; are products similar to other products listed in section 104(f)(2), such as crib mattresses, and sling carriers; and are commonly resold or ''handed down'' for use by other children over a period of years. In the NPR, the Commission proposed to amend 16 CFR part 1130 to include Infant Support Cushions as durable infant or toddler products. Section 1130.2(a)(20) is being finalized as proposed in the NPR.

X. Incorporation by Reference

The rule incorporates by reference ANSI Z535.4–2011(R2017), *American National Standard for Product Safety Signs and Labels,* and ASTM D3359–23, *Standard Test Methods for Rating Adhesion by Tape Test.* In accordance with the regulations of the Office of the Federal Register, 1 CFR part 51, section VII.H of this preamble summarizes the requirements of the ANSI Z535.4–2011(R2017) and ASTM D3359–23.

Both standards are reasonably available to interested parties in several ways. Interested persons may purchase a copy of ANSI Z535.4–2011(R2017) from the National Electrical Manufacturers Association (NEMA), 1300 17th St. N, Arlington, VA 22209; phone: (703) 841–3200; website: *www.nema.org.* This standard is also available from ANSI via its website, *www.ansi.org,* or by mail from ANSI, 25 West 43rd Street, 4th Floor, New York, NY 10036, telephone: (212)–642–4900. Once the rule takes effect, a read-only copy of ANSI Z535.4–2011(R2017) will be available for viewing, at no cost, on the ANSI website at: *https://ibr.ansi.org/Standards/nema.aspx.* Interested individuals may purchase a copy of ASTM D3359–23 from ASTM, through its website, *www.astm.org,* or by mail from ASTM International, 100 Barr Harbor Drive, P.O. Box 0700, West Conshohocken, PA 19428–2959. Once the rule takes effect, a read-only copy of the standard will be available for viewing, at no cost, on the ASTM website at: *www.astm.org/READINGLIBRARY/.* Alternatively, interested parties may inspect a copy of the standards at CPSC's Office of the Secretary by contacting Alberta E. Mills, Commission Secretary, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; phone: (301) 504–7479; email: *cpsc-os@cpsc.gov.*

XI. 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 the NPR the Commission proposed an effective date of 180 days after publication of the final rule in the **Federal Register**. This amount of time is typical for rules issued under section 104 of the CPSIA. We note that the 180-day effective date is the same amount of time that JPMA typically allows for products in their certification program to shift to a new standard once that standard is published. Therefore, juvenile product manufacturers are accustomed to adjusting to new standards within this time frame. We noted in the NPR that a 180-day effective date should also be sufficient for manufacturers to comply with this rule because the proposed requirements do not demand significant preparation by testing laboratories. For example, no new complex testing instruments or devices would be required to test infant support cushions for compliance with this rule. Based on the urgency of addressing the hazards associated with infant support cushions, the 180-day effective date proposed in

the NPR is appropriate and is being finalized as proposed.

XII. Regulatory Flexibility Act

When an agency is required to publish a notice of proposed rulemaking, the Regulatory Flexibility Act (5 U.S.C. 601–612) generally requires that the agency prepare an IRFA for the NPR and a final regulatory flexibility analysis (FRFA) for the final rule. 5 U.S.C. 603, 604. These analyses must describe the impact that the rule would have on small businesses and other entities. The FRFA must contain:

(1) a statement of the need for and objectives of the rule;

(2) significant issues raised by commenters on the IRFA, the agency's assessment of those issues, and changes made to the result as a result of the comments;

(3) a response to any comments filed by the Chief Counsel for Advocacy of the U.S. Small Business Administration (Advocacy), and changes made as a result of those comments;

(4) a description and estimate of the number of small entities to which the rule will apply;

(5) a description of the projected reporting, recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record; and

(6) steps the agency has taken to minimize the significant economic impact on small entities, consistent with the objective of the applicable statute, including the factual, policy, and legal reasons for selecting the alternative in the final rule and why other alternatives were rejected.

Staff prepared an IRFA for this rulemaking that was summarized in the NPR and provided in full Tab E of the Staff's NPR Briefing Package. The FRFA is provided below.

A. Need for and Objectives of This Rule

Section I of this preamble describes the reasons and legal basis for this final rule. As discussed in sections VI and VII of this preamble, the rule sets mandatory requirements for infant support cushions to address the suffocation, entrapment, and fall hazards associated with these products; adds infant support cushions to the list of products for which a registration card is required; and adds infant support cushions to the list of durable infant products for which an NOR is required.

B. Comments and Responses Concerning Impact on Small Entities

Comment: Boppy and Heroes Technology state that the maximum incline angle requirement, which limits product height to approximately 1.9 inches, would eliminate most products subject to this rule from the market, resulting in a significant loss of utility to consumers for compliant products, far in excess of CPSC's estimates.

Response: The IRFA stated that consumers might not purchase the redesigned compliant products and estimated a significant impact on a substantial number of small businesses. The commenters did not provide any data on their assertion that consumers might not want to buy products with a shorter side height. Given the number of playmats and similar items with no sides or short sides on the market, there is ample evidence that consumers are willing to purchase such items. The Commission has considered the significant impact on small entities in the IRFA, and it is discussed in the possible alternatives analysis in this FRFA and thus has taken this impact into account as required by the RFA.

Comment: JPMA states that this rule would require significant costly changes to make products compliant.

Response: JPMA did not provide quantitative estimates of supplier costs or consumer utility impacts to support a change in the burden estimates. The IRFA provided specific estimates of labor and materials costs for redesign. The scope of staff's analysis of burden, as required by 5 U.S.C. 603, was the impact on small U.S. businesses, and none of the comments provided information to support changing the estimates of impact on small U.S. businesses. The Commission has, however, considered the significant impact on small entities in finalizing this rule.

C. Issues Raised by the Small Business Administration

The Small Business Administration (SBA) did not submit a comment on the proposed rule.

D. Small Entities to Which the Rule Would Apply

The SBA sets size standards for what constitutes a U.S. small business for the purpose of various Federal Government programs,[34] 750 employees for manufacturers (NAICS code 314120) and 100 to 150 employees for wholesalers (NAICS codes 424350, 423990, and 424990).[35] Based on staff's assessment of prominent online and brick-and-mortar retail sources for infant support cushions in the Spring of 2023, there appear to be more than 2,000 suppliers of infant support cushions to the U.S. market, including small U.S. crafters, small importers, small manufacturers, and direct foreign shippers. Staff estimates that a significant number of these firms are small U.S. businesses based on the SBA thresholds cited above.

E. Compliance, Reporting, Paperwork, and Recordkeeping Requirements of the Rule

Suppliers will be required to comply with the performance requirements of the rule; provide a warning label, a consumer registration card, and user instructions; and conduct third-party testing to demonstrate compliance. Suppliers must demonstrate that they meet the performance requirements of the rule by providing certificates of compliance. As specified in 16 CFR part 1109, suppliers who are not the original manufacturer, such as importers, wholesalers, and retailers may rely on a certificate of conformity provided by their suppliers. Suppliers must also provide product registration cards. Recordkeeping and compliance documentation do not require specialized expertise. CPSC's public website provides instructions and examples for how to develop the certificates of compliance and product registration cards.[36] Similarly, because the final rule provides the text and graphics for the required labels and instructions, specialized graphics design expertise will not be required to develop the warnings and instructions.

F. Impact of the Rule on Small Entities

The rule will likely have a significant impact on a substantial number of U.S. small entities, based on the estimated costs of modifying the product to achieve compliance, and the ongoing cost of testing to demonstrate compliance. Staff considers one percent of annual revenue to be a ''significant''

[34] The size standards are in listed in the Code of Federal Regulations. *See* 13 CFR part 121.

[35] The North American Industry Classification System (NAICS) is the standard used by Federal statistical agencies in classifying business establishments for the purpose of collecting, analyzing, and publishing statistical data related to the U.S. business economy. For more information, see *www.census.gov/naics/*. Some programs use 6-digit NAICS codes, which provide more specific information than programs that use more general 3 or 4-digit NAICS codes.

[36] See for example: *www.cpsc.gov/Business—Manufacturing/Testing-Certification/Childrens-Product-Certificate;* and *www.cpsc.gov/Business—Manufacturing/Business-Education/Durable-Infant-or-Toddler-Products/FAQs-Durable-Infant-or-Toddler-Product-Consumer-Registration.*

economic impact on a company, consistent with economic analysis from other Federal Government agencies. Nearly all of the more than 2,000 suppliers of infant support cushions to the U.S. are small entities, although their products often are not manufactured in United States.

Most products on the market will require redesign to meet the requirements in the rule and no products on the market currently have the specific labels, customer registration forms, warnings, and third-party testing required by the rule. The effort required for a one-time redesign of a product is estimated to be 200 hours of professional staff time per model, including in-house testing of the prototypes and development of labels, customer registration forms, and instruction materials. Using the Bureau of Labor Statistics Employer Costs of Employee Compensation as of March 2024 [37] the estimated cost per model is $13,648, at a current cost for professional labor of $68.24 per hour, rounded for the purpose of analysis to $14,000 per model. Materials costs for prototyping are estimated to be minimal, likely under $1,000, given that pillows are typically made of fabric and stuffing materials. Third-party testing for infant support cushions will be an additional cost for all suppliers and is estimated to be between $600 and $1,100 per model, per year, depending on where the testing takes place and whether manufacturers' associations or groups add infant support cushions to their certification programs to receive volume discounts for third-party testing. The total first year costs of redesign are estimated to be approximately $16,000 per model ($14,000 for labor, $1,000 for materials, and $1,000 for third-party testing).

Staff considers one percent of annual revenue to be a ''significant'' economic impact on a small business. Applying the one percent threshold to the estimated redesign and testing costs from this rule, the threshold for a small business that would incur a significant impact are those small firms with less than $1.6 million in revenue ($16,000 costs ÷ 1 percent of revenue), assuming they only sell one product model. This cost estimate will scale with the number of different models each firm manufactures. With an estimated 2,000 models from firms that sell to the U.S. needing to be redesigned, the total cost for the entire industry could be as high as $32 million for redesign in the first year after the rule is published.[38]

As suppliers will need to redesign their products to comply with this rule, both small and large companies may raise prices to cover costs. Given this uniformity, these costs would not necessarily place small businesses at a competitive disadvantage. JPMA, Boppy, and Heroes Technology questioned whether a small retail price increase would be acceptable to consumers, or could cover compliance costs, but these commenters did not provide an alternative quantitative estimate of compliance costs or probable retail price increases.

In summary, given that all U.S. suppliers will have to redesign products to comply with this rule, and that these costs will likely be significant to many small businesses, this FRFA finds that this final rule will have a significant impact on a substantial number of U.S. small businesses.

G. Other Federal Rules That May Duplicate, Overlap, or Conflict With the Final Rule

CPSC has not identified any other Federal rules that duplicate, overlap, or conflict with the final rule.

H. Alternatives Considered To Reduce the Impact on Small Entities

The Commission considered alternatives to the final rule to reduce the impact on small businesses. The Commission considered using a public education campaign that would result in no regulatory impact on small businesses. However, given the education campaigns on safe sleep practices that CPSC and others have been undertaking for years, this approach would likely result in little to no mitigation of the current rates of deaths and injuries from infant support cushions. The Commission also considered allowing the voluntary standards process additional time to develop a voluntary standard to address the hazards posed by infant support cushions. However, there is no certainty that such a voluntary standard would be adopted, and a potential voluntary standard, if published, may not adequately address the identified hazards to infants. For example, the current ASTM draft voluntary standard for infant loungers would only cover infant loungers whereas the Commission's rule covers all infant support cushions and has more stringent performance requirements and warnings.

XIII. Paperwork Reduction Act

This rule contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA; 44 U.S.C. 3501–3521). The preamble to the NPR discussed the information collection burden of the proposed rule and specifically requested comments on the accuracy of CPSC's estimates. 89 FR 2530 (January 16, 2024). The NPR described the provisions of the proposed rule and provided an estimate of the annual reporting burden for the rule under the PRA. *See* 89 FR 2542. The estimated burden of this collection of information is unchanged from the NPR. CPSC did not receive any comments regarding the information collection burden in the NPR through OMB. OMB has assigned control number 3041–0202 to this information collection.

XIV. Preemption

Section 26(a) of the CPSA, 15 U.S.C. 2075(a), provides that when a consumer product safety standard is in effect and applies to a product, no state or political subdivision of a state may either establish or continue in effect a standard or regulation that prescribes requirements for the performance, composition, contents, design, finish, construction, packaging, or labeling of such product dealing with the same risk of injury unless the state requirement is identical to the Federal standard. Section 26(c) of the CPSA also provides that states or political subdivisions of states may apply to the Commission for an exemption from this preemption under certain circumstances. Section 104(b) of the CPSIA refers to the rules to be issued under that section as consumer product safety rules. Therefore, the preemption provision of section 26(a) of the CPSA apply to this final rule for infant support cushions.

XV. Environmental Considerations

Certain categories of CPSC actions normally have ''little or no potential for affecting the human environment'' and therefore do not require an environmental assessment or an environmental impact statement. Safety standards providing requirements for consumer products come under this categorical exclusion. 16 CFR 1021.5(c)(1). The final rule for infant support cushions falls within the categorical exclusion.

[37] *www.bls.gov/news.release/ecec.t02.htm.* The estimated costs in the link reflect the employers' cost for salaries, wages, and benefits for civilian workers.

[38] As noted earlier, this estimate is slightly higher than the estimate in the IRFA, because the relevant labor rate as reported by the Bureau of Labor Statistics has risen since the NPR was published.

XVI. Congressional Review Act

The Congressional Review Act (CRA; 5 U.S.C. 801–808) states that before a rule may take effect, the agency issuing the rule must submit the rule, and certain related information, to each House of Congress and the Comptroller General. 5 U.S.C. 801(a)(1). The CRA submission must indicate whether the rule is a major rule. The CRA states that the Office of Information and Regulatory Affairs determines whether a rule qualifies as a major rule.

Pursuant to the CRA, OMB's Office of Information and Regulatory Affairs has determined that this rule does not qualify as a major rule, as defined in 5 U.S.C. 804(2). To comply with the CRA, CPSC will submit the required information to each House of Congress and the Comptroller General.

List of Subjects

16 CFR Part 1112

Administrative practice and procedure, Audit, Consumer protection, Reporting and recordkeeping requirements, Third party conformity assessment body.

16 CFR Part 1130

Administrative practice and procedure, Business and industry, Consumer protection, Reporting and recordkeeping requirements.

16 CFR Part 1243

Consumer protection, Imports, Incorporation by reference, Infants and children, Labeling, Law enforcement, Pillows, Toys.

For the reasons discussed in the preamble, the Commission amends chapter II of title 16 of the Code of Federal Regulations as follows:

PART 1112—REQUIREMENTS PERTAINING TO THIRD PARTY CONFORMITY ASSESSMENT BODIES

■ 1. The authority citation for 16 CFR part 1112 continues to read as follows:

Authority: 15 U.S.C. 2063.

■ 2. Amend § 1112.15 by adding paragraph (b)(57) to read as follows:

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

* * * * *

(b) * * *

(57) 16 CFR part 1243, Safety Standard for Infant Support Cushions.

* * * * *

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

■ 3. The authority citation for 16 CFR part 1130 continues to read as follows:

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

■ 4. Amend § 1130.2 by adding paragraph (a)(20) to read as follows:

§ 1130.2 Definitions.

* * * * *

(a) * * *

(20) Infant support cushions.

* * * * *

■ 5. Add part 1243 to read as follows:

PART 1243—SAFETY STANDARD FOR INFANT SUPPORT CUSHIONS

Sec.

Authority: 15 U.S.C. 2056a.

§ 1243.1 Scope, purpose, application, and exemptions.

(a) *Scope and purpose.* The consumer product safety standard in this part prescribes requirements to reduce the risk of death and injury from hazards associated with *infant support cushions,* as defined in § 1243.2. This includes but is not limited to *infant positioners,* nursing pillows with a dual use for lounging, *infant loungers,* and infant props or cushions used to support an infant. All *infant support cushions* must be tested according to the requirements of § 1243.5 and comply with all requirements of this part.

(b) *Application.* All infant support cushions manufactured after May 5, 2025, are subject to the requirements of this part.

(c) *Exemptions.* Products subject to another standard listed in 16 CFR 1130.2(a) are exempt from this part. Nursing pillows that also meet the definition of infant lounger in § 1243.2, however, are not exempt from this part.

§ 1243.2 Definitions.

Conspicuous means visible, when the product is in each manufacturer's recommended use position, to a person while placing an infant into or onto the product.

Infant lounger means an infant support cushion with a raised perimeter, a recess, or other area that provides a place for an infant to recline or to be in a supine, prone, or recumbent position.

Infant positioner means a product intended to help keep an infant in a particular position while supine or prone.

Infant support cushion means an infant product that is filled with or comprised of resilient material such as foam, fibrous batting, or granular material or with a gel, liquid, or gas, and which is marketed, designed, or intended to support an infant's weight or any portion of an infant while reclining or in a supine, prone, or recumbent position. This definition includes any removable covers, or slipcovers, sold on or together with an infant support cushion.

Occupant support surface (OSS) means the area that holds up and bears the infant or any portion of the infant.

Seat bight line means the intersection of the seat back surface with the seat bottom surface.

Sidewall means any wall at the edge of the occupant support surface.

§ 1243.3 General requirements.

(a) *Hazardous sharp edges or points.* There shall be no hazardous sharp points or edges as determined by 16 CFR 1500.48 and 1500.49 before or after the product has been tested.

(b) *Small parts.* There shall be no small parts as determined by 16 CFR part 1501 before testing or presented as a result of testing.

(c) *Lead in paints.* All paint and surface coatings on the product shall comply with the requirements of 16 CFR part 1303.

(d) *Toys.* Toy accessories attached to, removable from, or sold with an infant support cushion, as well as their means of attachment, shall comply with the applicable requirements of 16 CFR part 1250.

(e) *Removal of components.* When tested in accordance with § 1243.5(k), any removal of components that are accessible to an infant while in the product or from any position around the product shall not present a small part, sharp point, or sharp edge as required in paragraphs (a) and (b) of this section.

(f) *Permanency of labeling and warnings.* (1) Warning labels, whether paper or non-paper, shall be permanent when tested in accordance with § 1243.5(b)(1) through (3).

(2) Warning statements applied directly onto the surface of the product by hot stamping, heat transfer, printing, wood burning, or any other method shall be permanent when tested in accordance with § 1243.5(b)(4).

(3) Non-paper labels shall not liberate small parts when tested in accordance with § 1243.5(b)(5).

(4) Warning labels that are attached to the fabric of the product with seams shall remain in contact with the fabric around the entire perimeter of the label when the product is in all manufacturer-recommended use positions and when tested in accordance with § 1243.5(b)(3).

(g) *Convertible products.* If the infant support cushion can be converted into another product for which a consumer product safety standard exists, the product also shall comply with the applicable requirements of that standard.

§ 1243.4 Performance requirements.

(a) *Restraint.* The product shall not include a restraint system.

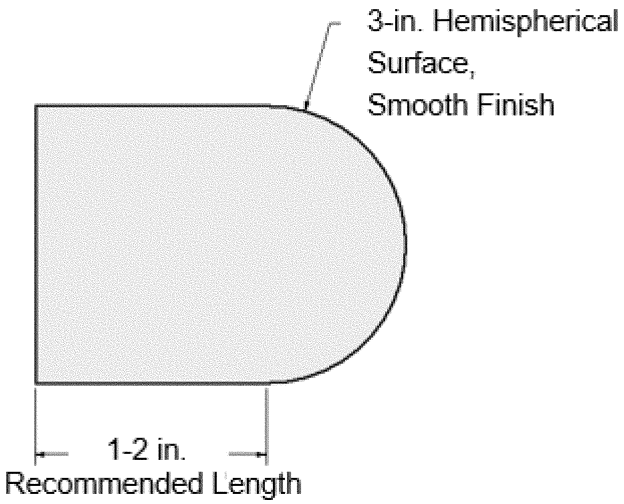
(b) *Seam strength.* When tested in accordance with § 1243.5(j), fabric/mesh seams and points of attachment shall not fail such that a small part, sharp point, or sharp edge is presented, as required in § 1243.3(a) and (b).

(c) *Bounded openings.* When tested to § 1243.5(c), all completely bounded openings that exist in the front, sides, or back of the occupant lounging area, or that are created when an accessory is attached to the product, shall not allow complete passage of the small head probe unless it allows the complete passage of the large head probe.

(d) *Maximum incline angle.* The maximum incline angle shall not exceed 10 degrees when tested in accordance with § 1243.5(d).

(e) *Firmness*—(1) *Occupant support surface firmness.* When the 3-inch diameter (figure 1 to this paragraph (e)(1)) hemispherical head probe is applied according to the test method for occupant support surface firmness, § 1243.5(f), the force required for a one-inch displacement shall be greater than 10 Newtons (N).

Figure 1 to paragraph (e)(1)—3-inch Head Probe



(2) *Sidewall firmness.* For products with a sidewall, when the 3-inch diameter hemispherical head probe is applied according to the test method for sidewall firmness in § 1243.5(g), the force required for a one-inch displacement shall be greater than 10 N.

(3) *Firmness at intersection of sidewall and occupant support surface.* For products with a sidewall, when the 3-inch diameter hemispherical head probe is applied according to the test method for firmness at the intersection of sidewall and occupant support surface in § 1243.5(h), the force required for a one-inch displacement shall be greater than 10 N.

(f) *Sidewall angle.* For products with a sidewall, the sidewall angle shall be greater than 90 degrees when determined according to the sidewall angle determination in § 1243.5(i).

§ 1243.5 Test methods.

(a) *Test conditions.* Condition the product for 48 hours at 23 °C +/− 2 °C (73.4 °F +/− 3.6 °F) and a relative humidity of 50% +/− 5%.

(b) *Permanence of labels and warnings.* (1) A paper label (excluding labels attached by a seam) shall be considered permanent if, during an attempt to remove it without the aid of tools or solvents, it cannot be removed, it tears into pieces upon removal, or such action damages the surface to which it is attached.

(2) A non-paper label (excluding labels attached by a seam) shall be considered permanent if, during an attempt to remove it without the aid of tools or solvents, it cannot be removed or such action damages the surface to which it is attached.

(3) A warning label attached by a seam shall be considered permanent if it does not detach when subjected to a 15-lbs (67–N) pull force applied in any direction using a ¾-inch diameter clamp surface.

(4) Adhesion test for warnings applied directly onto the surface of the product.

(i) Apply the tape test defined in Test Method B, Cross-Cut Tape Test of ASTM D3359 (incorporated by reference, see § 1243.8), eliminating parallel cuts.

(ii) Perform this test once in each different location where warnings are applied.

(iii) The warning statements will be considered permanent if the printing in the area tested is still legible and attached after being subjected to this test.

(5) A non-paper label, during an attempt to remove it without the aid of tools or solvents, shall not be removed or shall not fit entirely within the small parts cylinder defined in 16 CFR part 1501 if it can be removed.

(c) *Head entrapment test.* For all applicable openings, rotate the small head probe (figure 1 to this paragraph (c)) to the orientation most likely to fail and gradually apply an outward force from the occupant lounging area of 25 lbs (111 N). Apply the force to the probe in the direction most likely to fail within a period of 5 seconds and maintain it for an additional 10 seconds. If the small head probe can pass entirely through the opening in any orientation, determine if the large head probe (figure 2 to this paragraph (c)) can be freely inserted through the opening.

Figure 1 to paragraph (c)—Small Head Probe

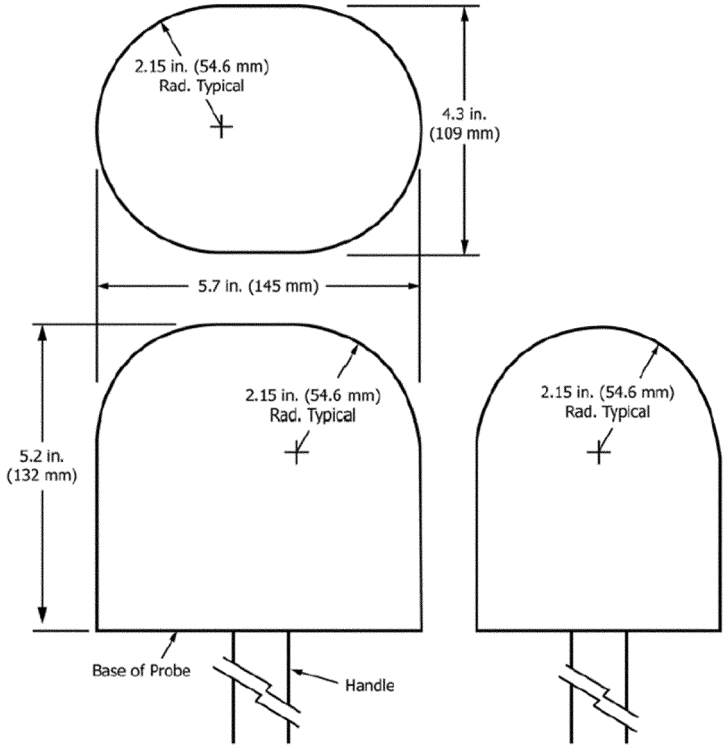
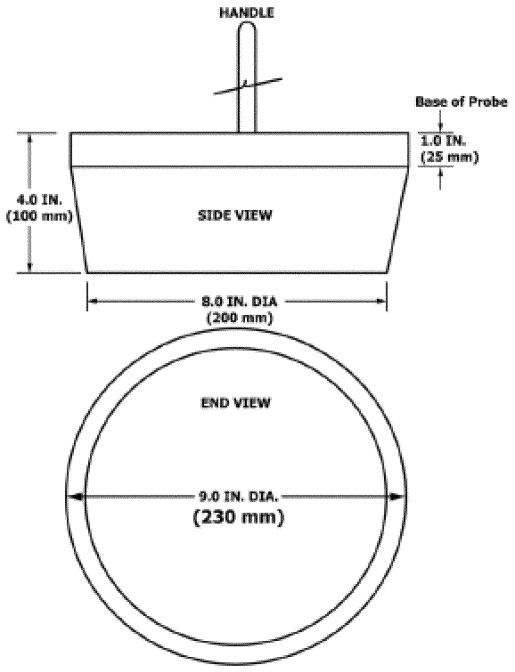


Figure 2 to paragraph (c)—Large Head Probe



(d) *Maximum incline test.* (1) Equipment shall include:

(i) Digital protractor with accuracy +/ − 1 degree;

(ii) Hinged weight gauge—newborn, requirements for part masses and assembly (figure 3 to this paragraph (d)(1)(ii));

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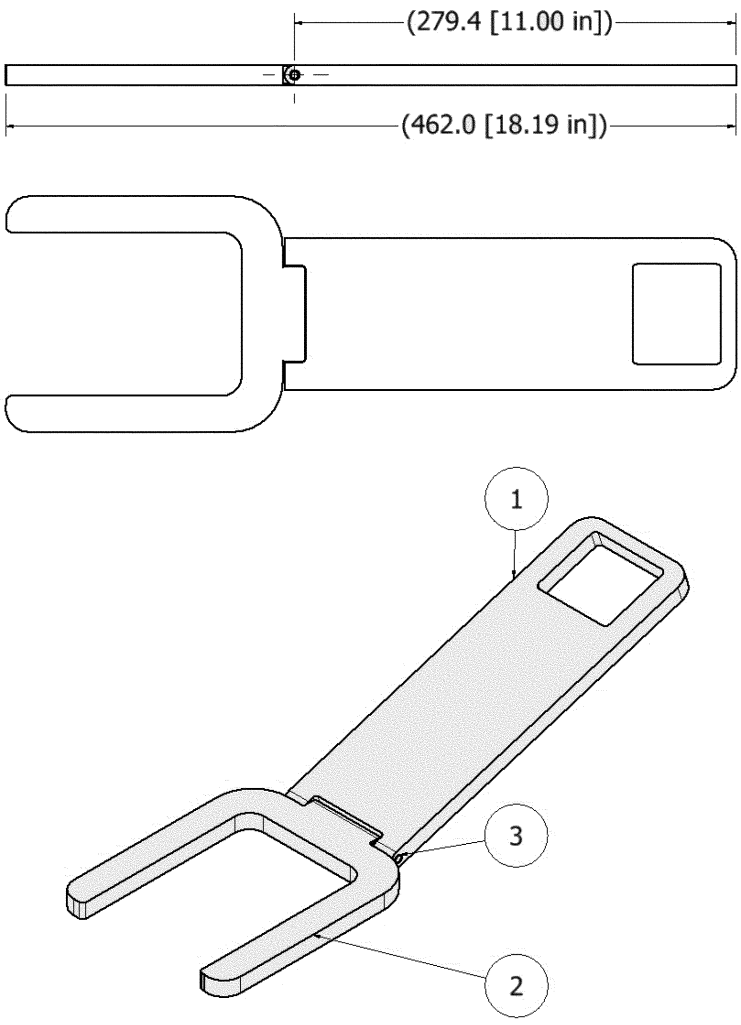
Figure 3 to paragraph (d)(1)(ii)—Hinged Weight Gauge—Newborn, Requirements for Part Masses and Assembly

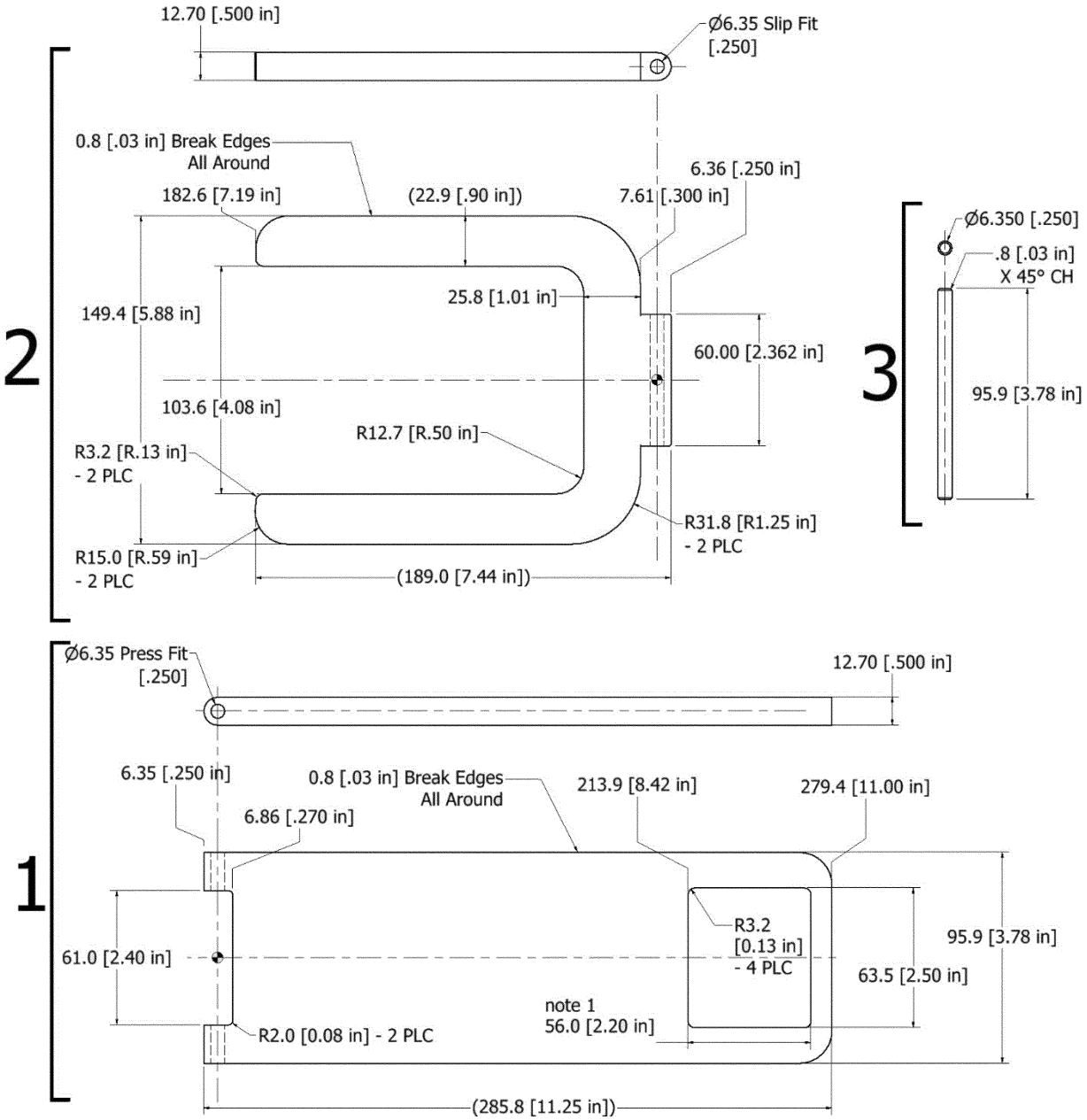
PARTS LIST			
ITEM	DESCRIPTION	MASS (1)	VOLUME
Assembly		3.378 ± .02 kg (7.447 ± .05 lb.)	
1	Upper Plate	2.275 kg (5.016 lb)	289.8 cm^3 (17.68 in^3)
2	Lower Plate	1.079 kg (2.379 lb)	137.4 cm^3 (8.385 cm^3)
3	Pin	0.024 kg (0.053 lb)	3.03 cm^3 (0.185 in^3)

Note 1. Part mass is calculated as Volume divided by the density for mild steel of 7.85 g/cm^3 (0.283 lbs/in^3).



(iii) Hinged weight gauge-newborn, requirements for part dimensions (figure 4 to this paragraph (d)(1)(iii)); and

Figure 4 to paragraph (d)(1)(iii)—Hinged Weight Gauge—Newborn, Requirements for Part Dimensions



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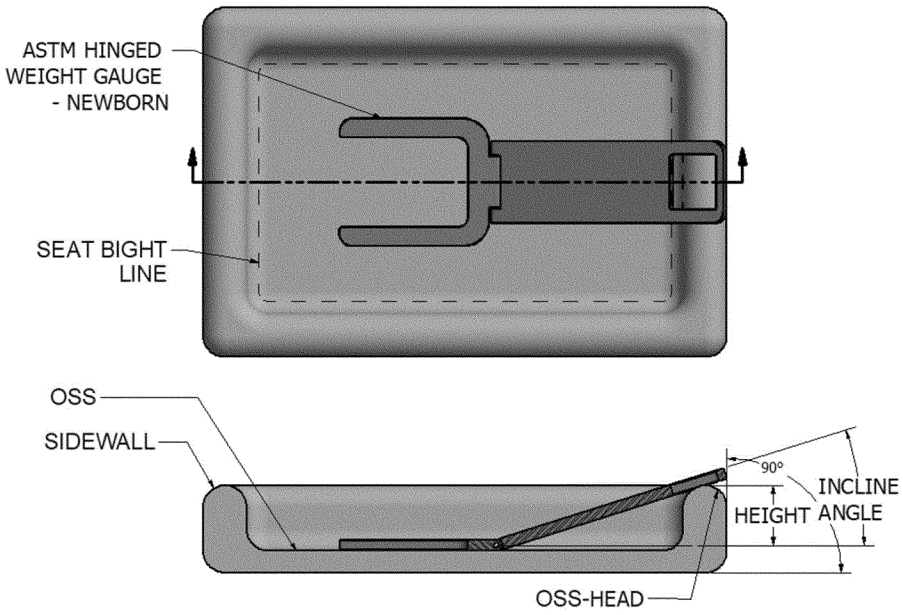
(iv) A test base that is horizontal, flat, firm, and smooth.

(2) If applicable, place the product in the manufacturer's recommended highest seat back angle position intended for lounging.

(3) If applicable, place the hinged weight gauge—newborn in the product and position the gauge with the hinge centered over the seat bight line and the upper plate of the gauge back. Place a digital protractor on the upper torso/head area lengthwise and measure the incline angle.

(4) Place the head/torso portion of the newborn hinged weight gauge on the product according to the manufacturer's recommended use position with the seat portion of the gauge, depending on the product design, allowed to lay freely on the product or on the test base (figure 5 to this paragraph (d)(4)).

Figure 5 to paragraph (d)(4)—Test Fixture Configuration to Measure Incline Angle on an Infant Support Cushion Product



(5) Move and rotate the newborn hinged weight gauge the minimum amount necessary such that the head/torso portion rests on an OSS that could foreseeably support an infant's head, and place the head/torso portion of the gauge according to all situations that apply:

(i) In tests on products with an OSS for the infant's body, align the top edge of the head/torso portion of the gauge to coincide with a plumb line to the outermost edge of the OSS-head.

(ii) In all tests, place the seat portion of the gauge on the test base, adjust the newborn gauge to the greatest incline angle in which the top edge of the gauge maintains contact with the top surface of the product.

(6) If a product's seating bight area prevents reasonable positioning of the head/torso portion to the outermost edge, then position the seat portion of the newborn hinged weight gauge as far forward as possible towards the outermost edge and allow the head/torso portion of the gauge to rest on the product.

(7) Place a digital protractor lengthwise on the head/torso portion of the gauge and measure the incline angle.

(8) Measure the incline angle at the manufacturer's recommended use location(s), at feasible locations such as perpendicular to the recommended use location(s), and at least one location likely to fail in which the newborn gauge seat is supported on the test surface.

(9) Determine the maximum incline angle from the incline angle measurements.

(e) *Firmness test setup.* (1) Equipment shall include:

(i) Force gauge with accuracy +/− 0.05 N (0.01 lbs).

(ii) Distance gauge with accuracy +/− 0.01 inches (0.03 cm).

(2) Align the axis of the 3-inch head probe (figure 1 to paragraph (e)(1) of § 1243.4) with a force gauge and parallel to a distance measurement device or gauge.

(3) Use a lead screw or similar device to control movement along a single direction.

(4) Support the firmness fixture to a test base such that the head probe does not deflect more than 0.01 inches (0.025 cm) under a 10.0 N (2.24 lbs) load applied in each orientation required in the test methods.

(f) *Occupant support surface firmness test method.* Perform the following steps to determine the occupant support surface firmness of the product as received from the manufacturer. For products sold with a slipcover on or together with the product, products shall be tested as assembled with the slipcover on the product. All products, including products one inch or less in thickness, are required to be tested. *See* figure 6 to this paragraph (f).

(1) Orient the axis of the 3-inch head probe perpendicular to the surface of the product at each test location that is oriented greater than five degrees relative to the test base or align the axis of the probe perpendicular to the test base (vertically) at each test location that is oriented equal to or less than five degrees to the test base.

(2) The first test location shall be at the location of maximum thickness of the surface being tested, perpendicular to the test base.

(3) Lay the product, with the occupant support surface facing up, on a test base that is horizontal, flat, firm, and smooth.

(4) Prevent movement of the product in a manner that does not affect the force or deflection measurement of the product surface under test. Provide no additional support beneath the product.

(5) Advance the probe into the product and set the deflection to 0.0 inches when a force of 0.1 N (0.02 lbs) force is reached.

(6) Continue to advance the head probe into the product at a rate not to exceed 0.1 inch per second and pause when the force exceeds 10.0 N (2.24 lbs), or the deflection is equal to 1.00 inches (2.54 cm).

(7) Wait 30 seconds. If the deflection is less than 1.00 inches and the force is 10.0 N or less, repeat the steps in paragraphs (f)(6) and (7) of this section.

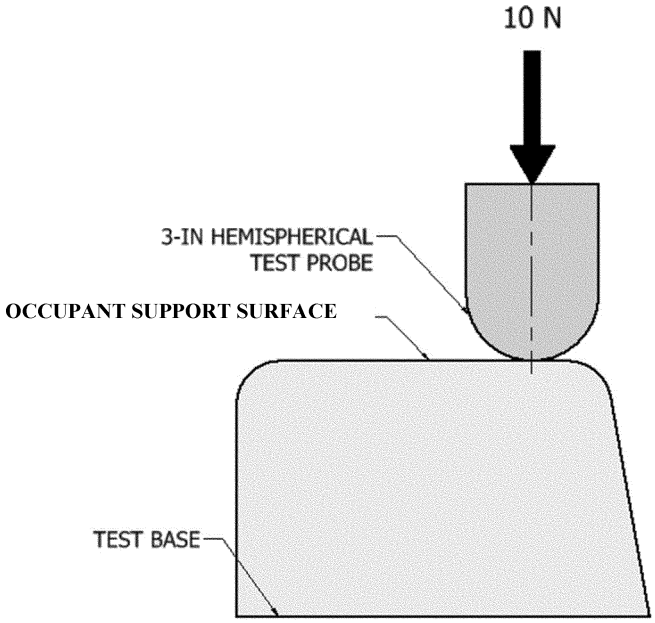
(8) Record the final force and deflection when the deflection has reached 1.00 inches or when the force has exceeded 10.0 N.

(9) If the maximum thickness of the OSS is greater than 1.0 inches (2.54 cm), perform additional tests, space permitting, at the geometric center of the OSS, at four locations along the product's longitudinal and lateral axes

therefrom, 1.5 inches (3.8 cm) towards center from the intersection of the sidewall and OSS, and at one location most likely to fail.

(10) Repeat the occupant support surface firmness tests on any other occupant support surface and in all intended and feasible configurations that could affect an occupant support surface, such as the folding or layering of parts of the product.

Figure 6 to paragraph (f)—Test Configuration for Occupant Support Surface Firmness Test



(g) *Sidewall firmness test method.* For products with a sidewall, perform the steps in paragraphs (f)(1) through (8) of this section to determine the sidewall firmness of the product as received from the manufacturer and then perform the following:

(1) Perform a minimum of four additional tests, located at intervals not to exceed 6 inches along the entire top perimeter of the sidewall, starting from the maximum side height location, and at one additional location most likely to fail.

(2) Repeat the sidewall firmness test in all the intended or feasible configurations that could affect the sidewall firmness, such as the folding or layering of parts of the product.

(h) *Intersection of sidewall and occupant support surface firmness.* For products with a sidewall, perform the following steps to determine the intersection firmness of the product as received from the manufacturer (figure 7 to this paragraph (h)).

(1) Orient the axis of the 3-inch head probe perpendicular to the sidewall perimeter at an angle from horizontal that bisects the angle determined in sidewall angle determination with the axis directed at the intersection of the occupant support surface and the sidewall.

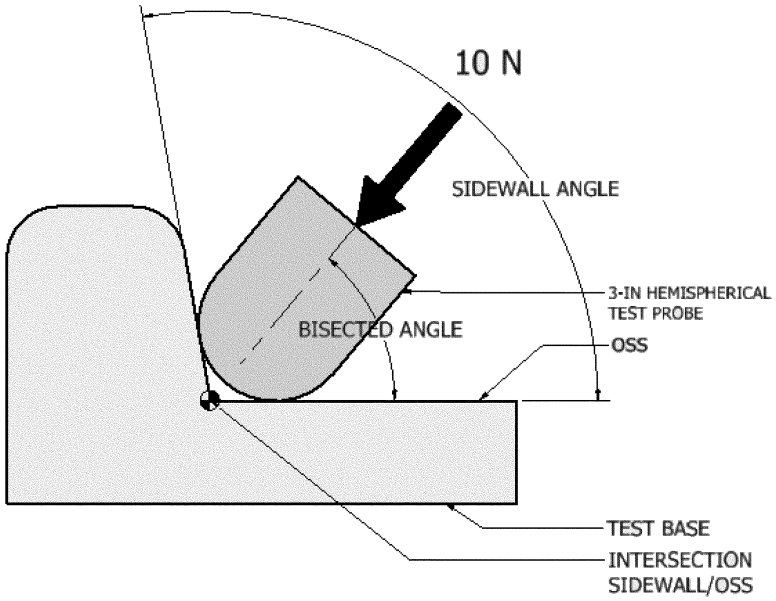
(2) The first test location shall be at the location of maximum product thickness parallel to the test base.

(3) Perform the steps in paragraphs (f)(3) through (8) of this section.

(4) Perform a minimum of four additional tests, located at intervals not to exceed six inches along the entire inside perimeter of the intersection of the sidewall and OSS, and at one additional location most likely to fail.

(5) Repeat the intersection of sidewall and occupant support surface firmness test in all the intended or feasible configurations that could affect the intersection firmness, such as the folding or layering of parts of the product.

Figure 7 to paragraph (h)—Test Configuration for Intersection of Sidewall and Occupant Support Surface Firmness



(i) *Sidewall angle determination.* For products with a sidewall, perform the following steps to determine if the angle between the sidewall and OSS is 90 degrees or less, or to measure the angle above 90 degrees. *See* figure 8 to this paragraph (i).

(1) Orient the 3-inch (7.62 cm) diameter hemispherical head probe vertically and place it over the OSS with the cylindrical surface of the probe tangent to the intersection of the sidewall and the OSS. Advance the probe into the product until a downward force of 10 N (2.2 lbs) force is reached.

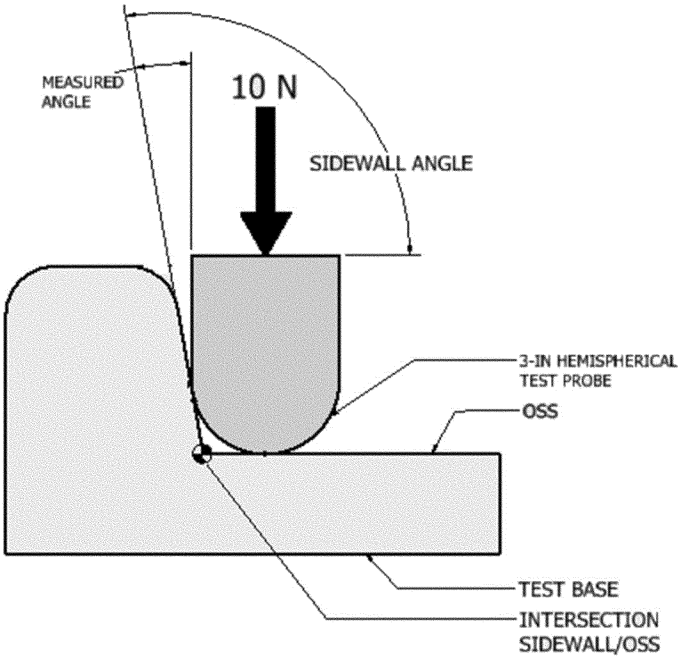
(2) After 30 seconds, determine whether the sidewall is in contact with the cylindrical side of the 3-inch head probe. If the sidewall contacts the cylindrical part of the probe, the sidewall angle is equal to or less than 90 degrees.

(3) For sidewall angles greater than 90 degrees, calculate the sidewall angle as 90 degrees plus the measured angle between the cylindrical side of the 3-inch head probe and the sidewall.

(4) Determine a minimum of four sidewall angles at locations not to exceed 6-inch (15.2 cm) intervals along the intersection of the sidewall and OSS.

(5) Measure the angle with a protractor or gauge placed to the depth of and in contact with the cylindrical side of the 3-inch probe side and the sidewall.

Figure 8 to paragraph (i)—Test Fixture Configuration for Sidewall Angle Measurement

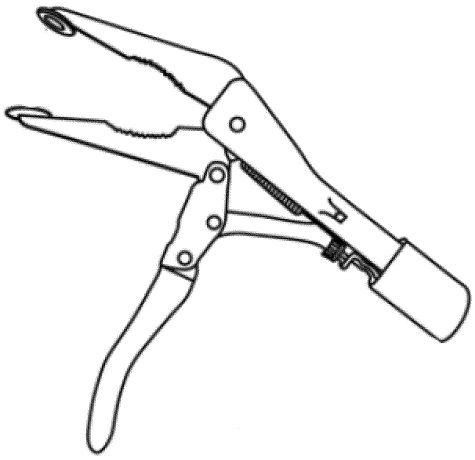


(j) *Seam strength test method.* (1) Equipment shall include:

(i) Clamps with 0.75 inches (1.9 cm) diameter clamping surfaces capable of holding fabric and with a means to attach a force gauge. *See* figure 9 to this paragraph (j)(1), or equivalent.

(ii) A force gauge, accuracy +/− 0.5 lbs (1.1 N).

Figure 9 to paragraph (j)(1)—Seam Clamp



(2) Clamp the fabric of the infant support cushion on each side of the seam under test with the 0.75 inches clamping surfaces placed not less than 0.5 inches (1.2 cm) from the seam.

(3) Apply a tension of 15 lbs (67 N) evenly over 5 seconds and maintain for an additional 10 seconds.

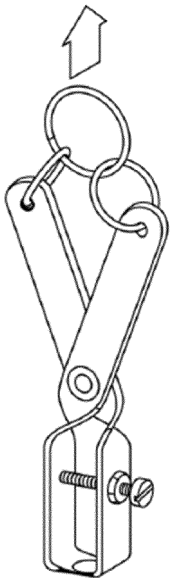
(4) Repeat the test on every distinct seam and every 12 inches (15 cm) along each seam.

(k) *Removal of components test method*—(1) *Suitable devices.* For torque and tension tests, any suitable device may be used to grasp the component that does not interfere with the attachment elements that are stressed during the tests.

(2) *Torque test.* Gradually apply a 4 lbs-in (0.4 N–m) torque over 5 seconds in a clockwise rotation to 180 degrees or until 4 lbs-in has been reached. Maintain for 10 seconds. Release and allow component to return to relaxed state. Repeat the torque test in a counterclockwise rotation.

(3) *Tension test.* For components that can reasonably be grasped between thumb and forefinger, or teeth, apply a 15 lbs (67 N) force over 5 seconds, in a direction to remove the component. Maintain for 10 seconds. A clamp such as shown in figure 10 to this paragraph (k)(3) may be used if the gap between the back of the component and the base material is 0.04 inches (0.1 cm) or more.

Figure 10 to paragraph (k)(3)—Tension Test Adapter Clamp



§ 1243.6 Marking and labeling.

(a) *General markings.* Each product and its retail package shall be marked or labeled clearly and legibly to indicate the following:

(1) The name, place of business (city, state, and mailing address, including zip code), and telephone number of the manufacturer, distributor, or seller.

(2) A code mark or other means that identifies the date (month and year as a minimum) of manufacture.

(3) The marking or labeling in paragraphs (a)(1) and (2) of this section

are not required on the retail package if they are on the product and are visible in their entirety through the retail package. When no retail packaging is used to enclose the product, the information provided on the product shall be used for determining compliance with paragraphs (a)(1) and (2) of this section. Cartons and other materials used exclusively for shipping the product are not considered retail packaging.

(b) *Permanency.* The marking and labeling on the product shall be permanent.

(c) *Upholstery labeling.* Any upholstery labeling required by law shall not be used to meet the requirements of this section.

(d) *Warning design for product.* (1) The warnings shall be easy to read and understand and be in the English language at a minimum.

(2) Any marking or labeling provided in addition to those required by this section shall not contradict or confuse the meaning of the required information or be otherwise misleading to the consumer.

(3) The warnings shall be conspicuous and permanent.

(4) The warnings shall conform to ANSI Z535.4–2011(R2017) (incorporated by reference, see § 1243.8) sections 6.1–6.4, 7.2–7.6.3, and 8.1, with the following changes.

(i) In sections 6.2.2, 7.3, 7.5, and 8.1.2, replace ''should'' with ''shall.''

(ii) In section 7.6.3, replace ''should (when feasible)'' with ''shall.''

(iii) Strike the word ''safety'' when used immediately before a color (for example, replace ''safety white'' with ''white'').

Note 1 to paragraph (d)(4)(iii): For reference, ANSI Z535.1, American National Standard for Safety Colors, provides a system for specifying safety colors. See note 1 to § 1243.8(a) for ANSI contact information.

(5) The safety alert symbol and the signal word ''WARNING'' shall be at least 0.2 inches (5 mm) high. The remainder of the text shall be in characters whose upper case shall be at least 0.1 inches (2.5 mm), except where otherwise specified.

Note 2 to paragraph (d)(5): For improved warning readability, typefaces with large height-to- width ratios, which are commonly identified as ''condensed,'' ''compressed,'' ''narrow,'' or similar, should be avoided.

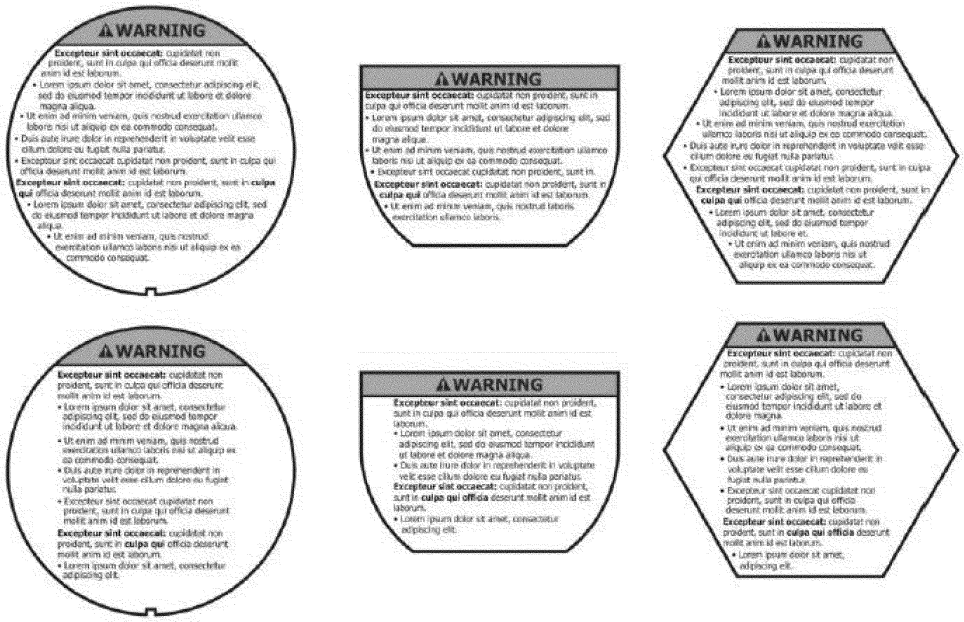
(6) The message panel shall have the following text layout requirements:

(i) The text shall be left-aligned, ragged-right for all but one-line text messages, which can be left-aligned or centered. *See* figure 1 to this paragraph (d)(6) for examples of left-aligned text.

Note 3 to paragraph (d)(6)(i): Left-aligned means that the text is aligned along the left margin, and in the case of multiple columns of text, along the left side of each individual column.

(ii) The text in each column should be arranged in list or outline format, with precautionary (hazard avoidance) statements preceded by bullet points. Multiple precautionary statements shall be separated by bullet points if paragraph formatting is used.

Figure 1 to paragraph (d)(6)—Examples of Left-Aligned Text



Note 4 to figure 1 to paragraph (d)(6): The text shown for the warnings in figure 1 to this paragraph (d)(6) is filler text, known as lorem ipsum, commonly used to demonstrate graphic elements.

(7) All infant support cushions are required to contain a warning with the content and format depicted in this section as figure 2 (for products without tummy time) or figure 3 (if the product has a tummy time feature) to this paragraph (d)(7).

Figure 2 to paragraph (d)(7)—Warning for Product Without Tummy Time

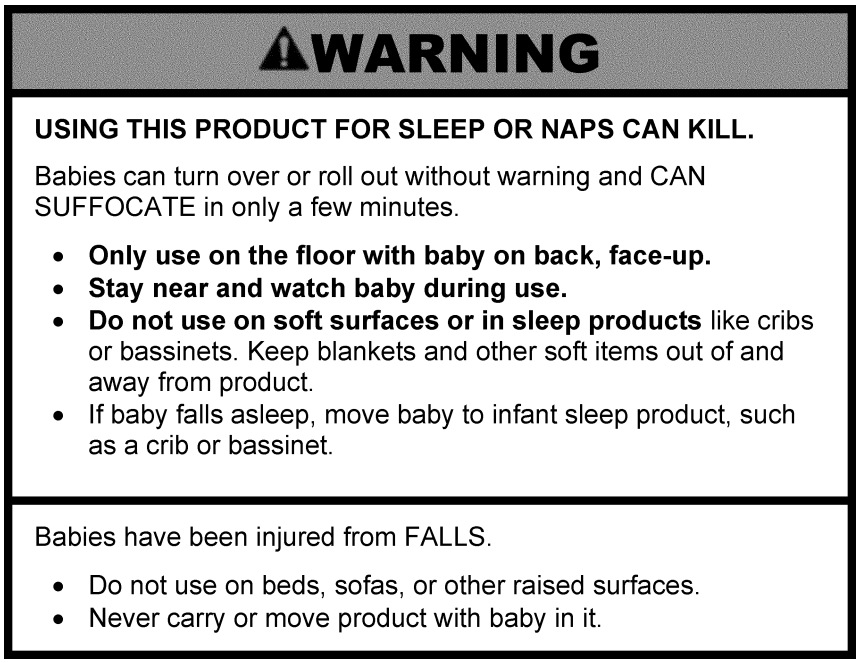
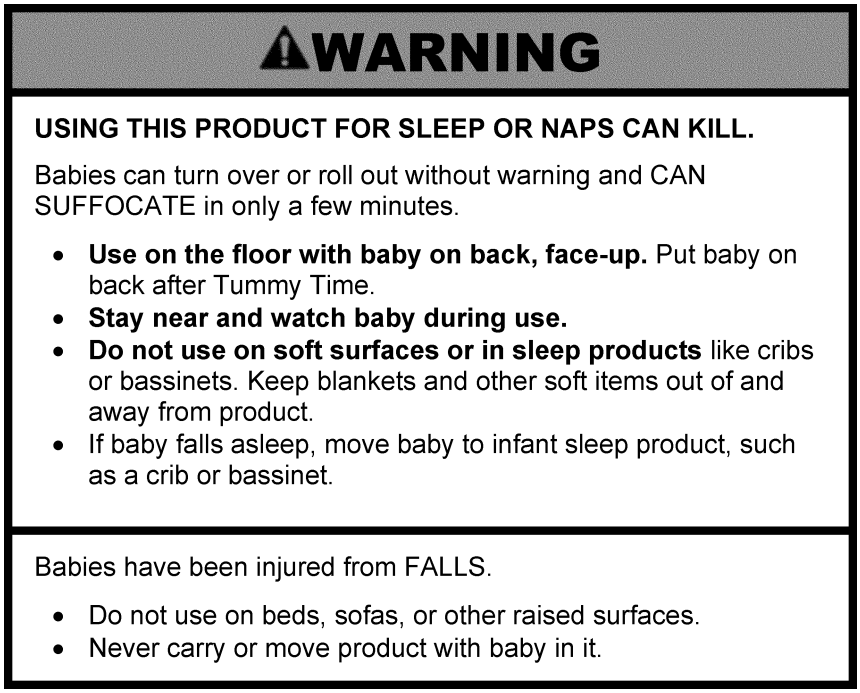


Figure 3 to paragraph (d)(7)—Warning for Tummy Time Product



(e) *Warning statements.* Each product shall contain the warning statements shown on figure 2 (for products without tummy time) or figure 3 (if the product has a tummy time feature) to paragraph (d)(7) of this section, at a minimum. Slipcovers sold on, or together with the product, shall contain the warning statement shown on figure 2 or 3 to paragraph (d)(7) of this section, as applicable.

§ 1243.7 Instructional literature.

(a) Instructions shall be provided with the product and shall be easy to read and understand and shall be in the English language at a minimum. These instructions shall include information

on assembly, maintenance, cleaning, and use, where applicable.

(b) The instructions shall address the following additional warnings:

(1) Read all instructions before using this product.

(2) Keep instructions for future use.

(3) Do not use this product if it is damaged or broken.

(4) Instructions shall indicate the manufacturer's recommended maximum weight, height, age, developmental level, or combination thereof, of the occupant for which the infant support cushion is intended. If this product is not intended for use by a child for a specific reason, the instructions shall state this limitation.

(c) The cautions and warnings in the instructions shall meet the requirements specified in § 1243.6(d)(4) though (6), except that section 6.4 and sections 7.2–7.6.3 of ANSI Z535.4–2011(R2017) (incorporated by reference, see § 1243.8) need not be applied. However, the signal word and safety alert symbol shall contrast with the background of the signal word panel, and the cautions and warnings shall contrast with the background of the instructional literature.

Note 1 to paragraph (c): For example, the signal word, safety alert symbol, and the warnings may be black letters on a white background, white letters on a black background, navy blue letters on an off-white background, or some other high-contrast combination.

(d) Any instructions provided in addition to those required by this section shall not contradict or confuse the meaning of the required information or be otherwise misleading to the consumer.

§ 1243.8 Incorporation by reference.

Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved incorporation by reference (IBR) material is available for inspection at the U.S. Consumer Product Safety Commission and at the National Archives and Records Administration (NARA). Contact the U.S. Consumer Product Safety Commission at: the Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; phone (301) 504–7479; email: *cpsc-os@cpsc.gov.* For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.* The material may be obtained from the following sources:

(a) National Electrical Manufacturers Association (NEMA), 1300 17th St. N, Arlington, VA 22209; phone: (703) 841–3200; website: *www.nema.org.*

(1) ANSI Z535.4–2011(R2017), *American National Standard for Product Safety Signs and Labels,* approved October 20, 2017; approved for §§ 1243.6 and 1243.7.

(2) [Reserved]

Note 1 to paragraph (a): NEMA standards are also available from the American National Standards Institute (ANSI), which provides a free, read-only copy of the standard at *https://ibr.ansi.org/Standards/nema.aspx.* Contact ANSI by mail at American National Standards Institute, 25 West 43rd Street, 4th Floor, New York, NY 10036, USA; phone: (212) 642–4900; website: *www.ansi.org.*

(b) ASTM International (ASTM), 100 Barr Harbor Drive, P.O. Box CB700, West Conshohocken, Pennsylvania 19428–2959; phone: (800) 262–1373; website: *www.astm.org.*

(1) ASTM D3359–23, *Standard Test Methods for Rating Adhesion by Tape Test,* approved February 1, 2023; approved for § 1243.5.

(2) [Reserved]

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2024–25181 Filed 11–1–24; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2024–0745]

RIN 1625–AA09

Drawbridge Operation Regulation; Sacramento River, Rio Vista, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary interim rule with request for comments.

SUMMARY: The Coast Guard is temporarily modifying the operating schedule that governs the draw of the California Department of Transportation Rio Vista (State Route 12) highway bridge across the Sacramento River, mile 12.8, at Rio Vista, CA. This action is necessary to allow the bridge owner to complete rehabilitation of the bridge.

DATES: This temporary interim rule is effective from November 4, 2024 through 5 p.m. on August 29, 2025.

Comments and related material must reach the Coast Guard on or before December 4, 2024.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov.* Type the docket number (USCG–2024–0745) in the ''SEARCH'' box and click ''SEARCH''. In the Document Type column, select ''Supporting & Related Material''.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary interim rule, call or email Carl Hausner, Chief, Bridge Section, Eleventh Coast Guard District; telephone 510–219–4366, email *D11Bridges@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

Caltrans California Department of Transportation
CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
MHW Mean High Water
NOTD Notice of Temporary Deviation
NPRM Notice of proposed rulemaking
Pub. L. Public Law
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary interim rule without prior notice and opportunity to comment pursuant to authority under the authority in 5 U.S.C. 553(b)(B). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' The Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable and contrary to the public interest due to Caltrans Headquarters continuing to add projects to the ongoing rehabilitation project, which will require extending the length of time for advance notice for opening the span. The current NOTD expires November 1, 2024 and the Coast Guard cannot add additional dates to that NOTD because it will extend the NOTD beyond the allowed 180 days. The continuation of the temporary deviation is necessary for the safety of the work crews on the bridge.

Also, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable and contrary to the public interest because Caltrans has allocated funds for additional rehabilitation work on the

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Memorandum

TO: The Commission
Alberta E. Mills, Secretary

DATE: September 25, 2024

THROUGH: Jessica L. Rich, General Counsel
Austin C. Schlick, Executive Director
DeWane Ray, Deputy Executive Director of Operations

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

Ashley A. Johnson, Ph.D., Physiologist
Infant Support Cushions Rulemaking Project Manager,
Division of Pharmacology and Physiology, Directorate for Health Sciences

Celestine Kish, Engineering Psychologist
Division of Human Factors, Directorate for Engineering Sciences

Brian M. Baker, Mechanical Engineer,
Division of Mechanical Engineering, Directorate for Laboratory Sciences

Kathryn OConnor, Mathematical Statistician,
Division of Hazard Analysis, Directorate for Epidemiology

Jeffrey D. Giliam, Economist
Directorate for Economic Analysis

Keysha L. Walker, Compliance Officer,
Division of Regulatory Enforcement, Office of Compliance and Field Operations

SUBJECT: Staff's Draft Final Rule for Infant Support Cushions

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On January 16, 2023, the Commission published a notice of proposed rulemaking (NPR) under section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA) that proposed a mandatory consumer product safety standard for infant support cushions to address the risk of death and injury associated with these products. 89 Fed. Reg. 2,530. Infant support cushions include products that support an infant for lounging, meaning reclining in a supine, prone, or recumbent position. On April 23, 2024, CPSC published a notice of availability (NOA) with a 30-day comment period that closed on May 23, 2024. 89 Fed. Reg. 30,295. The NOA announced the availability of, and sought comments from the public on, the incident data relied upon for the NPR.

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The NPR proposed to define an "infant support cushion" as "an infant product that is filled with or comprised of resilient material such as foam, fibrous batting, or granular material or with a gel liquid, or gas, and which is marketed, designed, or intended to support an infant's weight or any portion of an infant while reclining or in a supine, prone, or recumbent position". The definition would include products such as infant loungers that may have walls around their perimeters, infant head positioner pillows, infant sleep positioners[1] and anti-rollover pillows, crib pillows, wedge pillows for infants, stuffed toys or pads and mats marketed for use as infant support cushions, multi-purpose pillows marketed for both nursing and lounging, and tummy time pillows. Most infant support cushions on the market today are "loosely filled" or simply "filled" with some type of cushy foam or soft fibrous batting, rather than a "granular material," and are therefore not within the scope of the existing infant pillow ban that the Commission adopted years ago under the Federal Hazardous Substances Act.[2]

Notwithstanding warnings from the Commission and others that soft objects such as pillows and excess bedding should not be placed in an infant's sleep setting, some infant support cushions are, or have been, marketed for use in a crib or other infant sleep product. As a result, many soft products marketed as infant support cushions have been used in infant sleep settings where they create suffocation hazards. Examples of various types of infant support cushions can be found in the Briefing Memorandum of Staff's NPR Briefing Package.[3] Staff's draft final rule does not apply to removable padding or padded seat liners sold as part of products primarily used to transport, entertain, or feed infants. It also would not apply to infant products subject to other infant product rules listed at 16 C.F.R. § 1130.2(a), including infant sleeping accommodations, which are already regulated by CPSC's infant sleep products standard, 16 C.F.R. part 1236.

As described in the NPR, CPSC staff has identified 79 fatal incidents and 124[4] nonfatal incidents and consumer concerns reported to have occurred between January 1, 2010, and December 31, 2022, associated with infant support cushions and involved infants (up to 12 months old). Almost 81% of the infant support cushion-related fatalities involved infants 3 months old and younger, a particularly vulnerable age bracket. Nearly all reported fatalities (75

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[1] The FDA discourages the use of infant sleep positioners and has not approved pillow products for preventing sudden infant death syndrome (SIDS). See https://www.fda.gov/consumers/consumer-updates/do-not-use-infant-sleep-positioners-due-risk-suffocation

[2] 16 C.F.R. § 1500.18(a)(16) bans any article known as an "infant cushion" or "infant pillow," and any other similar article, which has all of the following characteristics:
- Has a flexible fabric covering;
- Is loosely filled with granular material, including but not limited to, polystyrene beads or pellets;
- Is easily flattened;
- Is capable of conforming to the body or face of an infant; and
- Is intended or promoted for use by children under 1 year of age.

[3] Staff's NPR Briefing Package, available at: https://www.cpsc.gov/s3fs-public/Briefing-Package-Notice-of-Proposed-Rulemaking-Safety-Standard-for-Infant-Support-Cushions.pdf?VersionId=rA60lesWHddS1.wrk_EvV00xeX75dsFc.

[4] The NPR listed 125 nonfatal incidents, but one of those incidents was a duplicate.

of 79) involved placement of the infant support cushion on another sleep-related consumer product. Of the 124 non-fatal reports, 22 consisted of emergency-department-treated injuries, three involved hospital admissions, 45 involved no injury, and for 54 the disposition was either unknown or unspecified. The incident data and hazard patterns cited in support of the NPR are unchanged in the draft final rule. For further discussion of the incident data and hazard patterns see the NPR and Tab A, B of Staff's NPR Briefing Package[5].

The draft final rule includes performance, testing, labeling, and instructional literature requirements to address the suffocation, entrapment, and fall hazards associated with infant support cushions. It addresses positional asphyxiation hazards by requiring that all surfaces be sufficiently firm that they are unlikely to conform to an infant's face and occlude the airway, and by setting a maximum incline angle that would prevent hazardous positioning of an infant's head and neck along the surfaces of the product. The draft final rule also sets a side angle requirement that addresses the risk of entrapment between the sidewall and the occupant support surface. Further, it addresses fall hazards because the maximum incline angle of 10 degrees results in preventing excessive sidewall height that could encourage caregivers to mistakenly believe these products are safe for unattended infants. The draft final rule also requires a strongly worded, conspicuous, and permanent on-product warning label.

There are no published U.S. voluntary standards for infant support cushions. ASTM is working on a voluntary standard for infant loungers under the Subcommittee F15.21 on Infant Carriers, Bouncers, and Baby Swings[6]. Staff has been working with ASTM to develop performance requirements intended to address the primary hazards associated with infant loungers. On March 25, 2024, ASTM issued ballot F15.21 (24-01), which included the latest draft of the infant lounger's voluntary standard. The ballot closed on April 29, 2024, and received eight negative votes and other comments including a comment from CPSC staff. On September 16, 2024, ASTM issued ballot F15 (24-18), Item #1 which addressed the negative comments and other comments on the draft standard for infant loungers included in ballot F15 (24-01). The ballot will close on October 16, 2024.

In the ASTM draft voluntary standard, an "infant lounger" would be a product "with a raised perimeter, a recess, or other area that is intended to be placed on the floor and to provide a place for an infant to sit, lie, recline, or rest, while supervised by an adult, but are not intended or marketed for sleep." The draft definition would govern only a subset of the products covered

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[5] Staff's NPR Briefing Package, available at: https://www.cpsc.gov/s3fs-public/Briefing-Package-Notice-of-Proposed-Rulemaking-Safety-Standard-for-Infant-Support-Cushions.pdf?VersionId=rA60lesWHddS1.wrk_EvV00xeX75dsFc.
[6] On March 25, 2024, ballot F15.21 (24-01) was issued for a draft standard for infant loungers, which included the latest draft of the infant lounger's voluntary standard. The ballot closed on April 29, 2024, and received eight negative votes and other comments, which are currently being addressed by task groups.
CPSC Staff Comment to Ballot ASTM F15.21 on Infant Loungers, available at: https://www.cpsc.gov/s3fs-public/CPSCStaffCommenttoBallotASTMF1521onInfantLoungers.pdf?VersionId=tGM05rvyA6WCUzQxHFCDkVHVxRLbtQLv

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by this rule, which includes infant positioners, nursing products with dual use for lounging, infant cushions, and other infant pillow-like products, as well as the infant loungers being considered by ASTM. The draft voluntary standard includes performance requirements that address stability, restraints, occupant support surface angle, fabric/mesh integrity, bounded openings, occupant support surface firmness, sidewall firmness, side angle measurements, and deflection at the occupant support surface and sidewall intersection. The draft voluntary standard for loungers also includes marking, labeling, and instructional literature requirements, such as warning the consumer about not using the product for sleep or naps, only using the product when the occupant baby is supervised, only using the product on the floor, keeping soft bedding out of the product, not using the product on raised surfaces, and not using the product to carry or move an infant.

Staff assesses that the ASTM draft standard for infant loungers primarily differs from the draft final rule regarding the scope of products subject to the standard, the performance requirements, and the warning statement. In particular, the draft final rule includes all types of infant support cushions such as infant positioners, infant loungers, and other types of infant mats and pads, while the scope of the ASTM draft standard includes only infant loungers. Given that ASTM has not finalized and published their draft standard, CPSC cannot rely on it. Because it is unclear whether and when ASTM will adopt a relevant standard, postponing the draft final rule for publication of an ASTM standard could constitute an indefinite delay in preventing infant support cushion-related injuries and deaths.

CPSC received 18 public comments on the NPR and 1 comment on the NOA. Section VI of the preamble to the draft final rule summarizes these comments and provides proposed responses. The topics addressed in these comments fell into several broad categories including scope, definitions, general requirements, the performance requirements of the rule and their associated test methods, the marking and labeling requirements, the effective date, small business issues, stockpiling concerns, and procedure and constitutional issues.

Based on comments on the NPR, the above-listed staff recommend the following changes and clarifications to the NPR's draft rule:

- The definition of "infant support cushion" in section 1243.2. has been revised to add the sentence "this definition includes any removable covers, or slipcovers, sold on or together with an infant support cushion" at the end of the definition.
- The definition of infant lounger in section 1243.2 has been revised to change "infant product" to "infant support cushion". This is a clarifying change.
- To remove ambiguity, a new definition of the term "sidewall" in section 1243.2 defined as "any vertical wall at the edge of the occupant support surface" has been added to the rule.
- A reference in the rule to "infant pillow" in section 1243.3(d) has been changed to "infant support cushion" for accuracy and consistency.
- The rule removes proposed section 1243.3(e) regarding side height as this requirement is redundant with maximum incline angle limits in the rule. The final rule renumbers the paragraphs following proposed section 1243.3(e) to reflect this change. The rule

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removes the corresponding test in section 1243.5(d)(8) for consistency. To reflect this change, all numbers after section 1243.5(d)(7) have been renumbered in the final rule.

- The performance requirements in section 1243.4(e)(2), 1243.4(e)(3), and 1243.4(f) as well as the corresponding test methods for sections 1243.5(g), 1243.4(h), and 1243.4(i), have been revised to clarify that the performance requirements and test methods apply specifically to products that contain a sidewall with language stating, "For products with a sidewall."
- The test method for section 1243.5(f) has been clarified to explain that products sold with a slipcover on or together with the product are to be tested as assembled with the slipcover on the product.
- The test method for 1243.5(f) has been clarified to explain that all products, including products one inch or less in thickness, shall be tested.
- Figure 2 (for products without a tummy time feature) to paragraph (d)(7) in section 1243.6 has been revised and a new Figure 3 (for products with a tummy time feature) has been added to reflect changes in warning content made in response to public comments. These changes include adding a statement to address prone use during tummy time, removing references to "an awake baby," separating the sleep and suffocating-relating warning content to provide clarity, adding a warning to address soft bedding both in and outside of the product, and deleting some of the statements to reduce length and increase clarity.
- Section 1243.6(e) has been revised to clarify that slipcovers sold with, on, or together with the product shall contain the warning statement shown in Figure 2 and Figure 3 to paragraph (d)(7), as applicable.

Section 604 of the Regulatory Flexibility Act (RFA, 5 U.S.C. §604) generally requires that agencies make a Final Regulatory Flexibility Analysis (FRFA) available when a final rule is published. Staff's FRFA, set out in section XII of the preamble to the draft final rule, assesses that this rule would have a significant economic impact on a substantial number of small U.S. firms, particularly small home crafters. Alternatives that could reduce the impact on small entities include reliance on a public education campaign, which would have no regulatory impact on small businesses, but would also result in continuing deaths and injuries from the use of infant support cushions while allowing the hazard to continue indefinitely. Another alternative is allowing the voluntary standards process time to develop a voluntary standard to address the hazards posed by infant support cushions. However, this standard, if one was published at all, may not adequately address the identified hazards to infants. Notably, the current ASTM draft voluntary standard for loungers would only cover loungers, while the draft final rule covers all infant support cushions and has more stringent performance requirements and warnings than the draft voluntary standard.

For the reasons stated in section XII of the preamble to the draft final rule, regarding the effective date, staff recommends an effective date of 180 days after publication of the final rule to allow time for suppliers to bring their products into compliance and to test to the new standard. No new complex testing instruments or devices would be required to test infant

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support cushions for compliance with the final rule. This amount of time is typical for rules issued under section 104 of the CPSIA. Six months is also the period that the Juvenile Product Manufacturers Association (JPMA) typically allows for products in their certification program to shift to a new standard once that new standard is published.

EXHIBIT 8

snuggleme™

4444 Centerville Road
Suite 130
White Bear Lake, MN 55127

March 18, 2024

Submitted Electronically

Alberta E. Mills
Commission Secretary
Office of the General Counsel
U.S. Consumer Product Safety Commission
4330 East-West Highway
Bethesda, MD 20814

Re: Consumer Product Safety Commission Notice of Proposed Rulemaking; Safety Standard for Infant Support Cushions; Docket No. CPSC-2023-0047

Dear Ms. Mills:

Heroes Technology (US) LLC d/b/a Snuggle Me Organic (hereafter Snuggle Me) appreciates the opportunity to comment on the Notice of Proposed Rulemaking (NPR) of the Consumer Product Safety Commission (CPSC) regarding the Safety Standard for Infant Support Cushions, 89 FR 2530 (January 16, 2024) (Proposed Rule). Snuggle Me is a member of the Juvenile Products Manufacturers Association, Inc. (JPMA), and we support JPMA's comments to the Proposed Rule. Below we submit Snuggle Me's further comments to the Proposed Rule, which are informed by our own unique product and experience.

We make infant loungers "uniquely designed to hug your baby's body and create a cozy space to play."[1] At Snuggle Me, baby safety is at the core of everything we do, and we firmly support CPSC's mission to protect young children from the hazards associated with unsafe sleep environments. We agree with CPSC that strong warnings against consumer misuse are needed for infant lounger products (although changes are likely needed to address uncertainties and unknown risks associated with the Proposed Rule), and we support CPSC's proposed amendment to add infant loungers to the list of durable infant products that must comply with the product registration requirements in 16 CFR § 1130. Snuggle Me already provides strongly worded and conspicuous warnings, including permanent on-product warnings, a safety page on our website with a consumer video, offers a product registration card, and has a product registration page on its website.[2]

[1] *See* https://snugglemeorganic.com/products/infant-lounger-natural.

[2] *See* https://snugglemeorganic.com/pages/product-registration.

Snuggle Me is deeply concerned, however, that several of CPSC's proposed changes—particularly mandated design changes and test methods for infant loungers, which are the focus of these comments—will make babies less safe and are unsupported by the record.[3]

First, as explained in Section II below, there is no support in the record for the extraordinarily large scope of the Proposed Rule, lumping together products that differ vastly in purpose, intended use, construction, size, shape, firmness and other defining characteristics. Infant loungers, head positioner pillows, stuffed toys marketed as support cushions, "self-feeding" pillows, padded accessories for use in cars, pads and mats—just a few of CPSC's non-exhaustive list of examples—have little in common. Attempting a one-size-fits-all solution that fails to consider the unique characteristics of these products and the differences among commercially available infant lounger products is not only wholly inadequate and lacks support in the record, but will likely reduce infant safety and serve as a perverse incentive for regrettable substitutions.

Second, as detailed in Section III below, the Proposed Rule is based on flawed proposed test methods that have not been demonstrated to be feasible, much less repeatable or reproducible. With regard to the proposed side angle testing intended to address possible entrapment hazards, it cannot be conducted effectively on the Snuggle Me infant lounger due to our lounger's unique design features. Our product has an unpadded occupant support surface (OSS) that works like a sling and, when an infant is placed in the lounger, is designed to leave *no gap* (and thus poses no entrapment hazard) between the "sidewall" and "the occupant support surface." Further, to the extent that the Proposed Rule requires that incline angle be measured at the manufacturer's recommended use location, which is the center sling on the Snuggle Me lounger, there is no "incline" in that position.

With regard to the proposed maximum incline testing, the Proposed Rule suffers from at least several serious deficiencies: It requires testing not only in positions outside of manufacturer's recommended uses, but also where product design "prevents *reasonable* positioning" at a proposed location. (§ 1243.5(d)(6) (emphasis added), 89 FR 2549.) It does not take into account that if firmness parameters are met, testing beyond manufacturer's recommendations and beyond otherwise "reasonable positioning" would represent an unreasonable misuse scenario. It also requires testing at undefined "feasible locations" and unidentified locations "likely to fail." (*Id.*) As CPSC expects that the maximum incline

[3] We share JPMA's concerns that the lack of evidentiary support for many significant aspects of the Proposed Rule contradicts the Administration's directive that agencies make evidence-based decisions, guided by science and data. Specifically, like JPMA we are concerned that CPSC has not made enough data available, and has failed to provide a risk/benefit analysis, risk/hazard analysis, and a consumer choice analysis, and has also failed to demonstrate that the Proposed Rule would result in safer products. (*See* Memorandum for the Heads of Executive Departments and Agencies; https://obamawhitehouse.archives.gov/the-press-office/memorandum-heads-executive-departments-and-agencies-3-9-09; Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking; https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/27/memorandum-on-restoring-trust-in-government-through-scientific-integrity-and-evidence-based-policymaking/.)

testing would result in much lower sidewall height than in current products (*i.e.*, approximately 1.9 inches vs. 4 inches) (89 FR 2539), CPSC should have considered—but did not—whether compliance with the sidewall firmness requirements in the Proposed Rule eliminates the need for lower sidewalls, and indeed, whether firmer 4-inch sidewalls are safer overall than the much lower sidewalls resulting from the maximum incline test methods. As noted below, the lower sidewalls exacerbate fall risks and may in fact result in parents and caregivers adding soft bedding in or around the product.

With regard to firmness testing, although a focus on sidewall firmness is appropriate, the Proposed Rule fails to propose established test methods and instead introduces ambiguous requirements. Two of the three firmness tests require that the "intersection" between OSS and sidewalls be located, which, by CPSC's own admission, "will be a challenge in some products." (Tab C, Briefing Package[4], OS 119.) The Proposed Rule provides subjective criteria, and as to firmness testing at the intersection of the OSS and sidewalls, in CPSC's view, "[b]ecause this transition varies among products, [CPSC] *does not have a recommendation for a method to determine the exact intersection of the sidewall to OSS*." (*Id.* (emphasis added).) In sum, the Proposed Rule is impermissibly vague and thus is arbitrary, capricious and an abuse of discretion because a regulated company could not determine what it needs to do and how the product must be repeatedly and reproducibly tested to comply, and a company's determination could be second-guessed by CPSC. *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43, 52, 103 S. Ct. 2856, 2866, 2871 (1983) (Under the "arbitrary and capricious" standard, an agency "must examine the relevant data and articulate a satisfactory explanation for its action," supply a "rational connection between the facts found and the choice made," and demonstrate that its action is "the product of reasoned decisionmaking.")

Third, as detailed in Section IV below, based on the information provided, the proposed mandatory changes resulting in a significant side height reduction—sidewall height of "approximately 1.9 inches"—not only lack support in the record, but are in fact contradicted by CPSC's own incident data, which shows that at least 56 non-fatal incidents (approximately 45% of all non-fatal incidents) and 22 fatal incidents (approximately 28% of all fatal incidents) involved babies moving out of a product and sustaining a fall injury or finding themselves in an unsafe environment. (Tab B, Briefing Package, OS 100-104.) The proposed sidewall height reduction will likely result in an increased risk of falls, the leading cause of non-fatal injuries, and an increased risk that babies will move outside the product into unsafe environments, a significant cause of fatal incidents. This change will also introduce additional hazards and invite regrettable substitutions. Neither the Boise State University contractor report (BSU Report)[5] appended to the NPR Briefing Package, nor any other evidence in the record, supports the drastic redesign across multiple product categories that CPSC proposes. Instead, some of the proposed changes are based solely on CPSC's "concern[] that [a 4-inch] side height *may* give consumers the mistaken impression that an

[4] https://www.cpsc.gov/content/Briefing-Package-Notice-of-Proposed-Rulemaking-Safety-Standard-for-Infant-Support-Cushions.

[5] https://www.cpsc.gov/content/Pillows-Product-Characterization-and-Testing.

infant can safely be left unattended in or on the product" (89 FR 2536 (emphasis added)), and on CPSC's unsupported supposition that a side height of "*approximately* 1.9 inches" would eliminate the purported consumer impression (89 FR 2539) (emphasis added)).

Concerns and suppositions, however, are not appropriate bases for mandatory standards. It is CPSC's "duty to identify and make available technical studies and data that it has employed in reaching the decisions to propose particular rules." *Window Covering Manufacturers Ass'n v. Consumer Prod. Safety Comm'n* (*WCMA*), 82 F.4th 1273, 1283 (D.C. Cir. 2023) (vacating final rule and finding CPSC acted arbitrarily where it failed to disclose data underlying its final rule), *citing Owner-Operator Indep. Drivers v. FMCSA*, 494 F.3d 188, 199 (D.C. Cir. 2007). No human factor studies or other data in the record supports CPSC's assumptions regarding the effects of reduced sidewall height. Furthermore, neither CPSC, nor the BSU Report, examined the negative impact of the proposed redesign on the hazards identified by CPSC. CPSC does not consider, for example, that more babies may roll over and out of loungers with significantly lower sides (leading to increased fall hazard), or that caregivers may use soft padded products, such as rolled blankets or pillows to compensate for a lower sidewall height (leading to increased asphyxiation and fall hazards).

Fourth, Snuggle Me is deeply concerned that the proposed warnings are insufficient to address the identified hazards, and inadequately warn consumers against misuse, despite CPSC's recognition that caregivers' "mistaken impression" and misuse are at the center of the identified hazards. (89 FR 2536.) Indeed, according to the NPR, 75 of 79 fatal incidents involved product placement on another sleep-related consumer product. (89 FR 2533.)[6] In Section V below, Snuggle Me proposes several important changes to the warnings to better address known misuse patterns, as well as to warn against foreseeable misuse, whether based on current designs or stemming from the proposed redesign (*i.e.*, use of soft bedding around the product to compensate for lower sidewall height).

Fifth, as explained in Section VI below, 180-day effective date is woefully insufficient for manufacturers and testing labs to implement multiple novel test methods, many of which call for subjective judgment, and for manufacturers to make and test new products with far-reaching design changes. Similar to the one-year effective date for manufacturers that were not on notice for the 2009 Registration Card Rule, CPSC should afford manufacturers here *at least 12 months* for compliance after a well-thought-out rule is finalized.

Sixth, as explained in Section VII below, CPSC is grossly mistaken about the magnitude of the Proposed Rule's impact, in terms of both significant loss of utility to consumers and very high costs of compliance to manufacturers. Since infant loungers are the most significant part of Snuggle Me's business, if these deficiencies are not addressed, the Proposed Rule could threaten Snuggle Me's very existence.

[6] Additional uncertainty results from the fact that CPSC's data does not specify which of the diverse products covered in this Proposed Rule was associated with each incident.

Because the Proposed Rule is not supported by record evidence, it fails to meet minimum standards for rulemaking. *See WCMA*, 82 F.4th at 1286 (noting that the record must "articulate a satisfactory explanation for [CPSC's] action including a rational connection between the facts found and the choice made," and the explanation must demonstrate that CPSC's action "was the product of reasoned decision-making."), *citing Motor Vehicle Mfrs. Ass'n*, 463 U.S. 29, 43, 52; *see also* footnote 3, *infra*. Moreover, the proposed mandatory redesign will likely have the unintended consequence of decreasing infant safety by increasing fall and asphyxiation hazards and providing a perverse incentive to parents and caregivers to adopt less safe products and practices. Snuggle Me respectfully submits the following comments and urges the Commission to withdraw the Proposed Rule and modify it once CPSC has developed adequate data, including a human factors study and effective, well-designed testing that is appropriately tailored to infant lounger products, including the Snuggle Me infant lounger, that addresses the manifest deficiencies identified in these comments. To reduce identified hazards, any final rule must also address caregiver misuse, which is, as CPSC recognizes, at the heart of those hazards, but is nevertheless not addressed or inadequately addressed in the Proposed Rule.

I. The Snuggle Me Infant Lounger

Snuggle Me is a small company based in White Bear Lake, Minnesota. Our story begins in 2007, when our founder handmade the first 12 infant loungers. Since then, we have sold more than a million infant loungers. Snuggle Me has a dedicated quality control team that monitors product fault rates, and each assembled unit is thoroughly inspected and quality controlled, before being released for sale. We are proud of our strong track record of safety.

A. Our Unique Design

The patented Snuggle Me lounger is unlike any other product on the market. It has an unpadded, suspended center sling, which can gently hold a baby in the supine position. When baby is placed in the center sling the lounger sides gently pull in at the shoulders and give the baby the sensation of being held or hugged. The lack of a separation between the occupant surface area and the sidewall means that there is no space for a baby to become entrapped. Additionally, the lounger's center sling is unpadded for safety. Our fabrics are organic cotton, and we use water based organic dyes.

(The Snuggle Me Organic Infant Lounger, Birch)[7]

If a baby turns inside of the lounger and ends up on their tummy, the unpadded occupant surface area will take on the firmness of the floor. Additionally, the unpadded bottom helps babies who may be strong enough to roll on their tummies to push up from the bottom and lift their torso and head.

A baby not yet physically developed enough to roll will be held gently at their shoulders in the supine position. If a baby can roll on a floor, they may be able to roll in the Snuggle Me infant lounger as well. When the Snuggle Me lounger is used correctly on a low, hard surface (such as the floor), the current design with four-inch high sides more effectively prevents babies from rolling out of the lounger and into a potentially unsafe outside environment than an alternative design that meets the lower proposed sidewall height. Lowering the sidewall height from its current four inches to "approximately 1.9 inches" as proposed in the NPR would likely make the Snuggle Me lounger too shallow and cause the center sling to not work as intended. It may also allow more developmentally advanced infants to roll outside of the lounger into a potentially unsafe environment. (*See* Section IV.B below discussing Exponent's comparison of the Snuggle Me lounger with a prototype with lower sidewalls.) Lowering the sidewall height would also eliminate the Snuggle Me "hug" effect.

[7] https://snugglemeorganic.com/products/infant-lounger-birch.

B. Our Warnings, Instructions for Safe Use, and Safe Sleep Resources

The safety of the babies using our products is our top priority. We feel strongly that clear and conspicuous warnings and instructions for safe use are needed for the entire infant lounger product category, and are proud of the content and consumer reach of our messaging. Snuggle Me loungers come with a permanently affixed on-product fabric label that warns caregivers against the dangers of suffocation, against using the lounger as a sleep device, or leaving baby unattended, and instructs consumers to only use the lounger on the floor and never carry the lounger with baby inside. Our product labels are attached at the side seams, and are tested to ensure that they remain attached when subjected to a 15-lbs (67 N) pull force applied in any direction using a 3/4-inch diameter clamp surface. We are exploring warning label wording options, as well as different on-product placement options to further improve prominence of the important safety messages we want consumers to see.

In addition to the on-product warning label, Snuggle Me provides detailed safe-use instructions and strongly worded warnings against unsafe uses in the user guide included with the loungers, on the packaging label, on all product listing pages in our online store, on a dedicated "Safety" page and an "FAQ" page on our website. For example, we tell customers that the lounger "is designed for actively engaging, playing, and bonding with your awake little one," and further warn them that the lounger is not a sleeping device, must never be used in a crib or another sleep device, and is for supervised awake time only. We warn against suffocation and fall hazards. We also provide a detailed safety checklist on our website, together with links to multiple third-party resources promoting safe sleep practices, including the American Academy of Pediatrics' "Updated Safe Sleep Recommendations," the Centers for Disease Control and Prevention's "Helping Babies Sleep Safely," the National Institute of Health's "Safe Sleep Environment" resources, Health Canada's "Safe Sleep" guidance, and the First Candle's "Safe Sleep Guidelines."[8]

C. Fostering Customer Engagement with Our Safety Message

Because making sure that parents and caregivers see and understand safety warnings and instructions is just as important as the content of those warnings and instructions, we are also leveraging technology to reach and engage with customers. In addition to print and online warnings, instructions and educational resources, we are adding a QR code sticker to retail packaging giving customers a significant incentive—15% off the purchase price[9]—to watch a two-minute safety video. We will also be adding the QR code with a discount incentive linking to the safety video in the user guide inside the packaging. This safety video can also be found on our website. It instructs parents and caregivers, among other things, to use the Snuggle Me lounger "on a flat, firm, ground surface," "make sure you are alert, present, and in the same room with your baby when using," and "if your baby falls asleep,

[8] *See, e.g.*, https://snugglemeorganic.com/collections/snuggle-me-organic-infant/products/infant-lounger-moss (Product listing); https://snugglemeorganic.com/pages/safety (Safety); https://snugglemeorganic.com/pages/smofaq (FAQ).

[9] Our infant loungers retail for about $100.

remove them immediately, and place them into a sleep-approved crib, cradle or bassinet, with a firm, tight-fitted sheet." The video also states, "The Snuggle Me infant lounger is not a sleep device. Never use this, or any lounger, in a crib, co-sleeper, or as a place to nap throughout the day. Use only if your baby is awake, and of course, never leave them unattended."[10]

(The Snuggle Me Infant Lounger Packaging Showing Placement of QR Code Sticker)

As detailed in these comments, we strongly believe that the Proposed Rule should be withdrawn, so that CPSC may consider design differences among covered products, perform necessary human factors studies to evaluate foreseeable consumer misuse of any redesigned products, conduct round robin studies involving multiple laboratories and multiple exemplar products in each category, with a view to reproposing and ultimately adopting testing and performance requirements that are supported by an adequate and complete record, including risk/benefit and risk/hazard analyses. In the meantime, Snuggle Me stands ready to work with CPSC on improving consumer outreach, education and engagement. We are proud of the many ways in which we deliver the all-important safety message, as we continue to innovate in this area. We welcome the opportunity to share our learnings, and to collaborate with CPSC on additional educational outreach.

[10] https://snugglemeorganic.com/pages/safety.

II. The Proposed Rule Is Overbroad and Inadequate in Its Treatment of Vastly Different Product Categories

Snuggle Me's comments are limited to the application of the Proposed Rule to the Snuggle Me infant lounger. Although these comments do not expressly address implications of applying the Proposed Rule to other product categories swept into this proposal, treating vastly different product categories the same requires support by the NPR record. Such support is lacking. Notably, incident data considered by CPSC fails to identify what type of products were involved in the various incidents, a significant flaw in the record, given the vast design differences among at least a dozen product categories now swept into the Proposed Rule. This lack of record support renders this Proposed Rule on a broad category of "infant support cushions" arbitrary, capricious and an abuse of discretion, requiring its withdrawal.

The NPR identifies twelve broad product categories: "head positioner pillows," "flat baby loungers," "crib pillows," "wedge pillows," "infant sleep positions," "stuffed toys marketed for use as an infant support cushion," "'tummy time' or 'lounging' pillows," "multi-purpose pillows," "anti-rollover pillows that hold a bottle," unspecified "pads and mats," and finally, a range of stand-alone "accessory pillows and other padded accessories, often marketed for use with an infant car seat, stroller, or bouncer." (80 FR 2531.) Many of these product categories do not have an "occupant support surface," which is at the core of CPSC's proposed testing. Intended purpose and use, construction, size, shape, and firmness also vary widely among the listed categories. Moreover, CPSC describes these diverse products as "[a] *non-exhaustive list of examples* of infant support cushions" covered by the Proposed Rule. *Id.* (emphasis added). Unidentified additional types of "infant support cushions" are also in scope, leaving regulated entities uncertain as to what products may be covered and rendering the proposal impermissibly vague.

The Snuggle Me lounger is not an "infant support cushion." It is not a sleep positioner (we expressly warn against using it for sleep). It is not any kind of infant pillow (we warn against putting it in any sleep environment). It is not an accessory for use with an infant car seat, stroller, or bouncer (we instruct parents and caregivers to use it only on the floor). It is not a pad or a mat (it has raised sides). In fact, the Snuggle Me lounger is unlike any of CPSC's illustrative examples, including "flat baby loungers." Flat loungers are designed with a padded OSS that is separate from the sides, creating an intersection where the OSS and sidewalls meet. In contrast, the suspended, unpadded center sling in the Snuggle Me lounger is designed to hold baby's head and torso, with baby's legs draping over the end of the lounger, creating the sensation of being hugged. The design of the Snuggle Me lounger creates a different sensory experience for baby than that of a flat lounger.

III. CPSC's Proposed Angle and Firmness Tests and Performance Requirements Are Ill-Suited for the Snuggle Me Infant Lounger and Other Product Categories, and Are Not Supported by the Record

A. Proposed Sidewall Angle Test

The proposed sidewall angle test is based on CPSC's assumption that babies will always be in an inclined position in any product in the category. In the Supplementary Information to the Proposed Rule, CPSC states:

> *The proposed rule, like ASTM's draft, requires that the angle formed between the product's OSS and any sidewall be greater than 90 degrees* ***to reduce potential entrapment hazards between the sidewall and the occupant support surfaces****. The proposed rule requires a slightly different methodology for measuring this angle than does ASTM's draft. While ASTM's draft requires that this angle be measured with a protractor or similar tool at four-inch intervals along the product's interior, the proposed rule specifies assessing this angle with the cylindrical side of the three-inch probe, with a 10 N force applied to the probe. The probe, which is designed to simulate the size and shape of an infant's head, is used to determine whether there is any contact between the sidewall and the probe's side when the "face" of the probe is pressed against the OSS/sidewall intersection. If there is such contact, indicating an entrapment risk, that indicates that the angle is less than 90 degrees, and the product would fail. Conversely, if there is no contact between the sidewall and the side of the probe, the angle is greater than 90 degrees and the product meets this requirement.*

(89 FR 2538 (emphasis added).) Although eliminating entrapment hazards is a noble goal, the proposed sidewall angle testing is a poor one-size-fits-all proposal that is unworkable across many product categories.

First, even a cursory look at the illustrative list of covered product categories reveals that CPSC failed to consider significant design and construction differences among the diverse product categories covered by the Proposed Rule. Many of the example product categories do not have a "sidewall" or an "occupant support surface," rendering the side angle testing meaningless for those categories.

Second, within the infant lounger category, the proposed side angle testing is not supported by the record because CPSC and BSU did not address the test's applicability across the range of commercially available lounger products. For example, with regard to the Snuggle Me infant lounger, there is no indication in the record that CPSC or BSU considered its unique design, which leaves no space between the lounger's center sling (the OSS) and the lounger's sides. If this and other products' unique designs had been considered, the Proposed Rule would have addressed how to test the "sidewall angle" on products that do not have a space between the sidewall and the OSS area, as well as products that do not have an OSS. It does not. Instead, the Proposed Rule provides a series of steps "to determine if the angle between the sidewall and OSS is 90 degrees or less." (§ 1243.5(i), 89 FR 2551.)

Third, the proposed "sidewall angle determination" requires the placement of the test probe "tangent to the *intersection* of the sidewall and the OSS," as well as the determination of "a minimum of four sidewall angles at locations not to exceed six-inch (15.2 cm) intervals along the *intersection* of the sidewall and OSS." (§ 1243.5(i)(1), (4) (emphasis added), 89 FR 2551.) The Proposed Rule provides, however, no instructions or even general guidance how that critical "intersection" point is to be determined. Indeed, CPSC recognizes that "[l]ocating the intersection or transition from sidewall to OSS will be a challenge in some products." (Tab C, Briefing Package, OS 119.) Instead of addressing that challenge, the agency has abdicated its responsibility, stating that "[b]ecause this transition varies among products, staff does not have a recommendation for a method to determine the exact intersection of the sidewall to OSS." (*Id.*) Thus, manufacturers and testing labs are left to guess the location for the placement of the test probe under proposed § 1243.5(i), which in CPSC's own words can be "an inexact, virtual intersection." (*Id.*) If CPSC disagrees with a company's determination, the company faces liability as a result.

B. Proposed Maximum Incline Angle Test

The draft ASTM infant lounger standard contemplates testing the incline angle in all the manufacturer's recommended use positions. Without adequate support on the record, the Proposed Rule seeks to also mandate testing "additional locations of potential inclined lounging, reclining and sleep," as well as other requirements. Specifically, in the Supplementary Information to the Proposed Rule, CPSC states:

> *The three ways in which the proposed rule modifies ASTM's proposed testing protocol are: (1) setting a maximum incline angle that applies not only to all of a manufacturer's recommended use positions, but also to* ***all other infant cushion surfaces that can feasibly support an infant's head****, including, for example, the angle from any sidewall to the OSS or from the sidewall to the floor; (2) use of a newborn hinged weight gauge, rather than an infant gauge; and (3) positioning the gauge differently throughout testing.*

(89 FR 2538 (emphasis added).) According to CPSC, these modifications are necessary "in order to improve test consistency across all infant support cushion products and to address additional locations of *potential* inclined lounging, reclining, and sleep." (*Id.* (emphasis added).) Despite the stated goals of measuring maximum incline angle at all "feasible" or "potential" lounging positions, the proposed testing parameters mandate positioning of the test probe in ways that are not representative of consumer use or even reasonable misuse, and CPSC does not consider if the Proposed Rule introduces new hazards.

For example, "[i]f a product's seating bight area *prevents reasonable positioning* of the head/torso portion to the outermost edge," the Proposed Rule instructs testing labs to "*then position the seat portion of the newborn hinged weight gauge as far forward as possible* towards the outermost edge and allow the head/torso portion of the gauge to rest on the product." (§ 1243.5(d)(6) (emphasis added), 89 FR 2549.) This type of testing may be intended to reflect misuse scenarios, but CPSC does not specify, and the record is not clear,

why these particular testing parameters that go beyond "reasonable positioning" are warranted. Furthermore, CPSC has not considered whether compliance with the firmness parameters in the Proposed Rule eliminates the need for this maximum incline testing and resulting lower sidewalls that introduce new risks. In other words, if product sidewalls meet new firmness performance parameters, it becomes highly unlikely that a caregiver would misuse the product to place a baby with their head on a 4-inch sidewall that has the firmness of a crib mattress, similar to the firmness of a yoga brick. In fact, CPSC should consider whether a lounger product with 4-inch sidewalls that meets the side angle and firmness requirements in the Proposed Rule is less likely to be misused, and is therefore safer for babies overall, than a lounger with approximately 1.9 inch high sidewalls. These are the types of risk/benefit and risk/hazard analyses needed to support a rule.

As another example of unworkable testing parameters, the Proposed Rule requires that, in addition to the manufacturer's recommended use location, the incline angle must also be measured at other "*feasible* locations" and "at least one location *likely to fail* in which the newborn seat is supported on the test surface." (§ 1243.5(d)(9) (emphasis added), 89 FR 2549.) One example of a "feasible location" is provided, but the term is not defined. A "location likely to fail" is also not defined, nor is any guidance provided as to how is such a location to be found. The firmness tests in the Proposed Rule mandate testing of at a location "mostly likely to fail," which is similarly undefined, yet CPSC does not explain the difference, if any, between "likely to fail" and "most likely to fail" locations in these provisions of the Proposed Rule. These undefined testing parameters are not linked to established test methods, or even objective, repeatable and reproducible requirements. Instead, each manufacturer and each testing lab must presumably come up with "a *suitable number* of locations that represent the *feasible uses* of the infant support cushion for inclined support." (Briefing Package, OS 121 (emphasis added).)

Besides these general flaws in the maximum incline angle testing parameters in the Proposed Rule, the proposed parameters should not be applied to the Snuggle Me infant lounger for several additional reasons. We recommend placing baby on their back in the center sling of the Snuggle Me lounger. For example, we instruct parents and caregivers: "To use your Snuggle Me, lay your baby in the center of the unpadded sling on their back, drape their legs over the bottom end of the lounger. Ensure the baby's body is straight and their chin is not tucked downwards."[11] In this position, baby's head is not at an incline and this position activates the hug effect intended by the center sling design. Further, as noted above, if the sidewall firmness requirement in the Proposed Rule is met (*i.e.*, "the force required for a one-inch displacement shall be greater than 10 N" (§ 1243.4(e)(2), 89 FR 2545)), it would be highly unlikely that a Snuggle Me lounger would be misused for inclined support by positioning a baby's head on the top of the firm, 4-inch high sidewall.

Finally, aside from the above test method deficiencies, the maximum incline angle requirements will result in sidewalls "limited to *approximately* 1.9 inches." (89 FR 2539 (emphasis added).) This represents a significant sidewall height reduction from the current 4-

[11] "*How to use your Snuggle Me*," https://snugglemeorganic.com/pages/safety.

inch side height for the Snuggle Me lounger and other lounger products. As detailed in Section IV below, adoption of the Proposed Rule is likely to amplify hazards identified by the CPSC and introduce new hazards that CPSC has not considered.

C. Proposed Firmness Tests

In the Supplementary Information to the Proposed Rule, CPSC states:

> *The Commission's proposed firmness requirements and associated test methods are consistent with those applicable to crib mattresses and more stringent than those currently included in ASTM's draft standard for infant loungers. As explained in Tab C of Staff's NPR Briefing Package, based upon the findings and recommendations in the BSU Final Report as well as staff's analysis of the incidents and hazard patterns associated with facial occlusion into infant support cushions, the proposed rule requires firmness testing at three locations: the* ***occupant support surface****, the* ***sidewall****, and the* ***intersection of the occupant support surface with the sidewall****.*

(89 FR 2536 (emphasis added).) According to CPSC, meeting the proposed firmness requirement would "indicate[] product firmness that is at least comparable to a crib mattress." (89 FR 2536.)

With regard to the OSS test, if the OSS is greater than 1.0 inches, additional firmness tests must be performed "at the geometric center of the OSS, *at four locations* along the product's longitudinal and lateral axes therefrom, 1.5 inches (3.8 cm) towards center from the *intersection* of the sidewall and OSS." (§ 1243.5(f)(9) (emphasis added), 89 FR 2549.) Similarly, the sidewall and the sidewall/OSS intersection test methods require "*a minimum of four additional* tests." (§§ 1243.5 (g)(1), (h)(4) (emphasis added), 89 FR 2550.) For each of the three firmness tests, the Proposed Rule vaguely requires, in addition to other requirements, that the test be performed (1) "at one location *most likely to fail*," and (2) "in *all* the intended or *feasible configurations that could affect* the [occupant support, sidewall, or intersection], such as the folding of layering of parts of the product." (§§ 1243.5(f)(10), (g)(2), (h)(5) (emphasis added), 89 FR 2549-50.)

These proposed firmness test methods are plainly not standardized test methods. Not surprisingly, the record is devoid of any data on the consistency or repeatability of these methods. For many of the same reasons discussed in Sections II.A and II.B above, these test methods must be rejected because they fail to comply with basic requirements for rulemakings. *See Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43.

The proposed firmness testing depends in large part on locating the *intersection* between the OSS and the sidewall of covered products, including infant loungers. By CPSC's own admission, "[l]ocating the intersection or transition from sidewall to OSS will be a challenge in some products," and "[b]ecause this transition varies among products, [CPSC] does not have a recommendation for a method to determine the exact intersection of the sidewall to OSS." (Tab C, Briefing Package, OS 119.) Again, the Proposed Rule does

not provide, with requisite specificity, rule language enabling manufacturers and test laboratories to solve the "challenge" of locating the intersection, which CPSC recognizes is, at least for some products, "an inexact, virtual intersection." (*Id.*)

CPSC speculates that because the Proposed Rule also includes "firmness requirements for sidewalls and [OSS], which are adjacent to th[e] firmness test for the intersection of sidewall and [OSS], the three firmness tests (sidewall, intersection, and OSS) will adequately cover the firmness of the product in representative locations." (*Id.*) Not so. This speculation ignores that the OSS test also hinges on locating the intersection (for all products with an OSS that is more than one inch thick). (*See* § 1243.5(f)(9), 89 FR 2549.) Thus, two out of the three proposed firmness tests depend on manufacturers and test labs finding "an inexact, virtual" location, and taking measurements based off of that location, to determine if a product passes or fails the Proposed Rule.

Further compounding this ambiguity, the Proposed Rule requires firmness testing at other locations "most likely to fail," even if the OSS is one inch thick or less. Yet how those locations are to be determined, and what criteria must be applied to identify them, are unspecified. Moreover, the Proposed Rule requires testing "in all … feasible configurations that could affect" firmness. (§§ 1243.5(f)(10), (g)(2), (h)(5); 89 FR 2549-50.) Again, these are neither objective, nor reproducible test parameters. While Snuggle Me believes that a general sidewall firmness requirement could enhance infant lounger safety without altering the current 4 inch sidewall height, the suite of proposed requirements outlined in the Proposed Rule are not adequately specific for manufacturers and test labs to identify and implement, and cannot be applied to the Snuggle Me design.

IV. CPSC's Proposed Reduced Sidewall Height of "Approximately 1.9 Inches" Is Not Supported by Available Data and May Significantly Decrease Infant Safety

In the Supplementary Information to the Proposed Rule, CPSC states:

> *The proposed rule limits the height of any sidewall of an infant support cushion, as does ASTM's draft. However, the proposed rule addresses the hazards associated with relatively high sidewalls* ***in a manner that is more closely tailored to the hazards****, and applies to all of the products that fall within the scope of the proposed rule.* ***These hazards are that caregivers may judge that an infant support cushion with relatively high sidewalls can safely contain an infant without supervision and is suitable for use on top of an adult bed or in a crib notwithstanding any contrary warnings****, and that* ***high sidewalls can cause hazardous positioning of the infant's neck when an infant's head is placed on top of the sidewall while their body is on a lower surface*** *either inside or outside of the product. See Staff's NPR Briefing Package, Tabs B and C. While ASTM's draft sets a four-inch limit on sidewall height, the proposed rule addresses these hazards by limiting the* ***maximum incline angle*** *and provides testing protocols based on the type of product (for example, lounger-type products or head cushions). Using the test methodology prescribed in the proposed rule, sidewall heights, for products that have sidewalls, would be limited to* ***approximately 1.9 inches****.*

(89 FR 2539 (emphasis added).) Thus, the Proposed Rule does not set an objective maximum sidewall height requirements; instead, a sidewall height of "approximately 1.9 inches" is the result of the prescribed maximum incline angle testing. (*See* § 1243.3(e) ("The maximum side height for the product, measured from OSS-body or test base, as appropriate, to the top of the sidewall shall not exceed the maximum of the side heights determined in § 1243.5(d)(8) [Maximum Incline Test].").) According to CPSC, the proposed maximum incline angle testing, together with the firmness testing, "would address positional asphyxiation hazards," while "effectively limiting sidewall height to discourage caregivers from mistakenly believing these products to be safe for unattended infants," would "address[] fall hazards." (89 FR 2531.)

As detailed below, a sidewall height of "approximately 1.9 inches" is not supported by the record, and is not only unlikely to ameliorate fall hazards, but may amplify them by enabling infants to roll out of products. This potential significant consequence of CPSC's proposed new requirements has not been considered. Another foreseeable consequence that has been ignored is that caregivers may try to compensate for the much lower sidewalls by using blankets, pillows and other soft material, thereby creating an increased potential asphyxiation hazard. Both foreseeable consequences may result in decreased infant safety, and therefore must be thoroughly studied before a rule is finalized.

A. The NPR Record Does Not Support a Sidewall Height of "Approximately 1.9 Inches"

The Proposed Rule reflects CPSC's unsubstantiated "concerns" that a four-inch side height gives parents and caregivers the "mistaken impression" that they can leave babies asleep and unattended in the product, including inside cribs and beds and on elevated surfaces. (89 FR 2536.) However, unsubstantiated concerns cannot be the basis of a rule; a rule must be supported by record evidence, which is lacking here.

There is no evidence in the record that 4-inch sidewalls are "relatively high" or that this height causes caregivers to "judge" that a product "can safely contain an infant without supervision … notwithstanding any contrary warnings." (89 FR 2539.) CPSC could have commissioned a human factors study to test its hypotheses, but did not. Likewise, the record is devoid of any support as to why "approximately 1.9 inches" is a "safe" sidewall height, which would no longer give caregivers "the mistaken impression that an infant can safely be left unattended in or on the product." (89 FR 2536.) Why not 2.1 inches or 2.75 inches, or any other number below the 4-inch sidewall height that CPSC is "concerned" about? And will caregivers be more likely to introduce soft bedding in and around a product with lower sidewalls?

In fact, it is not clear from the record what "approximately 1.9 inches" even means. Buried in a footnote in Tab C of the Briefing Package, is CPSC's only attempt to explain this elusive, yet mandatory, measurement. According to that footnote 10, "approximately 1.9 inches" may actually be a range, with "1.91 in." as a "minimum passing sidewall height," and a different "maximum sidewall height [that] depends on the sidewall construction." (OS 123,

n.10.) CPSC notes that two tested products with maximum incline angle "near 10 degrees" (10.6 degrees and 11.2 degrees) had sidewall heights of 2.72 inches and 2.66 inches, but determines no passing maximum value.

Moving beyond the arbitrary nature of the sidewall height measurement, ample evidence on the record goes against lowering the sidewall height of infant lounger products. According to CPSC Health Science Staff's ("HS Staff") assessment of incident data, the leading cause of non-fatal incidents was falls from the product (29 incidents), with threatened asphyxia, involving babies that were found partially or completely hanging or rolled off the product (27 incidents) as a close second leading cause of injuries. Thus, potentially as many as 56 incidents (approximately 45% of all reported non-fatal incidents) involved babies moving out of the product and sustaining a fall injury or finding themselves in an unsafe environment. (Tab B, Briefing Package, OS 100-104.) Furthermore, of the fatal incidents, at least 7 involved a baby that had moved partially or completely off the product, or was found wedged outside of the product, 1 involved a baby that partially rolled off the product and was found hyperextended, and 14 involved a baby rolling off the product and into a hazardous setting, for a total of 22 fatal incidents (approximately 28% of all reported fatal incidents) involving a baby escaping the product. (*Id.* OS 102-103.) This incident data strongly suggests that lowering the sidewall height may lead to more, not fewer, incidents, both fatal and non-fatal. CPSC *presumes* that caregivers would not use products with significantly lower sides in the same dangerous ways, **but there is no record evidence in support of CPSC's presumption.**

In contrast, the BSU Report, which considered the same incident data that CPSC had, did not recommend lowering the sidewall height, and instead recommended better consumer education, firmness, airflow, and sagittal-plane testing. (BSU Report at 106-07.) Surprisingly, CPSC appears to have considered an "Alternative Sidewall Height Method," but without much explanation, did not "recommend[]" it. (Tab C, Briefing Package, OS 123; Appendix, OS 132-34.) From CPSC's few notations comparing this rejected alternative (which would have preserved the existing 4-inch height) with the proposed Maximum Incline Angle (which would reduce sidewall height to "approximately 1.9 inches"), it appears that CPSC selected the latter "because most of the samples would not pass according to the CPSC test, but most would pass according to the ASTM test." (Appendix, OS 133.) Summarily dispensing with the alternative method, which aligns with the BSU Report and ASTM firmness tests, in favor of a method without support on the record, is not reasoned decisionmaking on which a final rule should stand, and the recommendation is not supported by well-conducted risk/benefit and risk/hazard assessments. This is a material omission given that the proposed lower sidewall height can exacerbate hazards as explained below.

B. Lower Sidewalls May Promote Rolling and Increase Fall Hazards

We are deeply concerned that the Proposed Rule could result in a reduction in infant safety because the mandated much lower sidewall height is likely to promote rolling out of the products, amplifying fall and other injury hazards of older infants capable of rolling. Babies rolling off or out of products has already been identified by CPSC as leading to both

fatal and non-fatal incidents with these products, although CPSC did not apparently consider how the Snuggle Me infant lounger's unique design prevents this scenario when used as directed.

Given the lack of analysis in the record on comparative risks and hazards related to the proposed lower sidewall height compared to the current 4-inch height, Snuggle Me asked Exponent to conduct a preliminary evaluation of the current Snuggle Me infant lounger on the market, with an approximately 4-inch sidewall height, and of a non-commercial prototype with an approximately 2-inch sidewall height (the Prototype). The current Snuggle Me lounger and the Prototype are made from identical fabric and fiber fill, and have the same interior occupant support surface dimensions. The evaluation was conducted with a 7.5-month-old and a 5.5-month-old baby, each of whom could roll in both directions when placed on a flat surface. Observationally, the 7.5-month-old displayed a preference to be on her tummy, and the 5.5-month-old favored being on her side. For Exponent's evaluation, the Snuggle Me lounger and the Prototype were placed on the floor, per user guide instructions. The babies were placed on their backs inside the Snuggle Me lounger and the Prototype and were enticed with a toy and assistance from parent(s) to move from their back and to roll over within or out of the product. Exponent observed that both babies were able to roll out of the Prototype, similar to their rolling behavior on a flat surface. Exponent also observed that the reduced sidewall height of the Prototype provides less of a barrier to roll out of the product. Neither baby rolled out of the current Snuggle Me lounger, as the four-inch sides appear to adequately contain the baby inside the product when placed on the floor. When, after encouragement and enticement, the 7.5-month-old baby rolled on her tummy, she was able to push up from the bottom of the Snuggle Me lounger placed on the floor, and moved out of the product. The 5.5-month-old was not able to roll inside the Snuggle Me lounger. (*See* Attachment, "Exponent Assessment.")

Exponent's evaluation strongly suggests that lowering the side height to approximately two inches would amplify both the fall hazard, if the product is placed on a bed, table, couch or other elevated surface, as well as other hazards associated with babies rolling off or out of the product, which CPSC documented as causing fatal and no-fatal injuries. (*See* Section IV.A above.) Exponent's compelling initial work further illustrates the lack of technical support for the Proposed Rule and the very real possibility that if finalized, the Proposed Rule could *increase* hazards to infants and cause *more* injuries and fatalities. CPSC must commission a much larger study before finalizing the Proposed Rule and must fully consider the potential of increasing other identified risks. Mandating compliance with unverified product standards without conducting an evidence-based analysis of human interaction with the product would be arbitrary, capricious and an abuse of discretion.

C. Proposed Redesign May Invite Regrettable Substitutions and Increase Asphyxiation Hazards

CPSC speculates that lower sides would cause parents and caregivers to not leave products on elevated surfaces, but no data in the record supports that speculation, and CPSC's proposed warning label fails to squarely identify new potential fall hazards in a way that is

meaningful for parents and caregivers. What is more, CPSC does not consider a likely alternative effect of the proposed re-design on parental and caregiver behavior. CPSC has not addressed whether parents would use pillows, blankets and other soft bedding materials to create a higher "sidewall" to contain the baby. The record does not include data about how babies will respond to the new design and behave inside a lounger with a low side height, and we submit for the record a summary of the Exponent assessment. Likewise, the record lacks any evidence as to how parents and caregivers will perceive the new design, and how and where they are likely to use the new product.

Snuggle Me is concerned that lower side height may incentivize parents and caregivers to use pillows or rolled blankets or other objects to compensate for lower sides, thereby creating different asphyxiation hazards from the presence of soft and bulky materials around baby's head. It is at least as, if not more, likely that parents and caregivers will resort to such regrettable substitutions as it is likely that they will no longer misuse products with lower sides for sleep, as CPSC speculates.

A rule intended to enhance baby safety cannot be based on untested hypotheses and speculation.

We respectfully submit that Section 104 of the Consumer Product Safety Improvement Act (CPSIA) is designed to drive improvements in children's product safety, authorizing CPSC to promulgate safety rules that would reduce the risk of injury to children, and to review and revise existing standards to ensure that such standards provide the *highest level of safety for such products that is feasible*." 15 U.S.C. § 2056a(b)(2) (emphasis added). CPSC's authority and discretion are not absolute, however. Instead, the record must "articulate a satisfactory explanation for [CPSC's] action including a rational connection between the facts found and the choice made," and the explanation must demonstrate that CPSC's action "was the product of reasoned decision-making." *WCMA*, 82 F.4th at 1286, *citing Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43, 52 (1983).

In enacting Section 104, Congress could not possibly have intended to empower a federal agency to rush to pass an unsupported, unduly vague and overbroad safety rule that is likely to result in products with higher risk profile than current products, and in consumer substitutions and practices that make children less safe. Both CPSC's incident data and the agency's supposition that a lower side height would reduce consumer misuse, demonstrate that consumer misuse is at the core of this proposal. It would be arbitrary, capricious and an abuse of discretion for CPSC to issue a rule that fails to objectively assess the potential for the new rule to increase misuse and **decrease infant safety**. Instead, CPSC should commission a robust study to evaluate the net effect of the proposed changes on human behavior, and the effect on overall safety profile of the covered products. Such study should evaluate, among other factors, the effect of significantly lower sides on **both** *infants' ability to roll outside the products* (potentially resulting in increased fall incidents), and *parental and caregiver behavior* (potentially resulting in the use of pillows, rolled blankets or similar soft objects to compensate for lower sides and resulting in increased asphyxiation hazard).

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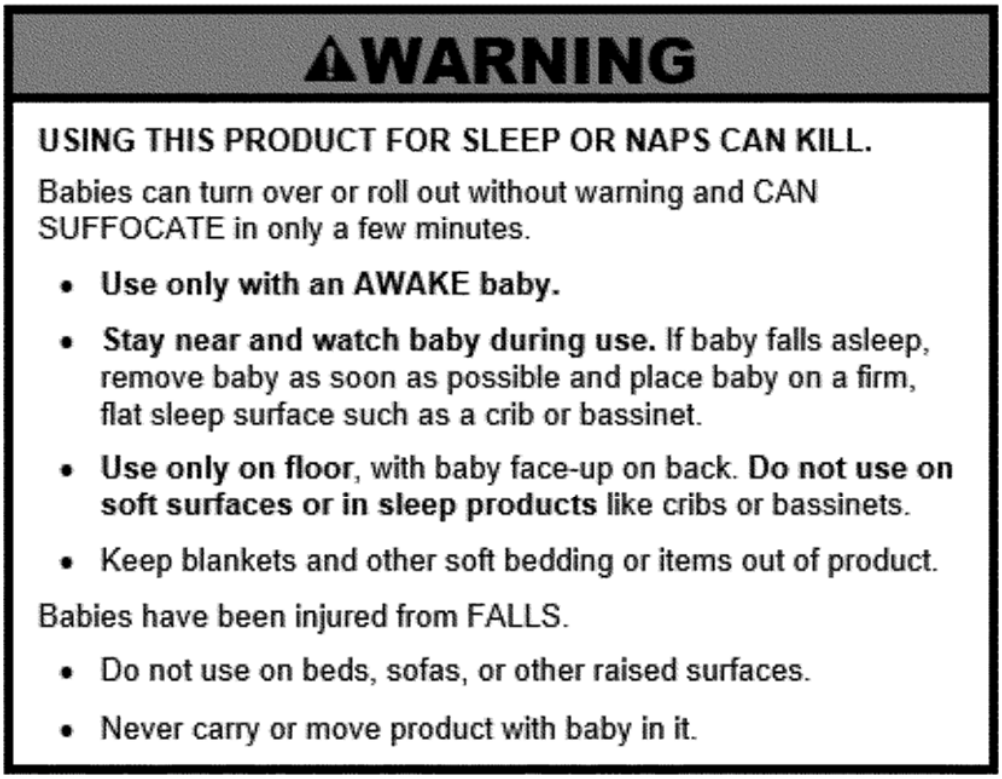
V. CPSC's Proposed Warnings Should Be Revised to Address Consumer Misuse Patterns

Snuggle Me agrees with CPSC that strongly worded warnings against consumer misuse are necessary. In the handful of reported injury incidents involving a Snuggle Me lounger, misuse played a major role, so we have spent much time and resources on clear and conspicuous safe-use instructions, and on strongly worded, clear and conspicuous warnings at multiple touch points with consumers. (*See* Section I above.)

CPSC has proposed the following warning label:

Figure 4: Example of Infant Support Cushion Warning



We agree directionally with the majority of the proposed warnings, but propose several ways to strengthen them. Because the record is insufficiently developed to address key issues that should be addressed in the warning statement, these comments simply highlight points to consider once additional data and studies, including comparative risk and hazard assessments and human factors studies, have been completed.

- As incident data shows that near asphyxiation and other injuries have resulted from babies rolling from lounger-type products improperly placed into sleep environments, we recommend changing the proposed "USING THIS PRODUCT

FOR SLEEP OR NAPS CAN KILL" to "**USING THIS PRODUCT FOR INFANT SLEEP OR NAPS CAN LEAD TO SERIOUS INJURIES OR DEATH**" (in bold lettering).

- CPSC's proposed warning to keep soft bedding and items ***out*** of the product does not go far enough. Placing soft bedding and other items ***around*** the product may also pose asphyxiation hazard as babies wriggle and roll, especially in a product with lower sidewalls where parents and caregivers may seek to compensate for lower sides by adding items around the product to keep babies contained.

- The proposed label states "Babies have been injured in FALLS," but stronger, more impactful language is needed to warn against the risk of falls. According to CPSC's incident data, falls are the leading cause of non-fatal injuries among babies, and we are deeply concerned that the risk of falls would increase if products are redesigned with significantly lower sides, as CPSC proposes. We urge CPSC to instruct caregivers that babies can turn over, roll out and fall without warning, to never place the product on raised surfaces, and always use on the floor. Some of these and similar statements are in the proposed warning label, but they are scattered and not connected to the statement that babies have been injured in falls, which dilutes the important fall hazard message.
- We also urge CPSC to warn consumers that babies develop differently and reach milestones at different ages. Caregivers should watch for signs that baby is ready to roll, and ensure that items that can hurt baby (e.g., small parts they can choke on, sharp corners of furniture, uncovered electrical outlets) are not present near the product, even when the product is properly placed on the floor.

Updated warnings, however, can only be based on a reliable updated record.

VI. Effective Date Must Be *at Least 12 Months* from a Final Rule

As explained above, CPSC must go back to the drawing board and not rush to pass a safety rule that is not supported by record evidence, is vague and ambiguous, and is likely to introduce new hazards. CPSC should commission human factor studies to evaluate the likelihood that that new hazards will be introduced, and conduct testing and seek other evidence as necessary to test the feasibility, repeatability, and reproducibility of the proposed tests to each product covered in the category. In each instance, tests and evaluations must be conducted on the range of commercially available products in this new, CPSC-created category. As it stands today, however, the record behind this Proposed Rule is woefully deficient. Much more testing and evaluations are necessary to establish that the tests and requirements in the Proposed Rule will achieve the claimed benefits, are repeatable and reproducible, and make products significantly safer. CPSC must also establish, based on an adequate record, that any benefits determined to be feasible and appropriate are not outweighed by new or increased hazards caused by a new rule. Potential regrettable

substitution scenarios that may result in more infant injuries and fatalities must be studied and addressed as appropriate.

Only after record evidence is developed and provisions in the Proposed Rule are modified accordingly should a revised Proposed Rule for infant loungers be issued for further public comment and ultimately finalized after due consideration of those comments.

After a well-thought-out and adequately supported final rule is published, manufacturers will need **at least 12 months** to make the many substantial changes expected to be needed throughout the supply chain, including to redesign their products, test prototypes, select a final design, and then source, test, package and distribute the new products. Additionally, Snuggle Me will need extra time to do the appropriate human factor testing to ensure we are producing the safest product possible.

Historical and regulatory precedent support a one-year effective date here, rather than 180 days. In the 2009 Registration Card Rule (74 FR 68668), CPSC set a 180-day effective date for the "original 12" durable infant product categories listed in the NPR to comply with the registration rule, but the manufacturers of the six products added to the definition of durable infant and toddler products were provided a one-year effective date. CPSC reasoned that since "CPSIA was enacted more than 15 months ago and manufacturers have been on notice of the requirement for registration of these twelve items since enactment, 180-day effective date was sufficient for those products. In contrast, CPSC gave manufacturers of the six additional categories "one year from publication of the final rule to implement the registration card and database." (74 FR 68672.)

Here too, there has been no prior NPR covering the example product categories, nor any other proposed or final rules mandating similar testing, performance, and registration requirements. As the Proposed Rule states, "[c]urrently, … no voluntary or mandatory safety standard exists for infant support cushions," nor do CPSIA Section 104 and 16 CFR § 1130 registration requirements apply to these product categories. (89 FR 2531.) The Proposed Rule would not only add infant loungers and several other product categories to the list of durable infant and toddler products subject to the registration requirements, but would also impose strict, yet ambiguous and often ill-defined product testing and performance requirements to all products in the category.

CPSC claims that 180-days would be sufficient because JPMA uses a six-month period for its certification program, (89 FR 2542), but this ignores the realities of the multiple new testing parameters at issue in this Proposed Rule and the many unclear, subjective aspects of the Proposed Rule. CPSC also claims that "[t]esting laboratories should have no difficulty preparing to test to the proposed new mandatory standards within 180-day period." (*Id.*) As detailed above, however, manufacturers and testing labs are going to need time to develop processes and tools to comply with multiple test methods—including maximum incline angle test, sidewall incline angle test, OSS firmness test, sidewall firmness test, and OSS/sidewall intersection firmness test—which involve not only multiples steps, but also aligning on how to identify "feasible locations," "reasonable positioning," locations that are

"likely to fail" or "most likely to fail," and "all intended and feasible configurations that could affect [a product surface]." (§§ 1243.5(d), (f), (g), (h), (i); 89 FR 2546-51.) Developing processes to apply multiple testing methodologies is *in addition to* developing an infrastructure for consumer registration and compliance with a registration card requirement.

Just as CPSC afforded a one-year effective date for manufacturers that were not on notice to comply with the 2009 Registration Card Rule, CPSC should afford *at least* a one-year effective date for manufacturers to comply with any final rule here. *See also Window Covering Manufacturers Ass'n*, 82 F.4th at 1290-93 (vacating final rule in part because CPSC did not find, as it must, that a 180-day effective date "is reasonably necessary to reduce or eliminate a risk of injury," and "neither the Final Rule, nor the administrative record examined how the timing of the effective date would affect the risk of injury").

VII. CPSC Has Grossly Miscalculated the Impact of the Proposed Rule

Assuming that the Proposed Rule is modified in a way that is fully supported by the record evidence and the resulting parameters allow Snuggle Me to make a reasonably safe and useful lounger product, we anticipate that costs would be significant, far exceeding CPSC's estimates (*e.g.*, "a modest retail price increase" of $2.70 expected to "cover the entire cost of redesign" for a company that makes 5,000 units per year (89 FR 2542)). Snuggle Me is a small company, and sales of infant loungers represent a significant portion of our total revenues. Finalizing this Proposed Rule without adopting our recommended changes based on appropriate record evidence could threaten the existence of the company.

The financial impact of this Proposed Rule is likely to be orders of magnitude higher than CPSC asserts. *First*, as no human factor studies have been performed by CPSC, Snuggle Me would want to conduct additional human factors testing to ensure that a re-designed product would be safe, and that regrettable substitutions and other types of consumer misuse would not render a redesigned product unsuitable. Sourcing, prototype development, human factors testing, and redesign are likely to require a months-long, iterative and costly process. Product performance testing before any new product is brought to market would add further time and expense. *Second*, as many of the parameters in the multiple proposed test methods have not been sufficiently defined, there will be significant expenses and time delays associated with manufacturers and testing labs working together to identify how these tests should be conducted, and to develop and implement testing programs. An effective date of 180 days after publication of the final rule provides an insufficient amount of time for manufacturers to complete the enormous amount of work required.

Apart from these uncertainties, the Proposed Rule's anticipated impact on Snuggle Me includes costs for materials and iterative prototype evaluations, finished prototype testing, additional human factors testing and risk assessments, qualification and finalization of new designs, manufacturing changes, consumer acceptance evaluations, and production line product testing. In addition to product redesign and development costs, we anticipate significant costs associated with the creation of new warnings, instructions, and safety collaterals, as well as website and other marketing changes. Return and destruction of

inventory, lost sales and retail price adjustments for new products are also likely to be significant.

More importantly, these substantial costs assume that Snuggle Me would be able to create a redesigned product that would be safe, useful, affordable and wanted in the marketplace. Given the ambiguities in the proposed test methods and other parameters in the Proposed Rule detailed above, we do not know if this is feasible. As the infant lounger product represents a substantial portion of Snuggle Me's annual revenues, if finalized without substantial necessary modifications outlined in these comments, the Proposed Rule would dramatically affect Snuggle Me's operations and staffing.

CPSC has completely ignored these significant impacts of the Proposed Rule. For example, CPSC claims that "the proposed requirements do not demand significant preparation by testing laboratories" (89 FR 2541), but does not consider the novelty and ambiguity in the several tests, each with multiple ill-defined steps. CPSC is also wrong in its unsupported assertion that a "modest retail price increases," such as $2.70 for a company that supplies 5,000 per year, "could cover the entire cost of redesign." (89 FR 2542.) Snuggle Me is a privately held Minnesota company and our sales and revenue data is confidential, but the costs outlined above are likely to be significantly higher.

CPSC is also wrong that "consumers would likely not experience a significant loss of utility as there are many different products available from different suppliers" from the market exit of small suppliers. (*Id.*) First, mandating a redesign of different loungers, feeding pillows, support pillows, and multiple other product categories to ensure "product firmness that is at least comparable to a crib mattress" (89 FR 2536), would undoubtedly result in "significant loss of utility" to consumers who seek these products for uses other than as crib mattresses. In addition, given the multiple significant testing requirements and strict performance requirements, it is highly unlikely that "many different products" would remain on the market in the aftermath of the Proposed Rule's adoption. Manufacturers and testing labs alike are likely to struggle with test methods that are neither objectively clear, nor demonstrably repeatable and reproducible. Likewise, the Proposed Rule also requires manufacturers to guess what is "feasible," "reasonable," "likely to fail," and "most likely to fail" (89 FR 2546-51), and where "an inexact, virtual intersection" between sidewalls and OSS exists, a challenge that CPSC expressly recognized but did not address (Tab C, Briefing Package, OS 119).

VIII. Conclusion

Products like the Snuggle Me infant lounger fulfill an important need. We agree that they should never be used for sleep or placed in sleep environments, that they should not be placed on a soft or elevated surface, and that babies should never be left unattended while using the products. These considerations form the core of Snuggle Me's warnings and safe use instructions. We support strongly worded and conspicuous warnings, including permanent on-product warnings, and are committed to consumer education. We are very concerned, however, that the Proposed Rule in its current form does not take into

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consideration significant differences among numerous covered product categories, includes provisions that are not supported by the BSU Report or other record evidence, does not adequately address parental and caregiver misuse, adopts requirements that cannot be applied to the Snuggle Me product, and instead introduces new hazards and amplifies existing hazards, thereby raising the potential risks of multiple baby product categories.

We urge CPSC to withdraw the Proposed Rule, and to work with manufacturers, industry leaders, testing labs, human factors experts, risk and safety experts, and consumer advocates to develop a plan to test products with a view to creating appropriate record support for an evidence-based revised rule that truly advances the cause of child safety. Snuggle Me would be pleased to work with CPSC on such an industry-wide approach.

Respectfully Submitted,

Alessio Bruni
President and Chief Executive Officer
Heroes Technology (US) LLC, d/b/a
Snuggle Me Organic

Attachment: Exponent Assessment

cc: Sheila A. Millar, Of Counsel

Attachment

Exponent®

Snuggle Me Organic Consulting

2311830.000

March 13, 2024

Michael Prange, Ph.D., P.E.

Juff George, P.E.

Karol Silva, Ph.D., M.P.H.

Scope

- Per Snuggle Me Organic's request, Exponent conducted an assessment of the performance of exemplar lounger products (current design and prototype design)
  - Current and prototype designs are made from identical fabric and fiber fill
  - Current and prototype designs have the same interior occupant support surface dimensions
  - The current design has an approximately 4-inch sidewall height
  - The prototype design has an approximately 2-inch sidewall height
- This assessment included surrogate work with two infant subjects to compare the effect of these product designs on infant movement, specifically in the following scenarios:
  - Rolling out of the product
  - Rolling over inside of the product
  - Kicking out of the back/top of the product

Limitations

- The summary formulated during this assessment are based on observations and information available at the time of the investigation. If new data becomes available or there are perceived omissions or misstatements in this report, we ask that they be brought to our attention as soon as possible so that we have the opportunity to fully address them
- Exponent has no direct knowledge of, and offers no warranty regarding, the conditions beyond what was exposed during our investigation. The samples examined may not be representative of the entire population of products. Although Exponent has exercised usual and customary care in the conduct of this assessment, Snuggle Me Organic has the ultimate responsibility for the design, manufacture, performance, compliance, and safety of their products
- The scope of services performed during this analysis may not adequately address the needs of other users, and any re-use of the feedback is at the sole risk of the user. Snuggle Me Organic acknowledges, represents, covenants, and warrants that Exponent's analysis, feedback, and the like shall be independently assessed and analyzed by Snuggle Me Organic with respect to its products or services, and that any such decision or action made or undertaken by Snuggle Me Organic, based in any way upon Exponent's analysis, feedback and the like, is Snuggle Me Organic's decision alone and Snuggle Me Organic assumes all risks in connection therewith
- Snuggle Me Organic shall not, without prior written consent of Exponent in each instance: (a) use in advertising, publicity, marketing, or for similar purposes the name of Exponent, its affiliates, its personnel, or Exponent's trade names, trademarks, trade dresses, symbols, or any abbreviations thereof; or (b) make any statements to third parties that could be construed as Exponent endorsing or promoting a Snuggle Me Organic product

Exemplar Products

1. Current Design
   - Occupant support surface: organic cotton fabric sling affixed to the approximate midpoint of sidewalls
   - Sidewall: tubular polyester fiber-filled structure
   - Sidewall height: Approximately 4 inches

Exemplar Products

2. Prototype Design (provided by Snuggle Me)
   - Identical materials and assembly as current design
     - Occupant support surface: organic cotton fabric sling
       - Affixed to the approximate midpoint of sidewalls
       - Same interior occupant support surface dimensions as current design
     - Sidewall: tubular polyester fiber-filled structure with same amount of fiber-fill as current design
   - Tubular sidewall dimensions changed
     - Lower sidewall height (approximately 2 inches) than current design (approximately 4 inches)

Surrogate Work – Methodology

- Two Infants utilized in this study
  - Less than 9 months-old
  - Proficient at rolling from prone-to-supine (stomach-to-back) and supine-to-prone (back-to-stomach) on a flat, firm surface
- Study protocol
  1. Placed surrogate on flat surface to observe rolling behavior
  2. Placed surrogate in prototype design
     a) The surrogate was initially placed according to user guide instructions. In addition, the surrogate was re-positioned upward such that their head was at the top edge of the product
     b) With toys and assistance from parent(s), encouraged surrogate to roll over within the product, roll out of the product, and kick up out of the product
  3. Placed surrogate in current design
     a) The surrogate was initially placed according to user guide instructions. In addition, the surrogate was re-positioned upward such that their head was at the top edge of the product
     b) With toys and assistance from parent(s), encouraged surrogate to roll over within the product, roll out of the product, and kick up out of the product
- Documented with photographs and video

Surrogate Work – Surrogate S01

- Surrogate
  - Female
  - 7 ½ months
- Physical Developmental Capabilities Observed
  - Easily rolls in both directions
  - Pushes up with extended arms in prone position
  - Leans on forearm and elbow in propped, lying on side position
  - Hold head up and chest off the ground when in a prone position
  - History: Prefers to be on stomach, can not crawl on hand and knees

Surrogate Work – S01 (Flat Surface)

Surrogate Work – S01 (Prototype Product) – Rolled Outside

Surrogate Work – S01 (Prototype Product) – Rolled Outside

Duration = ~1sec

Surrogate Work – S01 (Prototype Product) – Kicked Up

Surrogate Work – S01 (Current Product) – Rolled Inside



Surrogate Work – S01 (Current Product) – Rolled Inside

Surrogate Work – S01 (Current Product) – Kicked Up

Surrogate S01 Summary

Prototype Product	Current Product
Rolled supine-to-prone out of product	Did not roll out of product
Did not roll within product	Rolled from supine-to-prone inside product, pushed up from bottom of product on floor, and then moved out of product
Kicked up and off the back edge of the product with head reaching floor	Kicked up and off the back edge of the product with head reaching floor

Surrogate Work – Surrogate S02

- Surrogate
  - Female
  - 5 ½ months
- Rolling Behavior History
  - Rolls in both directions
    - Rolled supine-to-prone after a few unsuccessful attempts (initial attempts were supine-to-side)
  - Pushes up with straight arms when prone
  - Hold head up and chest off the ground when in a prone position
  - Preferred to be on side
  - History: can not crawl on hand and knees

Surrogate Work – S02 (Flat Surface)

Surrogate Work – S02 (Prototype Product) – Rolled Outside

Surrogate Work – S02 (Prototype Product) – Rolled Outside

Duration = ~5sec

Surrogate Work – S02 (Prototype Product) – Kicked Up

Surrogate Work – S02 (Current Product) – Attempted Roll Inside

Surrogate Work – S02 (Current Product) – Kicked Up

Surrogate S02 Summary

Prototype Product	Current Product
Rolled supine-to-prone out of product after several attempts	Did not roll out of product
Did not roll within product	Did not roll within product
Kicked up and moved up the back edge of the product, but would then roll out of product	Kicked up and onto the back edge of the product, but head did not reach the floor

Summary of Observations

- Roll out of product
  - Current design
    - Study participants were not able to roll out of current product
    - Sidewall height allows the child to be enveloped within the product and provides a barrier to roll out of product
  - Prototype design
    - Study participants were able to roll out of prototype product, similar to their rolling behavior on a flat surface
    - Reduced sidewall height reduces how much the child is enveloped within the product and provides less of a barrier to roll out of product

- Roll over inside of product
  - Current design
    - With a multi-step process one participant (7 ½ month-old) rolled supine-to-prone while the other participant (5 ½ month-old) did not roll into a prone position
    - The participant (7 ½ month-old) who rolled supine-to-prone within the product subsequently then moved out of the product
  - Prototype design
    - Rather than rolling within the product, study participants were able to roll out of product, similar to their rolling behavior on a flat surface

Summary of Observations

- Kick up and over product
  - The ability of the infants to kick up and over the product did not substantially differ between products
  - In the current design, the participants would use the sidewall to kick up
  - In the prototype design, the participants would use the floor either in the occupant surface or outside of the product (due to the lower sidewall height) to kick up

EXHIBIT 9

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

COMMISSIONER PETER A. FELDMAN

April 28, 2021

The Honorable Maria Cantwell
Chairman
U.S. Senate Committee on Commerce,
Science and Transportation
511 Hart Senate Office Building
Washington, DC 20510

The Honorable Roger Wicker
Ranking Member
U.S. Senate Committee on Commerce,
Science and Transportation
555 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Cantwell and Ranking Member Wicker:

I write today to offer my support for S. 1259, the "Safe Cribs Act," and to thank you for including it on today's markup. I urge you to consider this legislation favorably and to advance it for consideration by the full Senate.

The United States Consumer Product Safety Commission (CPSC), of which I am a member, has long known that crib bumpers pose a hidden and deadly hazard to infants. According to CPSC data, between 1990 and 2016, there were 41 fatal incidents involving an entrapment or wedging scenario where a crib bumper was present in the sleep environment.[1] CPSC has long advised that "bare is best" when it comes to safe sleep. Outside experts, including the American Academy of Pediatrics, strongly oppose the use of crib bumpers.

Despite these incidents and calls to ban these products, the Commission has failed to act. While the Commission is authorized to promulgate bans for hazardous products under Section 8 of the Consumer Product Safety Act (CPSA), 15 U.S.C. § 2057, it may do so only when "no feasible consumer product safety standard … would adequately protect the public from the unreasonable risk of injury associated with such product." This is an extraordinarily high bar. CPSC has considered, but failed, to promulgate a crib bumper safety standard under its existing authorities, including Sections 7 and 9 of the CPSA.

CPSC has considered promulgating a safety standard for crib bumpers under Section 104 of the Consumer Product Safety Improvement Act and, in early 2020, issued a Notice of Proposed Rulemaking to proceed under this authority. However, Section 104 applies to durable infant and toddler products. According to CPSC staff, crib bumpers are textile products with an expected

[1] Memorandum from George Borlase, Assistant Exec. Dir., Office of Hazard Identification & Reduction, to the U.S. Consumer Prod. Safety Comm'n, at 6 (Sept. 9, 2016), *available at* https://www.cpsc.gov/s3fs-public/StaffResponsetotheRecordofCommissionActiononCribBumper.pdf.

useful life of less than 3 years.[2] Agency staff has argued, since as early as 2009, that "textile products would not be considered durable infant or toddler products," thus calling into question the viability of any rulemaking on this product under Section 104.[3]

While the agency could proceed under these authorities, a statutory directive would enable the Commission to act most efficiently to address this issue. S. 1259, the "Safe Cribs Act," would provide the authority needed to protect infants from the deadly hidden hazard this product presents. Thank you again for your consideration of this important legislation. Please do not hesitate to contact me with any questions you may have.

Sincerely,

Peter Feldman
Commissioner

cc: The Honorable Richard Blumenthal, Chairman, Subcommittee on Consumer Protection, Product Safety, and Data Security

The Honorable Marsha Blackburn, Ranking Member, Subcommittee on Consumer Protection, Product Safety, and Data Security

[2] *See* Memorandum from Gregory B. Rodgers, Assoc. Exec. Dir., Directorate for Econ. Analysis, to Timothy Smith, Project Manager, Crib Bumper Project, Directorate for Engineering Sciences, at 26-30 (June 1, 2016) (discussing that crib bumpers would not be considered "durable products" by existing economic and commercial definitions and stating that "[b]umpers, along with apparel and other textile consumer goods, generally are classified in government statistics as non-durable goods with a useful life of less than 3 years"), *available at* https://www.cpsc.gov/s3fs-public/StaffResponsetotheRecordofCommissionActiononCribBumper.pdf.

[3] Memorandum from Robert J. Howell, Assistant Exec. Dir., Office of Hazard Identification & Reduction, to the U.S. Consumer Prod. Safety Comm'n (May 20, 2009), *available at* https://www.cpsc.gov/s3fs-public/pdfs/blk_pdf_registration.pdf.

EXHIBIT 10

March 18, 2023

Alberta Mills
Office of the Secretary
U.S. Consumer Product Safety Commission
4330 East West Highway
Bethesda, MD 20814

Re: Docket No. CPSC–2023–0047 - Safety Standard for Infant Support Cushions

Submitted Electronically

Dear Secretary Mills:

The Juvenile Products Manufacturers Association (JPMA) appreciates the opportunity to comment on the Federal Register Notice of Proposed Rulemaking, "Safety Standard for Infant Support Cushions" (Docket No. CPSC-2023-0047).

The Juvenile Products Manufacturers Association is a national not-for-profit trade organization representing 95% of the prenatal to preschool industry including the producers, importers, or distributors of a broad range of childcare articles that provides protection to infants and assistance to their caregivers. JPMA collaborates with government officials, consumer groups, and industry leaders on programs to educate consumers on the safe selection and use of juvenile products.

JPMA, our member companies, and CPSC staff have often worked together via the ASTM process to develop standards and rules that make products safer and better for parents and their babies. JPMA appreciates CPSC's commitment to consumer product safety and their collaboration in the development of voluntary standards. Given that, JPMA has concerns about this new proposed rule, specifically the scope of the rule, the procedure and data used to develop the rule, the interpretation and application of the data, as well as the effective date. All of JPMA's comments on this proposed rule are rooted in the safety and well-being of parents and their children.

Scope
The NPR defines the scope of this rule as, "products that support an infant for lounging, meaning reclining or lying in a supine, prone, or recumbent position." The NPR then goes on to list a non-exhaustive list of products, including: head positioner pillows; flat baby loungers; crib pillows; wedge pillows for infants; infant sleep positioners, unless regulated by the Food and Drug Administration (FDA) as medical devices; stuffed toys marketed for use as an infant support cushion; infant 'tummy time' or 'lounging' pillows, whether flat or

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inclined; multi-purpose pillows marketed for both nursing and lounging; anti-rollover pillows with or without straps that fasten the pillow to the infant; infant 'self-feeding' pillows that hold a bottle in front of the face of a reclining or lying infant; pads and mats; and accessory pillows and other padded accessories, often marketed for use with an infant car seat, stroller, or bouncer, but not sold with that product and therefore not included in the mandatory safety standard for those products." The CPSC staff seems to justify such requirements for such products as required if such products are unreasonably misused for sleep. However, the CPSC already enacted a rule comprehensively addressing if such products are primarily intended and marketed for sleep.[1] Similarly, CPSC already enacted a banning regulation for certain infant support cushions.[2], and is in the process of proposed Standard setting for certain nursing pillows.[3]

It is JPMA's position that it is plainly clear how different and unique each of these products are from one another. Some of these products and some of the proposed requirements simply do not belong together in the same category. Specifically, many play mats and stuffed toys should clearly not be subject to this rule, as they are already subject to 16 CFR 1250 which the Commission just updated by incorporation of ASTM F-963-23[4] The products excluded should also be further expanded to include products where there does not exist a substantial record of fatalities directly caused by reasonable use or reasonably foreseeable abuse of such products.

Furthermore, the requirements in this rule do not make sense when applied individually to each of these products. It is also not clear that the incident datasets upon which this rule relies applies to each of these products or just some. Since CPSC has not broken down the incident data by the different product categories as defined in its definitional scope (of which there are a dozen), it is impossible to know to which product categories the incident data applies. Lumping all of these products together only obfuscates the data's meaning. Requests for more granular data by ASTM subcommittees to facilitate further comment have inexplicably remained unanswered. [5] Further complications are evident when the CPSC Staff citations to ASTM requirements are inaccurate or out of date.[6]

The scope is overly broad without an adequate causal connection between between the requirements, the data, and the products in scope. This vague scope and creation of a new product category deemed "Infant Support Cushions" only confuses manufacturers, home crafters, and consumers, and it obfuscates what the data is indicating and what this rule is trying to accomplish.

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[1] 16 CFR 1236
[2] 16 CFR 1500.18(a)(16)
[3] Commission's proposed nursing pillow rule 88 FR 65865
4.16 CFR 1250, ASTM F963-23
5. Review of ASTM F15 subcommittees including but not limited to F22 Toy Safety, F65 General Juvenile Product Standards, F15.21 Infant Lounger and F15.16
[6] See Latest Drafts of F15.21 Infant Loungers and F15.16 requirements Infant feeding Supports.

Definitions

Definitions should fully align with ASTM Standards definitions for Loungers and Feeding Support Pillows and avoid conflict with the definitions used for nursing pillows, toys, other regulated products and other products desired by consumers without an established hazard pattern.

Procedure and Data

JPMA has concerns regarding the procedure and data used in developing this proposed rule. As JPMA has noted in previous comments (including on the Proposed Rule for Infant and Infant/Toddler Rockers, the Proposed Rule for Nursing Pillows, and the Draft CPSC Scientific Integrity Policy), in the Memorandum for the Heads of Executive Agencies and Departments, dated March 9, 2009, President Obama directed that "each agency should make available to the public the scientific or technological findings or conclusions considered or relied on in policy decisions".[7] As also previously noted by JPMA, this directive was reaffirmed by President Biden in the Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking, from January 27th, 2021.[8] Specifically, this rule has not made enough data available, providing neither a risk/benefit analysis, risk/hazard analysis, nor a consumer choice analysis in regard to this proposed rule. Further, it is not clear from the data provided that the proposed rule would make these products safer. What is clear, though, is that this rule would require significant costly changes to many safe products. Though CPSC is an independent agency of the US Government, the lack of data made available to support both the the proposed rule requirements and the efficacy of such imposed requirements in reducing risks from reasonably used or foreseeably abused products appears to contradict the directive of this administration.

Furthermore, the failure to justify a proposed rule with adequate data during rulemaking is subject to "the rule of prejudicial error" under the administrative procedure Act (5 U.S.C. § 706).

Limited Record Data

The agency staff bundled "associative" data and summarily concluded the rule is necessary. However, it cited to 79 fatal incidents [9] and 125 nonfatal incidents and consumer concerns [10] associated with the subject products reported to CPSC from 2010–2022. It further noted

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[7] Memorandum for the Heads of Executive Departments and Agencies; https://obamawhitehouse.archives.gov/the-press-office/memorandum-heads-executive-departments-and-agencies-3-9-09

[8] Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking; https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/27/memorandum-on-restoring-trust-in-government-through-scientific-integrity-and-evidence-based-policymaking/

[9] 89 FR 2533

[10] 89 FR 2534

that 80% of the fatalities involved infants under 3 months of age and that only 62% involved asphyxia or probable asphyxia (an undefined term), which the dynamic performance requirements seek to prevent. It is not clear that the remaining causes of fatalities would in any way be addressed by such requirements. The CPSC Staff also notes nearly all reported fatalities (75 of 79) involved placement of the infant support cushion on another sleep-related consumer product, contrary to generally accepted safe sleep practice.[11] Of the 125 incidents referenced during the Commission briefing, staff could not preclude unintended consequences of consumer use of adult pillows, bedding and makeshift products if the proposed rule was adopted.[12] Similarly, with nearly all reported fatalities involving placement of the "infant support cushion" on another sleep-related consumer product, contrary to generally accepted safe sleep practice, the record is devoid of any data to provide reasonable assurance that the sought performance requirements would eliminate such misuse. Finally, for some unexplained reason, the Staff in compiling such datasets failed to correlate the data to each of the dozen product categories it seeks to broadly define as falling within the scope of its proposed definition of "infant support cushions". In failing to do so, it does not provide the public, or Commission with an adequate record upon which to reasonably comment.

We do note that based upon the Commission Staff's citation of 40 percent of all fatalities arising in the past few years, that the category of products most likely involved is more accurately defined as an "Infant Lounger" or non-nursing feeding support cushions, but since CPSC Staff has not identified each category of product involved in incidents, it is difficult to substantiate the record upon which this regulation is to be legitimately based.

In addition to the lack of data available in regard to this proposed rule and demonstrable efficacy of the proposed requirements, there has also been a lack of transparency concerning the sourcing and material accuracy of the limited data data thus far presented on the record. The proposed rule cites the June 2022 Boise State University study, *Pillows Product Characterization and Testing (*the BSU Report"*)*, several times as a basis for many new or additional requirements provided in the rule.[13] However, the CPSC has never made clear on the record whether the products cited in its admittedly associative data, complied with existing ASTM Standards or verified how such products may have been unreasonably misused. In fact, all the limited, compiled datasets referenced also contain a disclaimer from CPSC that admits such data is associative and does not indicate the cited product caused the fatality. We have noted if intended and marketed for sleep, products already fall within the

[11] 89FR 2533

[12] Transcript 44-44.52, Commission NPR briefing dated 11/15/23

[13] Notice of Proposed Rulemaking: Safety Standard for Infant Support Cushions; there thus far has been no RFP or public accountability on the CPSC's selection process for awarding the cited federal contract to Boise State. Similarly, the study has not been peer reviewed and interaction between the agency and study authors has not been transparent. As a federal agency, the CPSC, and the rules that it makes, highly depend upon the public's trust as it pertains to data and a demonstrable correlation to reducing injuries caused by consumer products.

scope of the CPSC's infant sleep product rule. However, the products referenced are primarily loungers or feeding pillows which were admittedly misused with a non supine infant, often in conjunction with other sleep products contrary to generally accepted safe sleep practice.

Therefore, JPMA finds that the lack of transparency, especially regarding data to support a rule that admittedly would have a costly impact on manufacturers and consumers, to be concerning.

Associative Data and Improper Use

As JPMA has previously pointed out in prior comments, yet continues to be the case, this NPR relies on associative incident data – which leaves any reader wondering if the requirements laid out in the NPR will actually make the products safer. The fact is that the data indicates that the products themselves are not dangerous by utility or design, but that they have been associated with incidents when placed into environments that are externally unsafe. CPSC acknowledges this in the proposed rule: "Nearly all reported fatalities (75 of 79) involved placement of the infant support cushion on another sleep-related consumer product. For the remaining four fatalities, the placement of the infant support cushion was either undetermined or unknown."[14]

Even when describing then nonfatal incidents, the data indicates that it is the external unsafe environments in which these products are placed that are the root cause: "In the case of falls, the reports revealed that in most incidents, infant support cushions had been placed on elevated surfaces including adult beds and couches. The injuries associated with falls include concussions, facial injuries, and scalp injuries. In the case of threatened asphyxia, the narratives described scenarios of infants being rescued after being found hanging partially or completely off of the infant support cushion with their mouths and noses obstructed, with their heads wedged between sleep positioner side cushions, or having rolled to a face-down position that put them at risk of an obstructed airway."[15]

This data itself is indicative of the fact that improper use of the products that the CPSC describes as Infant Support Cushions (which covers a broad swath of unique and specific product categories), specifically for sleep and often in externally unsafe environments such as on elevated surfaces, has contributed to the vast majority of incidents associated with these products since 2010. The clear majority of the products in the scope of this rule are not marketed or intended for sleep and have an acknowledged great deal of utility for parents who need a safe product in which to place their child during awake time interaction, play and engagement. Regulating and significantly altering safe products, due to associative (and decidedly not causative) incident data involving admitted instances of improper product use, only limits the safe options for parents. It is imperative that we keep

[14] 89 FR 2533
[15] 89 FR 2534

safe and useful juvenile products such as the many specific products covered in the scope available to parents. It is even more imperative to confront the issues that are causing most incidents and aim to robustly educate consumers of all backgrounds about the safe and proper use of such publicly desirable products. JPMA and its industry foundation JPMA Cares are taking a leadership role in this work.

Inconsistent Messaging in Warnings

We have consistently favored safe sleep messaging on all types of products, whether or not intended and marketed for sleep. However, warnings must be clear. Warnings grounded in reasonable advice (not to use these products for sleep or in other sleep environments) are distinct from recommending that products used for activities such as nursing, feeding, or prone-use products for tummy time and development of head and neck strength and dexterity be used only with an infant in a supine position. Similarly, medical advice for use of products to reduce the risk of plagiocephaly[16] or other medical conditions should not be undermined. There are inconsistent messages being promoted in the NPR must be avoided.

A Longer Effective Date Should be Considered.
JPMA believes that the effective date of any proposed final rule in this category should be one year, in contrast to the 180 days currently proposed. When, in the 2009 Registration Card Rule, the Commission set a 180-day effective date for the "original 12" durable infant products to comply, it stated a rationale that those product categories were already subject to the Commission's rules, noting it would be less burdensome on those manufacturers to incorporate the registration card requirements. However, the manufacturers of the six products added to the definition of durable infant and toddler products were provided a one-year effective date, because those products had not previously been subject to a mandatory rule. In doing so, the Commission explained: "The Commission is maintaining the 180-day effective date it had proposed…for the 12 product categories listed in the CPSIA and a compliance date of one year for the additional six products enumerated in the final rule" (74 FR 68673).[17]

As this proposed rule itself states, "The Commission is issuing this notice of proposed rulemaking (NPR) to establish a consumer product safety rule for infant support cushions to further implement section 104 of the CPSIA."[18] In the instant matter, not only is the Commission attempting to add a vague and unfamiliar new category that encapsulates many different and unique products to the list of durable infant and toddler products that are subject to this purported Section 104 rulemaking - it is also including in this proposed rule strict product performance requirements that will necessitate extensive product redesign and registration card requirements. As the Commission in 2009 found that such

[16] See:https://publications.aap.org/pediatriccare/article/doi/10.1542/aap.ppcqr.396215/98/Plagiocephaly and AAP recommendations for tummy time
[17] Requirements for Consumer Registration of Durable Infant or Toddler Products; Final Rule
[18] https://www.federalregister.gov/d/2023-27324/p-13

circumstances justify a one-year effective date, it should also recognize that manufacturers of "infant support cushions" should be afforded the same relief. The historical and legal precedent set by the Commission justifies such compliance dates.

Conclusion

All of JPMA's comments listed above are made with consideration of the safety of infants, their parents and caregivers. JPMA is also mindful of the many comments received from parents about the utility and desirability of the different products under which the CPSC has placed the umbrella term "Infant Support Cushions". The scope of this rule is exceptionally overly broad, and it is entirely unclear to which products within the vague scope the incident data applies. This rule would also mandate a less-usable product, creating a situation where improvisation would increase. The data directly points to improper use of these products (although, again, we are not sure which products specifically because the incident data has not been broken down by product-in-scope), as well as external unsafe environments, as the cause of most cited fatality incidents. Finally, JPMA has concerns about the lack of transparent, publicly available correlative data as a basis for this proposed rule. These issues should clearly be addressed, even if necessary to issue a SNPR.

JPMA's first priority is the safety and well-being of infants, toddlers, and their parents. We appreciate the opportunity to provide comment on this matter and look forward to remaining engaged as leaders in ensuring the safe design, manufacture, and use of juvenile products.

Respectfully submitted,

Lisa Trofe, CAE
Executive Director

EXHIBIT 11

Commissioner advisor shall be subject to the following treatment. Written communications and summaries or transcripts of oral communications shall be placed on the rulemaking record if the communication is received before the end of the comment period. They shall be placed on the public record if the communication is received later. Unless the outside party making an oral communication is a member of Congress, such communications are permitted only if advance notice is published in the Weekly Calendar and Notice of ''Sunshine'' Meetings.[27]

By direction of the Commission.

Joel Christie,

Acting Secretary.

[FR Doc. 2024–00678 Filed 1–12–24; 8:45 am]

BILLING CODE 6750–01–P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1112, 1130, and 1243

[CPSC Docket No. 2023–0047]

Safety Standard for Infant Support Cushions

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Danny Keysar Child Product Safety Notification Act, section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), requires the U.S. Consumer Product Safety Commission (Commission or CPSC) to promulgate consumer product safety standards for durable infant or toddler products. Under this statutory direction, the Commission is proposing a safety standard for infant support cushions. The Commission is also proposing to amend CPSC's consumer registration requirements to identify infant support cushions as durable infant or toddler products and proposing to amend CPSC's list of notices of requirements (NORs) to include infant support cushions.

DATES: Submit comments by March 18, 2024.

ADDRESSES: Comments related to the Paperwork Reduction Act aspects of the marking, labeling, and instructional literature requirements of the proposed rule should be directed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: CPSC Desk Officer, FAX: 202–395–6974, or emailed to *oira_submission@omb.eop.gov.*

Other comments, identified by Docket No. CPSC–2023–0047, may be submitted electronically or in writing, as follows:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: *https://www.regulations.gov.* Follow the instructions for submitting comments. Do not submit through this website: confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. CPSC typically does not accept comments submitted by email, except as described below.

Mail/Hand Delivery/Courier/Confidential Written Submissions: CPSC encourages you to submit electronic comments by using the Federal eRulemaking Portal. You may, however, submit comments by mail, hand delivery, or courier to: Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone: (301) 504–7479.

Instructions: All submissions received must include the agency name and docket number for this proposed rulemaking. CPSC may post all comments without change, including any personal identifiers, contact information, or other personal information provided, to: *www.regulations.gov.* If you wish to submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public, you may submit such comments by mail, hand delivery, or courier, or you may email them to: *cpsc-os@cpsc.gov.*

Docket: For access to the docket to read background documents or comments received, go to: *https://www.regulations.gov,* insert the docket number, CPSC–2023–0047, into the ''Search'' box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Stefanie Marques, Ph.D., Project Manager, Directorate for Health Sciences, U.S. Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; email: *smarques@cpsc.gov;* telephone: (301) 987–2581.

SUPPLEMENTARY INFORMATION:

I. Background and Statutory Authority

Section 104(b) of the CPSIA requires the Commission to (1) examine and assess the effectiveness of voluntary consumer product safety standards for durable infant or toddler products, in consultation with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts and (2) promulgate consumer product safety standards for durable infant and toddler products. 15 U.S.C. 2056a(b)(1). The Commission must continue to promulgate standards for all categories of durable infant or toddler products ''until the Commission has promulgated standards for all such product categories.'' 15 U.S.C. 2056a(b)(2).

The Commission is issuing this notice of proposed rulemaking (NPR) to establish a consumer product safety rule for infant support cushions to further implement section 104 of the CPSIA.[1] The proposed rule defines an ''infant support cushion'' as ''an infant product that is filled with or comprised of resilient material such as foam, fibrous batting, or granular material or with a gel, liquid, or gas, and which is marketed, designed, or intended to support an infant's weight or any portion of an infant while reclining or in a supine, prone, or recumbent position.'' This includes infant pillows, infant loungers, nursing pillows with a lounging function, infant props or cushions used to support an infant for activities such as ''tummy time,'' and other similar products.

CPSC staff identified at least 79 reported fatalities involving infant support cushions from January 1, 2010, through December 31, 2022, as well as 125 nonfatal incidents or reports involving these products within the same time period. There were 17 deaths in 2020, and at least 17 more in the potentially incomplete data from 2021. More than 80 percent of the fatalities associated with these products involved infants three months old and younger. In more than 60 percent of the fatalities, the official cause of death was either asphyxia or probable asphyxia, and these incidents typically involved use of an infant support cushion placed in or on a sleep-related consumer product such as an adult bed, futon, crib, bassinet, play yard, or a on a couch. For the nonfatal incidents, the most common circumstances involved an infant falling from an infant support cushion placed on a raised surface such as a bed or a sofa or the threat of asphyxia or entrapment.

This proposed rule addresses the risk of death and injury associated with

[27] *See* 15 U.S.C. 57a(i)(2)(A); 16 CFR 1.18(c).

[1] On November 29, 2023, the Commission voted (4–0) to publish this notice of proposed rulemaking, with an amendment proposed by Commissioner Trumka. Commissioners Trumka and Boyle issued statements in connection with their votes, available at: *https://www.cpsc.gov/s3fs-public/2023-11-29-Commission-Meeting-Minutes-Infant-Support-Cushions-NPR-Decisional.pdf?VersionId=9Y0qjnS2A74SHa932SzV9txWDIaMddXU.*

infant support cushions primarily due to suffocation, entrapment, and fall hazards. The proposed rule would address positional asphyxiation hazards by requiring that all surfaces be sufficiently firm that they are unlikely to conform to an infant's face and occlude the airways, and by setting a maximum incline angle that would prevent hazardous positioning of an infant's head and neck along the surfaces of the product. The proposed rule would set a side angle requirement that addresses the risk of entrapment between the sidewall and the occupant support surface. It addresses fall hazards by effectively limiting sidewall height to discourage caregivers from mistakenly believing these products to be safe for unattended infants. The proposed rule also requires a strongly worded, conspicuous, and permanent on-product warning.

Consistent with section 104(b)(1)(A) of the CPSIA, CPSC consulted with manufacturers, retailers, trade organizations, laboratories, consumer advocacy groups, consultants, and the public to develop this rule, including through participation in the juvenile products subcommittee meetings of ASTM.[2] Currently, however, no voluntary or mandatory safety standard for infant support cushions exists to address the hazards posed by these products.

Infant support cushions are a durable infant or toddler product under section 104(f) of the CPSIA. Section 104(f)(1) defines the term ''durable infant or toddler product'' as ''a durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years.'' 15 U.S.C. 2056a(f)(1). Section 104(f)(2) of the CPSIA provides a non-exhaustive list of product categories within the definition of ''durable infant or toddler products.'' Although infant support cushions are not specifically listed in section 104(f)(2), they are ''durable infant or toddler products'' because (as explained in Part II, below) they are: not disposable; have a useful life of up to several years and often are used by multiple children successively; are similar to other durable infant and children's products such as crib mattresses and sling carriers; and are primarily intended to be used by children five years old or younger.

Section 104(d) of the CPSIA requires manufacturers of durable infant or toddler products to establish a product registration program and comply with CPSC's rule for product registration cards, 16 CFR part 1130. The Commission proposes to amend part 1130 to include infant support cushions in the list of durable infant or toddler products that must comply with these product registration requirements. *See* 16 CFR 1130.2(a).

Manufacturers of children's products also must comply with product registration requirements, as well as testing and certification requirements for children's products that are codified in 16 CFR parts 1107 and 1109. Section 14(a)(3) of the Consumer Product Safety Act (CPSA) requires the Commission to publish an NOR for the accreditation of third party conformity assessment bodies (test laboratories) to assess conformity with a children's product safety rule to which a children's product is subject. The proposed rule would be a children's product safety rule that requires issuance of an NOR.

II. The Product Category

A. Infant Support Cushions

Infant support cushions include products that support an infant for lounging, meaning reclining or lying in a supine, prone, or recumbent position. Infant products within this category may or may not contain infants with perimeter walls. Most infant support cushions on the market today are filled with cushy foam or soft fibrous batting, covered by flexible fabric. Some infant support cushions are marketed for use in a crib or other infant sleep product, notwithstanding warnings from the Commission and others, including the American Academy of Pediatrics (AAP), that soft objects, such as pillows and excess bedding, should not be placed in an infant's sleep environment.

Illustrative pictures of infant support cushions can be found in Tab C of staff's briefing package for this proposed rule.[3] A non-exhaustive list of examples of infant support cushions includes:

- head positioner pillows;
- flat baby loungers;
- crib pillows;
- wedge pillows for infants;
- infant sleep positioners, unless regulated by the Food and Drug Administration (FDA) as medical devices;
- stuffed toys marketed for use as an infant support cushion;
- infant ''tummy time'' or ''lounging'' pillows, whether flat or inclined;
- multi-purpose pillows marketed for both nursing and lounging;
- anti-rollover pillows with or without straps that fasten the pillow to the infant;
- infant ''self-feeding'' pillows that hold a bottle in front of the face of a reclining or lying infant;
- pads and mats; and
- accessory pillows and other padded accessories, often marketed for use with an infant car seat, stroller, or bouncer, but not sold with that product and therefore not included in the mandatory safety standard for those products.

These in-scope products would be required to meet the performance standards of this rule. To avoid potentially duplicative or conflicting obligations, however, the scope of products that would be subject to this proposed rule does not include durable infant products that are already regulated by the Commission and included in the list of products at 16 CFR 1130.2(a).

Illustratively, the following products are not infant support cushions within the scope of this proposed rule:

- Pillows not marketed or intended for use by infants, such as adult bed and throw pillows;
- nursing pillows if subject to Commission's proposed nursing pillow rule 88 FR 65865 (Sept. 26, 2023) if that rule is finalized, unless they are also marketed for lounging;
- crib and play yard mattresses that are in scope of the play yard and crib mattress standard in 16 CFR part 1241;
- purely decorative nursery pillows, such as those personalized with a baby's name and birthdate, that are not for infant use;
- stuffed toys (unless they meet the definition of an infant support cushion in this proposed rule);
- padded seat liners that are sold with a rocker, stroller, car seat, infant carrier, swing, highchair, or bouncer that are specifically designed to fit that product; and
- sleeping accommodations, which are regulated under the Commission's infant sleep product rule at 16 CFR part 1236.

B. Market Description

Most types of new infant support cushions are sold online, including from

[2] CPSC formally began the consultation process for this rulemaking in December 2021, via a letter from CPSC staff requesting that ASTM form a working group to develop a voluntary standard to reduce the risk of death and injury from hazards associated with infant pillow products, including nursing pillows. In response, ASTM formed two subcommittees intended to develop two separate voluntary standards: the F15.16 Infant Feeding Supports subcommittee, intended to develop a standard for nursing pillows; and the F15.21 Infant Loungers subcommittee. CPSC staff has been actively participating in both ASTM subcommittees to develop voluntary standards that address hazards associated with these products.

[3] Staff Briefing Package: Staff's Draft Proposed Rule for Infant Support Cushions (November 8, 2023) (Staff's NPR Briefing Package), available at: *https://www.cpsc.gov/s3fs-public/Briefing-Package-Notice-of-Proposed-Rulemaking-Safety-Standard-for-Infant-Support-Cushions.pdf?VersionId=rA60lesWHddS1.wrk_EvV00xeX75dsFc.*

general online retailers, online sites for ''big box'' stores, online baby products sites, and online marketplaces for handcrafted items. A few types of infant support cushions, however, are also available from brick-and-mortar baby specialty stores and general retail stores, particularly crib pillows and baby loungers. Prices for new infant support cushions average roughly $30 and range from less than $15 for a simple head positioner pillow or crib pillow to more than $250 for a lounger with a removable cover or a large stuffed toy marketed for sleep. Several thousand manufacturers and importers, including hundreds of handcrafters and direct foreign shippers, supply infant support cushions to the U.S. market. *See* Staff's NPR Briefing Package, Tab E.

Infant support cushions may be reused for multiple children or sold for use after an infant outgrows the product. Commission staff observed that used infant support cushions are widely available on secondary marketplaces such as eBay and Mercari. In June 2023, for example, staff found listings on Mercari for used changing pads, large stuffed toys marketed for infant sleep, crib wedge pillows, baby neck pillows, baby sleep positioners, baby loungers, baby sleep mats, baby ''pillow chairs,'' infant ''self-feeding'' pillows, baby/toddler bean bag chairs, and crib pillows.

C. Infant Cushion/Pillow Ban

In 1992, pursuant to the Commission's authority under the Federal Hazardous Substances Act (FHSA), 15 U.S.C. 1261–1278, the Commission issued a ban on certain infant cushions and pillows filled with foam, plastic beads, or other granular material. 57 FR 27912 (June 23, 1992). That ban prohibits ''infant cushions,'' ''infant pillows,'' and similar articles that are:

- made with a flexible fabric covering;
- loosely filled with granular material, including but not limited to, polystyrene beads or pellets;
- easily flattened;
- capable of conforming to the body or face of an infant; and
- intended or promoted for use by children under one year of age.

16 CFR 1500.18(a)(16). This proposed rule for infant support cushions does not change the FHSA ban. That ban was limited to products with the specific hazard presented by loosely filled granular material such as polystyrene beads or pellets, and those products will continue to be banned under the FHSA. Infant support cushions that are not subject to the ban are within the scope of this proposed rule and would be required to comply with the performance requirements of this proposed rule.[4]

III. Incident Data and Hazard Patterns

CPSC staff searched the Consumer Product Safety Risk Management System (CPSRMS)[5] and National Electronic Injury Surveillance System (NEISS)[6] databases for fatalities, incidents, and concerns associated with infant support cushions and involving infants up to 12 months old, reported to have occurred between January 1, 2010, and December 31, 2022. Tab A of Staff's NPR Briefing Package describes the incident and hazard patterns associated with infant support cushions.

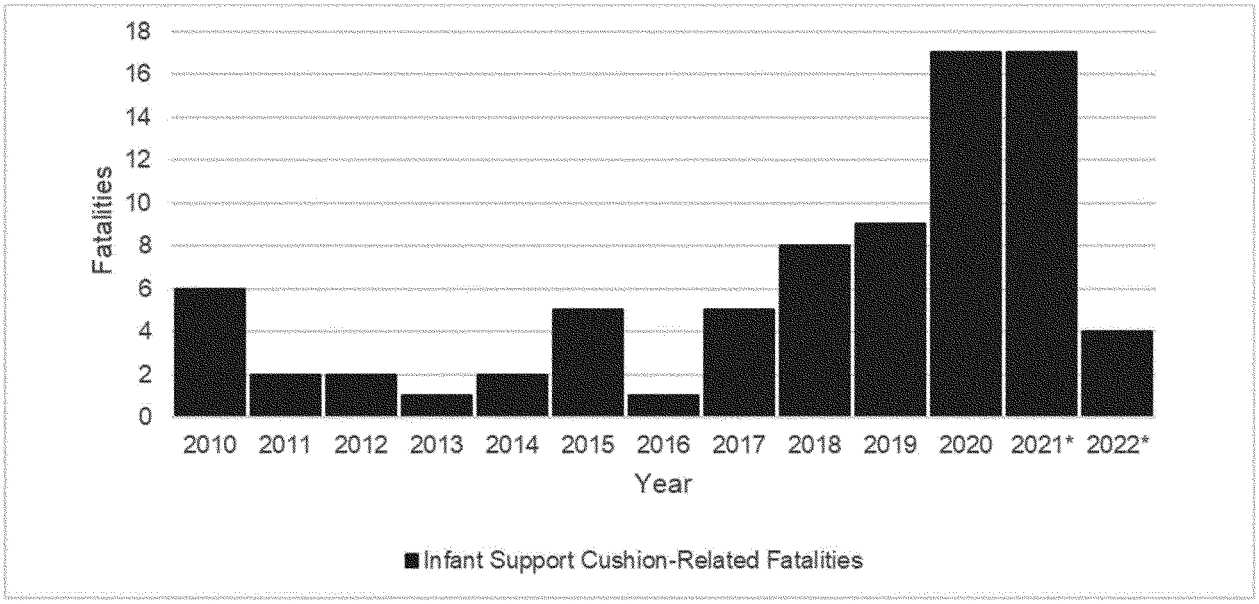
Commission staff identified 79 fatal incidents and 125 nonfatal incidents and consumer concerns reported to CPSC from 2010–2022. Of the 125 nonfatal reports. 22 consisted of emergency-department-treated injuries, three involved hospital admissions, 46 reports involved no injury, and for 52 reports the disposition was either unknown or unspecified. Table 1 provides the distribution of fatal incidents by year.

[4] An exemption to the infant pillow ban applies to Boston Billow nursing pillows and substantially similar nursing pillows that are designed to be used only as nursing aids for breastfeeding mothers. 16 CFR 1500.86(a)(9). The exemption applies specifically to the FHSA ban and is not applicable to this proposed rule or to the proposed standard for nursing pillows.

[5] CPSRMS is the epidemiological database that houses all anecdotal reports of incidents received by CPSC, ''external cause''-based death certificates purchased by CPSC, all in-depth investigations of these anecdotal reports, as well as investigations of select NEISS injuries. CPSRMS documents include hotline reports, online reports, news reports, medical examiner's reports, death certificates, retailer/manufacturer reports, and documents sent by state and local authorities, among others.

[6] NEISS is a statistically valid surveillance system for collecting injury data. NEISS is based on a nationally representative probability sample of hospitals in the U.S. and its territories. Each participating NEISS hospital reports patient information for every emergency department visit associated with a consumer product or a poisoning to a child younger than five years of age. The total number of product-related hospital emergency department visits nationwide can be estimated from the sample of cases reported in the NEISS. *See https://www.cpsc.gov/Research-Statistics/NEISS-Injury-Data.*

Table 1: Infant Support Cushion-Related Fatalities Reported by Year for Children 12 Months of Age or Younger: 2010-2022



Source: CPSRMS and NEISS databases.
Asterisks (*) indicate that reporting is ongoing for CPSRMS; the years 2021–2022 are considered incomplete.

Table 2 summarizes the number of reported fatalities related to infant support cushions for victims 12 months and younger by age in months and by gender. As reflected in Table 2, 80 percent of the fatalities with a known age were infants in the zero to three month age range. Among the 76 fatalities for which the sex is known, half were male and half were female.

TABLE 2—INFANT SUPPORT CUSHION-RELATED FATALITIES FOR VICTIMS AGES 12 MONTHS AND YOUNGER AND SEX: 2010–2022

Age (In months)	Total (% of total)	Male (% of total)	Female (% of total)	Unknown (% of total)
Total	79 (100%)	38 (48%)	38 (48%)	3 (4%)
1	26 (33%)	12 (15%)	14 (18%)	0
2	19 (24%)	10 (13%)	9 (11%)	0
3	18 (23%)	8 (10%)	10 (13%)	0
4	7 (9%)	4 (5%)	3 (4%)	0
5	3 (4%)	1 (1%)	0	2 (3%)
6	1 (1%)	0	1 (1%)	0
7	2 (3%)	1 (1%)	1 (1%)	0
8	0	0	0	0
9	0	0	0	0
10	1 (1%)	1 (1%)	0	0
11	1 (1%)	1 (1%)	0	0
12	0	0	0	0
Unknown	1 (1%)	0	0	1 (1%)

Source: CPSRMS and NEISS databases. Percentages may not add to 100 due to rounding; the years 2021–2022 are considered incomplete.

The official cause of death reported by the medical examiner in the majority of the 79 reported fatalities 49 (62 percent) was asphyxia or probable asphyxia; 13 (17 percent) were determined to be due to sudden unexpected infant death (SUID) events; 12 (15 percent) had an undetermined cause of death; and for five (six percent), no medical examiner's report was available. Nearly all reported fatalities (75 of 79) involved placement of the infant support cushion on another sleep-related consumer product. For the remaining four fatalities, the placement of the infant support cushion was either undetermined or unknown.

In the 125 nonfatal incidents associated with infant support cushions that involved children ages 12 months and younger and occurred between January 1, 2010, and December 31, 2022, three infants were admitted to the hospital and 22 infants were reported to have been treated and released from an emergency department. In 52 of these nonfatal incidents, the severity of the injury was unspecified or unknown, and in 46 of the incidents no injury was reported. Table 3 summarizes the disposition of the nonfatal incident reports associated with infant support cushions and victims ages 12 months and younger.

TABLE 3—INFANT SUPPORT CUSHION-RELATED NONFATAL REPORTS BY SEVERITY FOR VICTIMS AGES 12 MONTHS AND YOUNGER: 2010–2022

Severity	Total reports (% of total)
Total Non-Fatal Reports	125 (100%)
Hospital Admissions	3 (2%)
Emergency Department Treated	22 (18%)
Left without being seen	1 (1%)
Seen by a Medical Professional	1 (1%)
Unspecified/Unknown	52 (42%)
No Injury Reported	46 (37%)

Source: CPSRMS and NEISS databases. Percentages may not add to 100 due to rounding; the years 2021–2022 are considered incomplete.

For the 46 reports for which no injury was reported, many of the descriptions in the incident reports indicated the potential for serious injury or death. Staff's analysis of the narratives associated with these incident reports indicated that in 29 reports (23 percent) of the incidents, an infant support cushion occupied by an infant had been place on an elevated surface (such as an adult bed or couch) and the infant had fallen off; 27 (22 percent) specified threatened asphyxia; and 17 incidents (14 percent) involved various types of rashes caused by the product. Table 4 summarizes the hazard patterns for infant support cushion-related nonfatal incidents.

TABLE 4—INFANT SUPPORT CUSHION-RELATED NON-FATAL REPORTS BY HAZARD PATTERN FOR VICTIMS AGES 12 MONTHS AND YOUNGER: 2010–2022

Event	Number of non-fatal reports (% of total)
	Children (0 to 12 months)
Fall	29 (23%)
Threatened Asphyxia	27 (22%)
Rash	17 (14%)
Limb Entrapment	1 (1%)
Mold	1 (1%)
Choking	1 (1%)
Near Strangulation	1 (1%)
Vomiting	1 (1%)
Consumer Complaints	47 (38%)
Total Non-Fatal Reports	125 (100%)

Source: CPSRMS and NEISS databases. Percentages may not add to 100 due to rounding; the years 2021–2022 are considered incomplete.

Staff, based on review of nonfatal incident and report data, identified falls and threatened asphyxia as the two major nonfatal hazard patterns associated with infant support cushions. In the case of falls, the reports revealed that in most incidents infant support cushions had been placed on elevated surfaces including adult beds and couches. The injuries associated with falls include concussions, facial injuries, and scalp injuries.

In the case of threatened asphyxia, the narratives described scenarios of infants being rescued after being found hanging partially or completely off of the infant support cushion with their mouths and noses obstructed, with their heads wedged between sleep positioner side cushions, or having rolled to a face-down position that put them at risk of an obstructed airway.

IV. International Standards for Infant Support Cushions

The Commission is aware of two international standards, both British, that contain performance requirements that address suffocation and asphyxiation hazards associated with infant pillows. BS 1877–8:1974, *Specification for Domestic bedding—Part 8: Pillows and bolsters for domestic use (excluding cellular rubber pillows and bolsters)* (BS 1877–8:1974) and BS 4578:1970, *Specification for Methods of test for hardness of, and for air flow through, infants' pillows* (BS 4578:1970). The scope of BS 1877–8:1974 includes both adult and cot pillows (infant pillows), and recommends that cot pillows be filled firmly enough to prevent infants' heads from sinking into the products and that the pillow covering not be loose enough to be drawn into an infant's mouth. BS 1877–8:1974 has requirements for cot pillow size, filling, and covering. Cot pillows must be 58 x 38 cm (23 x 15 inches) and their covering must be of open construction to allow air permeability. Both the filling and covering must meet performance requirements described in BS 4578:1970 for ''hardness'' (*i.e.,* firmness) and air permeability.

The hardness test in BS 4578:1970 requires that a 100 mm diameter probe be placed in the center of the product with 10 newtons (N) of force for one minute. BS 1877–8:1974 requires that displacement of the pillow when the force is applied shall not exceed 25 percent of the thickness. Staff assesses that the proportional approach used in this standard allows thicker pillows to have a greater displacement than thinner pillows, which does not sufficiently protect against the suffocation and asphyxia hazards associated with infant support cushions because that greater displacement could allow the product to obstruct the infant's airways.

V. Boise State University Contractor Report

CPSC awarded a contract to Boise State University (BSU) for infant biomechanics and suffocation research and consultancy services. This research included an analysis of the risk of injury or death to infants associated with the use of nursing pillows and infant support cushions during activities such as feeding, nursing, sleeping, propping, and lounging. *See* Staff's NPR Briefing Package, Tab C.

BSU delivered its final report on June 30, 2022 (the BSU Final Report).[7] The BSU Final Report provides recommendations and conclusions related to the performance and design of infant support cushions, including the following.

Firmness Testing. The BSU Final Report recommends that all infant support cushions be required to undergo firmness testing because products that lack firmness are more likely to conform around an infant's nose and mouth and present a suffocation hazard. The report recommended testing all infant pillows for firmness using a three-inch diameter, anthropometry-based hemispheric probe that is geometrically similar to, and sized to represent the breadth of, an infant's face. The report recommends that the probe should be applied to the product at three locations: the location of maximum thickness, the location of minimum thickness, and a subjective location of interest (*i.e.,* another soft location most likely to result in failure). The force required to displace the probe one inch into the product at each location must exceed 10 N. Meeting this requirement would mean that the product has firmness comparable to crib mattresses.

Airflow Testing. The BSU Final Report recommends that products that do not pass firmness testing be required to pass an airflow test. Passing the airflow test would mean that the product has airflow characteristics comparable to current mesh crib liners, which the BSU researchers concluded would mitigate the suffocation hazard. However, the report recommends against requiring that airflow testing for products that pass the BSU Final

[7] Mannen, E.M., Davis, W., Goldrod, S., Lujan, T., Siddicky, S.F., Whitaker, B., & Carroll, J. (2022). *Pillows Product Characterization and Testing.* Prepared for the U.S. Consumer Product Safety Commission under contract no. 61320620D0002, task order no. 61320621F1015. Available at: *https://www.cpsc.gov/content/Pillows-Product-Characterization-and-Testing.*

Report's proposed firmness testing, because a firm product is unlikely to form a seal around an infant's nose and mouth.

Sagittal-Plane Testing. BSU developed prototype sagittal-plane testing devices to allow for more comprehensive assessments of infant positioning in and on infant support cushions.[8] The BSU Final Report recommends further research to determine appropriate worst-case positions for testing and to set threshold values for acceptable body positions that would not negatively impact infant breathing.

Tab C of Staff's NPR Briefing Package contains staff's summary of how the Commission's proposed rule reflects the conclusions and recommendations of the BSU Final Report.

VI. ASTM's Working Draft Standard

There are no published U.S. voluntary standards for infant support cushions. ASTM is working toward a voluntary standard for infant loungers under Subcommittee F15.21 on Infant Carriers, Bouncers, and Baby Swings.[9] In the draft voluntary standard, an ''infant lounger'' is a product ''with a raised perimeter, a recess, or other area that is intended to be placed on the floor and to provide a place for an infant to sit, lie, recline, or rest, while supervised by an adult.'' That draft definition would govern only a subset of the products covered by this proposed rule, which includes infant positioners, nursing products with dual use for lounging, infant cushions, and other infant pillow-like products, as well as the infant loungers being considered by ASTM. Staff has been working with ASTM to develop performance requirements intended to address the primary hazards associated with infant loungers, but to date ASTM has not issued a ballot on a standard for infant loungers.

ASTM's draft voluntary standard includes general requirements typically found in other ASTM juvenile product standards, such as requirements addressing lead content, small parts, hazardous sharp edges or points, and toy accessories that are attached to, removable from, or sold with the products. The ASTM draft also specifies that if the lounger can be converted to another product it shall comply with the applicable requirements of that product's standard. The general requirements of the draft infant lounger standard also state that the sidewall height of the product shall be less than four inches when measured according to the sidewall height measurement test method specified in the draft standard. The draft voluntary standard further includes the following performance requirements:

- *Stability:* The product shall not tip over and shall retain the CAMI dummy[10] when tested in all manufacturers' use positions.
- *Infant Restraints:* The product shall not have a restraint system.
- *Fabric/Mesh Integrity:* This requirement is intended to address product integrity issues such as seam failures and material breakage.
- *Bounded Openings:* This requirement is intended to address potential entrapment hazards associated with openings in the product.
- *Occupant Support Surface:* This requirement is intended to address the thickness of, dimensions of, and potential gaps in the occupant support surface.
- *Occupant Support Surface Firmness:* This requirement uses an eight-inch diameter, disc-shaped ''firmometer'' probe and requires that there shall be no point where the feeler arm of the device, which hangs over the edge of a disc, comes in contact with the occupant support surface.
- *Sidewall Firmness:* The top of the sides of the product cannot be displaced more than one inch when a three-inch diameter hemispheric probe is applied to the product with 10 N of force.
- *Side Angle and Deflection:* To address potential entrapment hazards at the intersection of the side wall and occupant support surface, the angle between the sidewall and the occupant support surface of the infant support cushion shall be greater than 90 degrees.

The draft voluntary standard also includes marking, labeling, and instructional literature requirements, such as warning the consumer on the product about not using the product for sleep or naps, only using the product when the occupant baby is supervised, only using the product on the floor, keeping soft bedding out of the product, not using the product on raised surfaces, and not using the product to carry or move an infant. The draft standard requires the warnings to be ''permanent'' and ''conspicuous.''

The product's instructions must, among other requirements, indicate the manufacturer's recommended maximum weight, height, age, developmental level, or combination of these attributes for any infant using the product, as well as any limitation on use of the product by a child for any specific unintended use.

VII. Description of the Proposed Mandatory Standard for Infant Support Cushions[11]

To address established risks of death and injury associated with infant suffocations, asphyxiations, entrapments, and falls, and as section 104 of the CPSIA requires, the Commission is issuing this proposed rule to establish mandatory performance and labeling requirements for infant support cushions.

The text of the proposed rule is based on an evaluation of incident data associated with infant support cushions, the ASTM working draft standard for infant loungers that is under development, and the recommendations of the BSU Final Report. The proposed rule is summarized below and explained in more detail in Tabs C and F of Staff's NPR Briefing Package.

A. Scope and Definitions

Section 1243.1 of the proposed rule explains that the rule would apply to infant support cushions, including infant positioners, nursing products with a dual use for lounging, infant loungers, infant props, or cushions used to support an infant for activities such as ''tummy time,'' and other infant pillow-like products. It would exclude, however, products already regulated by other Commission mandatory standards for durable infant products, which are listed in 16 CFR 1130.2(a). The proposed rule would apply to all infant support cushions manufactured after the effective date of the rule.

Section 1243.2 of the proposed rule defines ''infant support cushion'' as ''an infant product that is filled with or comprised of resilient material such as foam, fibrous batting, or granular material or with a gel, liquid, or gas, and which is marketed, designed, or intended to support an infant's weight or any portion of an infant while reclining or in a supine, prone, or recumbent position.''

The scope of ''infant support cushions'' is intended to encompass the products described in Part II above.

As noted previously, this proposed definition of ''infant support cushions'' includes, but is not limited to, the infant

[8] The sagittal plane is an anatomical plane that runs vertically through the human body, dividing it into left and right sections. It can be thought of as viewing the human body in profile.

[9] *See* Staff's NPR Briefing Package, Tab B. This ASTM standard is still in draft form and has not completed the full consensus process to be an approved standard and the draft language is subject to change.

[10] CAMI (Civil Aeromedical Institute) dummies, which are designated ASTM test devices, are based on child anthropometric data and come in multiple sizes. ASTM's working draft references the six-month-old size.

[11] *See* Staff's NPR Briefing Package, Tab C.

loungers that would be subject to ASTM's draft voluntary standard. The proposed rule would define ''infant lounger'' as ''an infant product with a raised perimeter, a recess, or other area that provides a place for an infant to recline or to be in a supine, prone, or recumbent position.'' Because, however, incident data show that the suffocation, asphyxiation, and fall hazards this rule seeks to address are posed by other infant pillow-like products, in addition to those with a raised perimeter or recess, the proposed broader definition more effectively addresses the hazards posed by these products. For example, the proposed rule would apply to ''infant positioners,'' defined as a product intended to help keep an infant in a particular position while supine or prone.

As discussed above, ASTM is working concurrently on developing voluntary standards for both ''infant feeding supports'' and ''infant loungers.'' The draft ASTM standards address hazards posed by ''dual use'' products intended to be used both to feed an infant and to support a lounging infant by requiring such products to comply with both standards. Adopting ASTM's approach, the proposed rule would apply to nursing pillows with a dual use for lounging, while excluding those nursing pillows that are solely intended to be used for nursing or feeding, along with other products already regulated by other Commission mandatory standards for durable infant products.

The Commission invites public comment on the scope of the proposed rule, including whether it addresses all products that pose the identified hazards and whether it is sufficiently clear and administrable. For example, the Commission invites public comment on whether it is appropriate to subject ''dual use'' products to both the proposed nursing pillow rule and the proposed infant support cushion rule (assuming that both are finalized), and what nursing products should be considered ''dual use.''

B. General Requirements

The proposed rule includes many of the general requirements included in the ASTM draft standard for infant loungers to address sharp edges or points, small parts, and lead in paints. It also requires that toy accessories that are attached to, removable from, or sold with the products comply with 16 CFR part 1250, which establishes a mandatory safety standard for toys, as well as requirements for the permanency of labels and warnings. However, while ASTM's draft standard for infant loungers would allow a maximum sidewall height of four inches, the Commission is concerned that this height may give consumers the mistaken impression that an infant can safely be left unattended in or on the product. For that reason, the proposed rule addresses the positional asphyxia hazard with a maximum incline requirement that effectively sets a lower limit on sidewall height, rather than the maximum side height requirement currently favored by ASTM. The Commission invites public comment on side height limit and incline angle requirements.

C. Proposed Performance Requirements

1. Firmness

The Commission's proposed firmness requirements and associated test methods are consistent with those applicable to crib mattresses and more stringent than those currently included in ASTM's draft standard for infant loungers. As explained in Tab C of Staff's NPR Briefing Package, based upon the findings and recommendations in the BSU Final Report as well as staff's analysis of the incidents and hazard patterns associated with facial occlusion into infant support cushions, the proposed rule requires firmness testing at three locations: the occupant support surface, the sidewall, and the intersection of the occupant support surface with the sidewall, as follows:

a. Occupant Support Surface (OSS) Firmness

The proposed rule includes a firmness test for the occupant support surface [12] that is based on the BSU Final Report, with modifications to improve the test methodology. The firmness test is intended to reduce the likelihood that the OSS can conform to an infant's face and cause suffocation. The proposed rule requires that OSS firmness be tested using the three-inch diameter hemispheric probe developed by BSU, rather than the eight-inch firmometer probe in the ASTM draft standard. The three-inch probe is more consistent, in both size and shape, with the size and dimensions of an infant's head, enabling it to more accurately detect any material deformations and surface features that an infant's face may come in contact with on an infant support cushion. In addition, staff's testing showed that an eight-inch disc probe may not be as accurate as a three-inch hemispheric probe when used on certain models of infant support cushions with smaller dimensions or an OSS surface that is not completely flat, so that the eight-inch firmometer cannot fit well enough in the product to provide accurate measurement.

To meet the proposed rule's firmness requirement, the force required to displace the probe one inch into the OSS test location (as well as the two other test locations) must exceed 10 N (about 2.25 pounds), which indicates product firmness that is at least comparable to a crib mattress. Figure 1, below, illustrates the firmness test being applied to the OSS of an infant support cushion.

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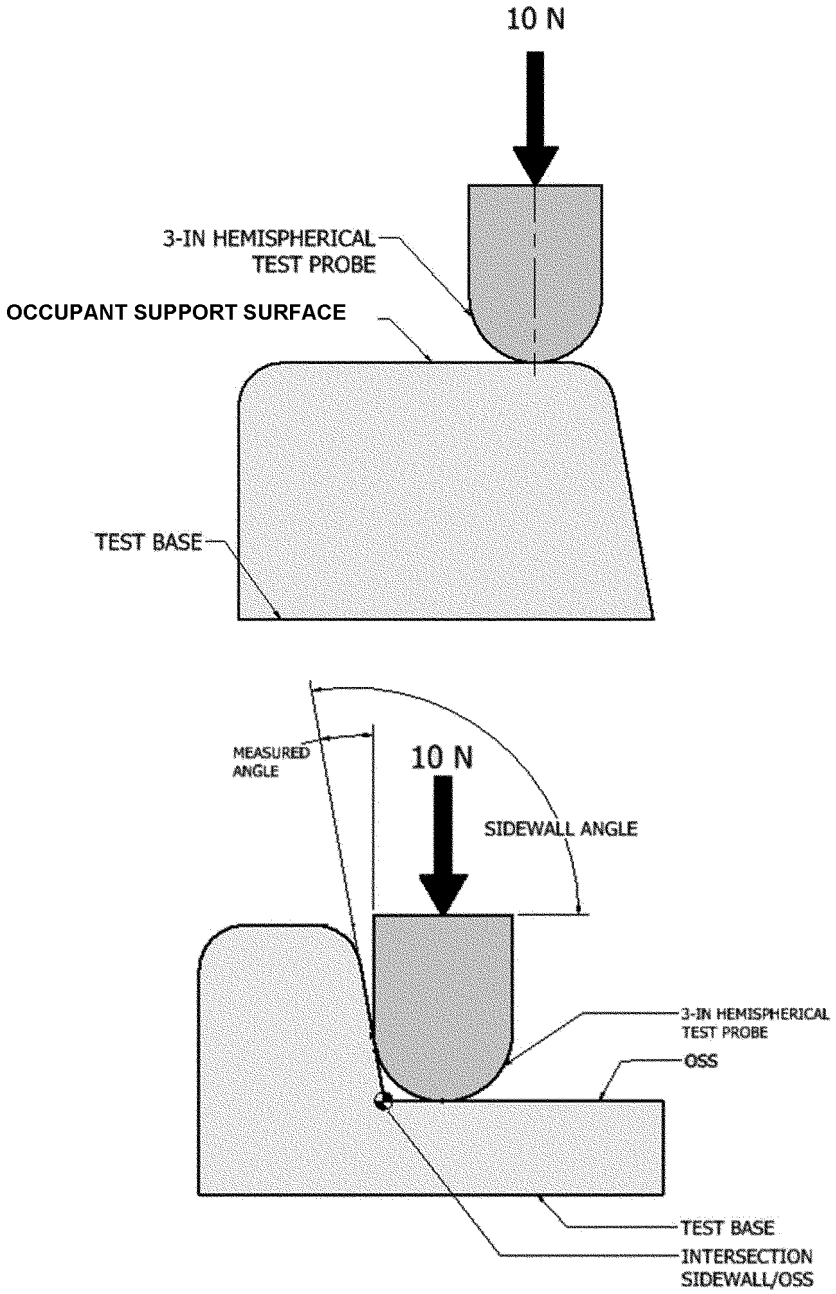
[12] The proposed rule uses ASTM's draft definition of an infant support cushion's ''occupant support surface'' or OSS as ''the area that holds up and bears the infant or any portion of the infant.''

Figure 1: Firmness Test Applied to OSS or Sidewall



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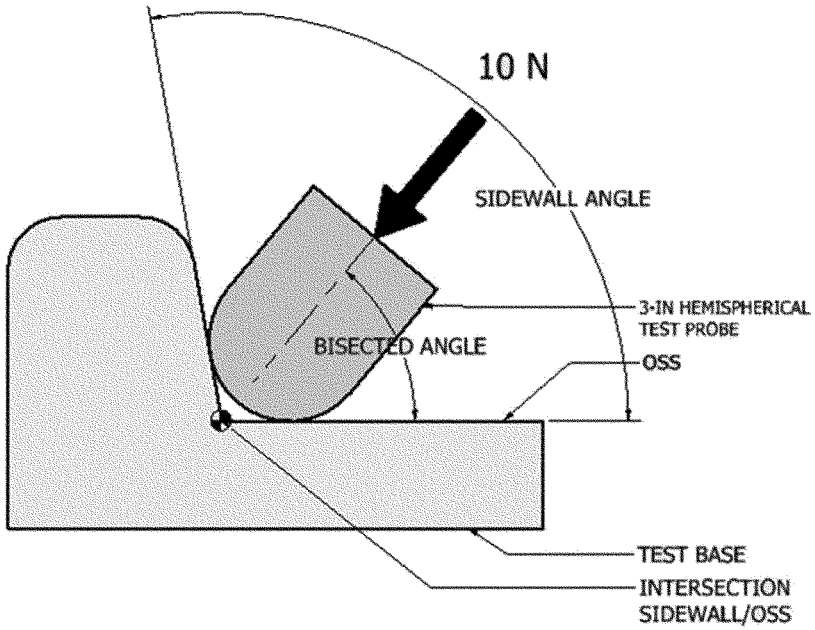
Because an infant's head or face may rest on the sidewall of a product, as well as on the product's OSS, the proposed rule includes firmness requirements for any product sidewall. While the ASTM working draft also requires firmness testing of sidewalls, the proposed rule requires testing a minimum of four sidewall locations, including the location of maximum sidewall height, and requires that the test locations include at least one location most likely to fail, rather than requiring that sidewalls be tested in six-inch increments around the product as stated in ASTM's draft. The differences from ASTM in testing protocol are intended to provide more accurate testing for both smaller head pillows and larger lounger products.

b. Intersection of OSS With Sidewall

To address the hazard of suffocation when an infant's face is surrounded on two sides by the OSS and a sidewall, the proposed rule includes firmness requirements based on testing the angle at which the two surfaces intersect, to ensure sufficient firmness to prevent the product from conforming to the infant's mouth or face and obstructing airways. It requires testing of firmness with the three-inch hemispherical probe positioned to bisect the angle formed where the two surfaces intersect, as shown in Figure 2.

Figure 2: Test Configuration for Intersection of Sidewall and Occupant Support Surface Firmness



The proposed rule's firmness requirements for the OSS/Sidewall intersection are similar to those in ASTM's draft standard.

2. Sidewall Angle

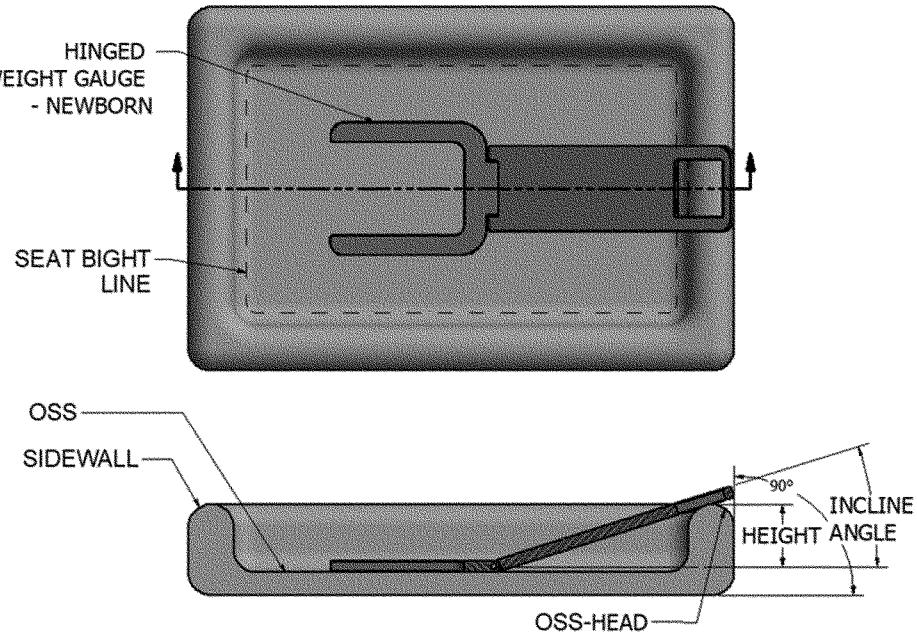
The proposed rule, like ASTM's draft, requires that the angle formed between the product's OSS and any sidewall be greater than 90 degrees to reduce potential entrapment hazards between the sidewall and the occupant support surfaces. The proposed rule requires a slightly different methodology for measuring this angle than does ASTM's draft. While ASTM's draft requires that this angle be measured with a protractor or similar tool at four-inch intervals along the product's interior, the proposed rule specifies assessing this angle with the cylindrical side of the three-inch probe, with a 10 N force applied to the probe. The probe, which is designed to simulate the size and shape of an infant's head, is used to determine whether there is any contact between the sidewall and the probe's side when the ''face'' of the probe is pressed against the OSS/sidewall intersection. If there is such contact, indicating an entrapment risk, that indicates that the angle is less than 90 degrees and the product would fail. Conversely, if there is no contact between the sidewall and the side of the probe, the angle is greater than 90 degrees and the product meets this requirement.

3. Maximum Incline Angle

The proposed rule, like ASTM's draft, requires that any incline of the OSS of an infant support cushion not exceed 10 degrees. This requirement is consistent with incline test of CPSC's *Safety Standard for Infant Sleep Products,* 16 CFR part 1236, and the ban of inclined sleepers for infants in the Safe Sleep for Babies Act, 15 U.S.C. 2057d, and similarly it addresses the hazards associated with inclined sleep products.

The proposed rule, however, differs from ASTM's maximum incline angle requirements and test procedures in order to improve test consistency across all infant support cushion products and to address additional locations of potential inclined lounging, reclining, and sleep. The three ways in which the proposed rule modifies ASTM's proposed testing protocol are: (1) setting a maximum incline angle that applies not only to all of a manufacturer's recommended use positions, but also to all other infant cushion surfaces that can feasibly support an infant's head, including, for example, the angle from any sidewall to the OSS or from the sidewall to the floor; (2) use of a newborn hinged weight gauge, rather than an infant gauge; and (3) positioning the gauge differently throughout testing. Figure 3 below, shows the use of a hinged weight gauge to measure the incline on an infant support cushion with a sidewall. The proposed rule requires use of a newborn hinged weight gauge, rather than the heavier infant gauge specified in the ASTM draft, because infant support cushions are commonly used for newborns, who are at higher risk of suffocation.

Figure 3: Test Fixture Configuration to Measure Incline Angle on an Infant Lounger



4. Sidewall Height

The proposed rule limits the height of any sidewall of an infant support cushion, as does ASTM's draft. However, the proposed rule addresses the hazards associated with relatively high sidewalls in a manner that is more closely tailored to the hazards, and applies to all of the products that fall within the scope of the proposed rule. These hazards are that caregivers may judge that an infant support cushion with relatively high sidewalls can safely contain an infant without supervision and is suitable for use on top of an adult bed or in a crib notwithstanding any contrary warnings, and that high sidewalls can cause hazardous positioning of the infant's neck when an infant's head is placed on top of the sidewall while their body is on a lower surface either inside or outside of the product. *See* Staff's NPR Briefing Package, Tabs B and C. While ASTM's draft sets a four-inch limit on sidewall height, the proposed rule addresses these hazards by limiting the maximum incline angle and provides testing protocols based on the type of product (for example, lounger-type products or head cushions). Using the test methodology prescribed in the proposed rule, sidewall heights, for products that have sidewalls, would be limited to approximately 1.9 inches.

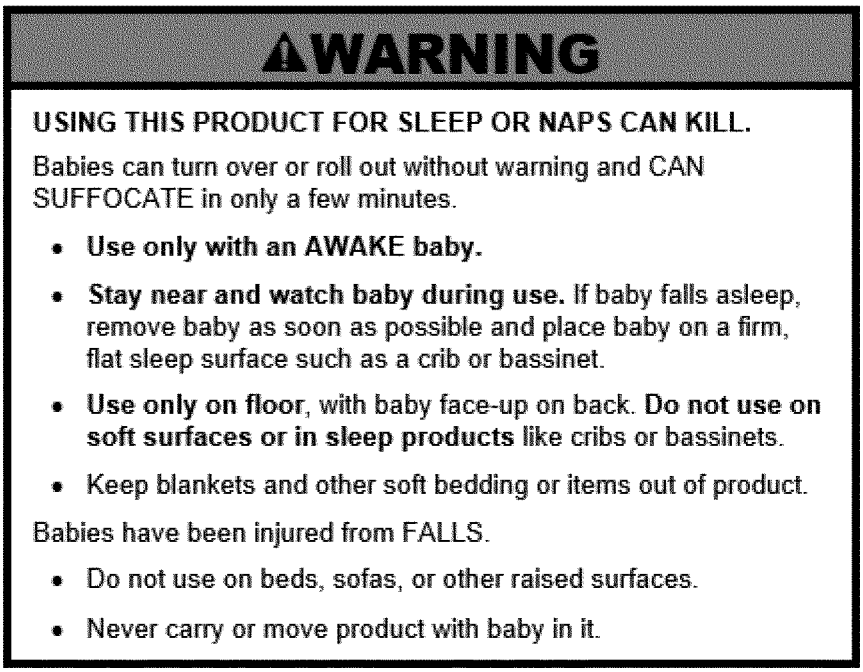
The Commission invites public comments on the proposed rule's method for addressing hazards posed by sidewall heights via measurement of maximum incline angle and what methodology would most effectively address the identified fall and positional asphyxia hazards.

D. Warning and Instructional Requirements

Compared to the performance requirements described above, warnings are less effective in eliminating or adequately reducing exposure to hazards associated with infant support cushions. Nevertheless, prominent and well-designed warnings can provide consumers with important information about the hazards associated with these products and appropriate behaviors to avoid the hazards. Thus, the proposed rule includes requirements for on-product warnings that address the primary hazards associated with infant support cushions.

The proposed rule includes warning content and format requirements similar to those in the ASTM draft standard. Figure 4 shows the warning statements and format that would be required on infant support cushions:

Figure 4: Example of Infant Support Cushion Warning



The proposed rule, like ASTM's draft, requires on-product warning labels to be ''conspicuous,'' defined as ''visible, when the product is in each manufacturer's recommended use position, to a person while placing an infant into or onto the product.'' Also, like ASTM's draft, the proposed rule requires such warning labels to be ''permanent,'' with permanence requirements based on ASTM's draft but better addressing the potential for consumers to attempt to remove on-product warning labels. The draft ASTM warning label for infant loungers indicates that the product should only be used on the floor, ''with baby face-up on back.'' This proposed rule would adopt ASTM's draft language. However, this proposed rule for infant support cushions includes products that can be used for ''tummy time,'' for which infants are on their stomach. The Commission invites public comments in answer to the following questions: Should manufacturers have flexibility to remove or change the ''with baby face-up on back'' language in the warning label? If so, in what circumstances?

The proposed rule incorporates by reference American National Standards Institute (ANSI) ANSI Z535.4, *Product Safety Signs and Labels,* which includes requirements related to safety alert symbol use; signal word selection; warning panel format, arrangement, and shape; color requirements for each panel; and letter style. The Commission specifically references the warning format requirements published in sections 6.1–6.4, 7.2–7.6.3, and 8.1. *See* Staff's NPR Briefing Package, Tab D, 80–81.

In addition to on-product warnings, the ASTM draft standard includes basic warning requirements for instructional literature that are the same as those in ASTM's draft.

VIII. Proposed Amendment to 16 CFR Part 1112 To Include NOR for Infant Support Cushions

Products subject to a consumer product safety rule under the CPSA, or to a similar rule, ban, standard, or regulation under any other act enforced by the Commission, must be certified as complying with all applicable CPSC-enforced requirements. 15 U.S.C. 2063(a). Certification of children's products subject to a children's product safety rule must be based on testing conducted by a CPSC-accepted third-party conformity assessment body. 15 U.S.C. 2063(a)(2). The Commission must publish an NOR for the accreditation of testing laboratories as third party conformity assessment bodies to assess conformity with a children's product safety rule. 15 U.S.C. 2063(a)(3). The proposed standard for infant support cushions would be a children's product safety rule that requires the issuance of an NOR.

The Commission's rules, at 16 CFR part 1112, establish requirements for accreditation of third party conformity assessment bodies to test for conformance with a children's product safety rule in accordance with section 14(a)(2) of the CPSA. Part 1112 also lists the NORs that the CPSC has published. The Commission proposes to amend part 1112 to include the *Safety Standard for Infant Support Cushions* in the list of children's product safety rules for which the CPSC has issued NORs.

Laboratories applying for acceptance as a CPSC-accepted third party conformity assessment body to test to the new standard are required to meet the third party conformity assessment body accreditation requirements in part 1112. When a laboratory meets the requirements as a CPSC-accepted third party conformity assessment body, the laboratory can apply to the CPSC to have the *Safety Standard for Infant Support Cushions* included in its scope of accreditation as reflected on the CPSC website at: *www.cpsc.gov/labsearch.*

IX. Product Registration Rule Amendment

In addition to requiring the Commission to issue safety standards for durable infant or toddler products, section 104 of the CPSIA directed the Commission to issue a rule requiring that manufacturers of durable infant or toddler products establish a program for consumer registration of those products. 15 U.S.C. 2056a(d). Section 104(f) of the CPSIA defines the term ''durable infant or toddler product'' as ''a durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years,'' and lists 12 distinct product categories. 15

U.S.C. 2056a(f). The product categories listed in section 104(f)(2) of the CPSIA represent a non-exhaustive list of durable infant or toddler product categories. Infant support cushions are not included in the statutory list of durable infant or toddler products.

In 2009, the Commission issued a rule implementing the consumer registration requirement. 74 FR 68668 (Dec. 29, 2009) (establishing 16 CFR part 1130). As section 104(d) of the CPSIA directs, the consumer registration rule requires each manufacturer of a durable infant or toddler product to provide a postage-paid consumer registration form with each product; keep records of consumers who register their products with the manufacturer; and permanently place the manufacturer's name and certain other identifying information on the product.

When issuing the consumer registration rule, the Commission identified six additional products as durable infant or toddler products: children's folding chairs; changing tables; infant bouncers; infant bathtubs; bed rails; and infant slings. 74 FR 68669. The Commission explained that the specified statutory categories are not exclusive, and that the Commission is charged with identifying the product categories that are covered. ''Because the statute has a broad definition of a durable infant or toddler product but also includes 12 specific product categories,'' the Commission noted, ''additional items can and should be included in the definition, but should also be specifically listed in the rule.'' *Id.* at 68670.

The Commission proposes in this NPR to amend part 1130 to include ''Infant Support Cushions'' as durable infant or toddler products. Infant support cushions are a category of ''durable infant or toddler product'' for purposes of CPSIA section 104 because they: (1) are intended for use, and may be reasonably expected to be used, by children under the age of five years; (2) are products similar to other products listed in section 104(f)(2), such as crib mattresses and sling carriers; and (3) are commonly resold or ''handed down'' for use by other children over a period of years.

X. Incorporation by Reference

The proposed rule incorporates by reference ANSI Z535.4–2011, *American National Standard for Product Safety Signs and Labels* and ASTM D3359, *Standard Test Methods for Rating Adhesion by Tape Test.* In accordance with regulations of the Office of the Federal Register (OFR), 1 CFR part 51, Part VII.D of this preamble summarizes ANSI Z535.4–2011. ASTM D3359 covers procedures for assessing the adhesion of relatively ductile coating films to metallic substrates by applying and removing pressure-sensitive tape over cuts made in the film.

Both standards are reasonably available to interested parties in several ways. By permission of ANSI, the ANSI standard can be viewed as a read-only document during the comment period on this NPR, at: *https://www.surveymonkey.com/r/DQVJYMK.* To download or print the standard, interested persons may purchase a copy of ANSI Z535.4–2011 from ANSI via its website, *https://www.ansi.org,* or by mail from ANSI, 25 West 43rd Street, 4th Floor, New York, NY 10036, telephone: (212)–642–4900. By permission of ASTM, this ASTM standard can be viewed as a read-only document during the comment period on this NPR, at: *https://www.astm.org/cpsc.htm.* To download or print the standard, interested persons may purchase a copy of ASTM D3359 from ASTM, through its website, *https://www.astm.org,* or by mail from ASTM International, 100 Barr Harbor Drive, P.O. Box 0700, West Conshohocken, PA 19428–2959. Alternatively, interested parties may inspect a copy of the standards at CPSC's Office of the Secretary by contacting Alberta E. Mills, Commission Secretary, U.S. Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814; telephone: (301) 504–7479; email: *cpsc-os@cpsc.gov.*

XI. 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). The Commission proposes an effective date of 180 days after publication of the final rule in the **Federal Register**, such that the requirements of the rule would apply to all infant support cushions manufactured after that date. This amount of time is typical for rules issued under section 104 of the CPSIA. It is also the period that the Juvenile Products Manufacturers Association (JPMA) typically allows for products in their certification program to shift to a new standard once that new standard is published. Therefore, juvenile product manufacturers are accustomed to adjusting to new standards within this time. A 180-day effective date should also be sufficient for manufacturers to comply with this rule because the proposed requirements do not demand significant preparation by testing laboratories. For example, no new complex testing instruments or devices would be required to test infant support cushions for compliance with the proposed rule. The Commission invites comments, particularly from small businesses, that provide specific data addressing whether the proposed 180-day effective date period is appropriate.

XII. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA; 5 U.S.C. 601–612) requires that agencies review a proposed rule's potential economic impact on U.S. small entities, including small businesses. Section 603 of the RFA generally requires that agencies make an initial regulatory flexibility analysis (IRFA) available to the public for comment when the NPR is published. The IRFA must describe the impact of the proposed rule on small entities and identify significant alternatives that accomplish the statutory objectives and minimize any significant economic impact of the proposed rule on small entities. Staff prepared an IRFA for this rulemaking that appears at Tab E of the Staff's NPR Briefing Package. We summarize the IRFA below.

A. Reasons and Legal Basis for the NPR

Part I of this preamble describes the reasons and legal basis for this NPR. As discussed in Parts VII–IX of this preamble, and detailed in Tab B of Staff's NPR Briefing Package, the proposed rule sets out mandatory requirements for infant support cushions to address the suffocation, entrapment, and fall hazards associated with these products; adds infant support cushions to the list of products for which a registration card is required; and adds infant support cushions to the list of durable infant products for which an NOR is required.

B. Small Entities to Which the Proposed Rule Would Apply

As explained in Tab E to Staff's NPR Briefing Package, Commission staff has identified more than 2,000 suppliers of infant support cushions to the U.S. market, including manufacturers, importers, and foreign direct shippers. The majority of these suppliers are small businesses.

C. Impact of the Proposed Rule on Small Manufacturers and Importers

Most in-scope products on the market will require redesign to meet the requirements in the proposed rule, and redesign costs would be potentially significant for a substantial number of small firms, particularly small-volume home crafters, for the first year that a rule is effective. Staff considers a ''significant'' impact to be at least one

percent of annual revenue, which is consistent with the regulatory flexibility analyses of other federal agencies. With an estimated 2,000 models to be redesigned, the total cost of redesign to the industry in the first year could be up to $27 million. However, as discussed in Tab E of Staff's Briefing Package, suppliers may be able to cover these costs by implementing modest retail price increases which would reduce the rule's impact on individual small entities. For example, a firm supplying 5,000 infant support cushions per year could cover the entire cost of redesign by raising the retail price by $2.70.

If issued, a final rule would require all manufacturers and importers of infant support cushions to meet additional third party testing requirements under section 14 of the CPSA. As specified in 16 CFR part 1109, entities that are not manufacturers of children's products, such as importers and wholesalers, may rely on the certificates of compliance provided by others. However, manufacturers could pass on at least some of the cost of testing for compliance to U.S. importers and wholesalers.

Third party testing costs for infant support cushions are estimated to be $500 to $1,000 per model. The annual cost of samples for testing is estimated at around $100, bringing the overall annual testing cost to an estimated $600 to $1,100 per model. The costs of testing per model would be similar for suppliers of all sizes, although larger firms may be more likely to qualify for volume discounts. As with redesign costs, these testing costs could largely be covered by modest retail price increases.

The hand crafters of infant support cushions with the smallest sales volumes may not have sufficient sales volume to cover these costs and may exit the market. However, consumers would likely not experience a significant loss of utility as there are many different products available from different suppliers.

D. Other Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rule

The Commission has not identified any federal rules that duplicate, overlap with, or conflict with the proposed rule.

E. Alternatives Considered To Reduce the Impact on Small Entities

The Commission considered the following alternatives to the proposed rule to reduce the impact on small businesses. The Commission requests comments on these alternatives and other alternatives that could reduce the potential burden on U.S. small entities.

1. Not Establishing a Safety Standard

The Commission considered not establishing a safety standard for infant support cushions. While this alternative would result in no regulatory impact on small entities, deaths and injuries from the use of infant support cushions would likely continue to occur at similar rates as those observed during the period from 2010 through 2022. In 2020 alone, there were 17 fatalities involving infant support cushions. Another 17 fatalities have been recorded in the potentially incomplete data for 2021. *See* Staff NPR Briefing Package, Tab A.

2. Delay To Await Publication of a Voluntary Standard

The Commission considered delaying the draft proposed rule to allow possible publication of a voluntary standard. Although this alternative would delay any impact on small businesses, it would also allow the hazard to continue indefinitely, as there is no clear date at which ASTM or any other voluntary standards organization will adopt a relevant standard, nor any assurance that a voluntary standard, if published, would be complied with by industry or adequately address the identified hazards.

3. Earlier or Later Effective Date

The Commission is proposing an effective date 180 days after publication of the final rule in the **Federal Register**. An earlier effective date would achieve the safety benefits of the rule more quickly, but it would also increase the burden on small businesses to quickly redesign and test their products. In addition, a significantly earlier effective date could result in temporary shortages of infant support cushions due to a potential lack of availability of testing laboratory resources.

The Commission is not proposing a later effective date, which would somewhat reduce burdens on small suppliers, because 180 days has generally been sufficient time for suppliers to come into compliance with durable infant or toddler product rules. Additionally, six months from the change in a voluntary standard is the period that JPMA uses for its certification program, so compliant manufacturers are used to this time frame to comply with a modified standard. Testing laboratories should have no difficulty preparing to test to the proposed new mandatory standards within a 180-day period.

F. Impact on Testing Labs

The proposed rule should not have a significant adverse impact on testing laboratories. Laboratories will not need to acquire complex or costly testing instruments or devices to test infant support cushions for compliance, and laboratories will decide for themselves, based on expected demand for their testing services, whether to offer testing services for infant support cushion compliance.

XIII. Environmental Considerations

Certain categories of CPSC actions normally have ''little or no potential for affecting the human environment'' and therefore do not require an environmental assessment or an environmental impact statement. Safety standards providing requirements for consumer products come under this categorical exclusion. 16 CFR 1021.5(c)(1). The proposed rule for infant support cushions falls within the categorical exclusion.

XIV. Paperwork Reduction Act

This proposed rule contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA; 44 U.S.C. 3501–3521). In this document, pursuant to 44 U.S.C. 3507(a)(1)(D), we set forth:

- a title for the collection of information;
- a summary of the collection of information;
- a brief description of the need for the information and the proposed use of the information;
- a description of the likely respondents and proposed frequency of response to the collection of information;
- an estimate of the burden that shall result from the collection of information; and
- notice that comments may be submitted to the OMB.

Title: Safety Standard for Infant Support Cushions.

Description: The proposed rule would require each infant support cushion within the scope of the rule to meet the rule's performance and labeling requirements. It would require suppliers to conduct third party testing to demonstrate compliance and provide the specified warning label and instructions. These requirements fall within the definition of a ''collection of information,'' as defined in 44 U.S.C. 3502(3).

Description of Respondents: Persons who manufacture or import infant support cushions.

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

TABLE 7—ESTIMATED ANNUAL REPORTING BURDEN

Burden type	Number of respondents	Frequency of response	Total annual responses	Hours per response	Total burden hours
Labeling and instructions	2,000	1	2,000	2	4,000

While some infant support cushion products currently have labels, all of these products would have to meet the specific labeling requirements and instructions specified in the proposed rule, which provides the text and graphics for the required labels and instructions. Specialized expertise in graphics design would not be required to develop the warnings and instructions. Most reporting and recordkeeping requirements in this proposed rule would be new for all suppliers.

CPSC estimates there are 2,000 entities that would respond to this collection annually, the majority of which would be small entities. We estimate that the time required to create and/or modify labeling and instructions is about two hours per response. Therefore, the estimated burden associated with this collection is 2,000 responses × one response per year × two hours per response = 4,000 hours annually.

We estimate the hourly compensation for the time required to respond to the collection is $37.88 (U.S. Bureau of Labor Statistics, ''Employer Costs for Employee Compensation,'' June 2023, Table 4, total compensation for all sales and office workers in goods-producing private industries: *https://www.bls.gov/news.release/archives/ecec_09122023.pdf.* Therefore, the estimated annual cost of the collection is $151,520 ($37.88 per hour × 4,000 hours = $151,520).

Based on this analysis, the proposed standard for infant support cushions would impose a burden to industry of 4,000 hours at a cost of $151,520.

Comments. CPSC has submitted the information collection requirements of this proposed rule to OMB for review in accordance with PRA requirements. 44 U.S.C. 3507(d). CPSC requests that interested parties submit comments regarding information collection to the Office of Information and Regulatory Affairs, OMB (see the **ADDRESSES** section at the beginning of this NPR). Pursuant to 44 U.S.C. 3506(c)(2)(A), the Commission invites comments on:

- whether the collection of information is necessary for the proper performance of CPSC's functions, including whether the information will have practical utility;
- the accuracy of CPSC's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- ways to enhance the quality, utility, and clarity of the information to be collected;
- ways to reduce the burden of the collection of information on respondents, including the use of automated collection techniques when appropriate and other forms of information technology; and
- the estimated burden hours associated with label modification, including any alternative estimates.

XV. Preemption

Section 26(a) of the CPSA, 15 U.S.C. 2075(a), provides that when a consumer product safety standard is in effect and applies to a product, no state or political subdivision of a state may either establish or continue in effect a standard or regulation that prescribes requirements for the performance, composition, contents, design, finish, construction, packaging, or labeling of such product dealing with the same risk of injury unless the state requirement is identical to the federal standard. Section 26(c) of the CPSA also provides that states or political subdivisions of states may apply to the Commission for an exemption from this preemption under certain circumstances. Section 104(b) of the CPSIA refers to the rules to be issued under that section as ''consumer product safety rules.'' Therefore, if finalized, the preemption provision of section 26(a) of the CPSA would apply to this rule for infant support cushions.

XVI. Request for Comments

The Commission seeks public comment on all aspects of the proposed rule. In particular, the Commission seeks comments on the scope of the proposed rule, with respect to both in scope and out of scope products, including comments on whether the proposed definition of ''infant support cushion'' is sufficient to include all infant support cushions that are not subject to the FHSA infant pillow ban, 16 CFR 1500.18(a)(16). The Commission would also welcome comments on the wording of proposed warning label as well as on whether the on-product warning label requirement included in the proposed rule should be applied to replacement covers for infant support cushions in addition to the cushions themselves. In addition, the Commission invites public comment on the proposed limit on sidewall height and whether the proposed rule's incline angle requirements provide appropriate protection against positional asphyxiation. The Commission also seeks comment on whether an anti-stockpiling provision should be included and, if so, whether the Commission should include an anti-stockpiling provision comparable to the one proposed in the recent SNPR for portable generators at 88 FR 24346, 24372 (Apr. 20, 2023). Finally, the Commission requests comments on the proposed effective date and the costs of compliance with, and testing to, the proposed rule.

Submit comments in accordance with the instructions in the **ADDRESSES** section at the beginning of this NPR.

List of Subjects

16 CFR Part 1112

Administrative practice and procedure, Audit, Consumer protection, Reporting and recordkeeping requirements, Third party conformity assessment body.

16 CFR Part 1130

Administrative practice and procedure, Business and industry, Consumer protection, Reporting and recordkeeping requirements.

16 CFR Part 1243

Consumer protection, Imports, Incorporation by reference, Infants and children, Labeling, Law enforcement, Pillows, Toys.

For the reasons discussed in the preamble, the Commission proposes to amend chapter II of title 16 of the Code of Federal Regulations as follows:

PART 1112—REQUIREMENTS PERTAINING TO THIRD PARTY CONFORMITY ASSESSMENT BODIES

■ 1. The authority citation for 16 CFR part 1112 continues to read as follows:

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

■ 2. Amend § 1112.15, as proposed to be amended at 88 FR 65865 (Sept. 26, 2023), by:
■ a. Removing the semicolons at the ends of paragraphs (b)(1) through (9) and (11) through (27), (b)(28)(v), (b)(29)(iv), (b)(30)(iv), and (b)(31)(ii) and adding periods in their place;
■ b. Adding periods at the ends of paragraphs (b)(32)(ii)(A) through (KK); and
■ c. Adding paragraph (b)(57).
The addition reads as follows:

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

* * * * *
(b) * * *
(57) 16 CFR part 1243, Safety Standard for Infant Support Cushions.
* * * * *

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

■ 3. The authority citation for 16 CFR part 1130 continues to read as follows:

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

■ 4. Amend § 1130.2, as proposed to be amended at 88 FR 65865 (Sept. 26, 2023) and 88 FR 73551 (Oct. 26, 2023), by:
■ a. Removing the semicolons at the ends of paragraphs (a)(1) through (16) and adding periods in their place;
■ b. Removing ''; and'' at the end of paragraph (a)(17) and adding a period in its place; and
■ c. Adding paragraph (a)(21).
The addition reads as follows:

§ 1130.2 Definitions.

* * * * *
(a) * * *
(21) Infant support cushions.
* * * * *

■ 5. Add part 1243 to read as follows:

PART 1243—SAFETY STANDARD FOR INFANT SUPPORT CUSHIONS

Sec.

Authority: 15 U.S.C. 2056a.

§ 1243.1 Scope, purpose, application, and exemptions.

(a) *Scope and purpose.* The consumer product safety standard in this part prescribes requirements to reduce the risk of death and injury from hazards associated with *infant support cushions,* as defined in § 1243.2. This includes but is not limited to *infant positioners,* nursing products with a dual use for lounging, *infant loungers,* and infant props or cushions used to support an infant. All *infant support cushions* must be tested according to the requirements of § 1243.5 and comply with all requirements of this part.
(b) *Application.* All infant support cushions manufactured after [effective date of the final rule], are subject to the requirements of this part.
(c) *Exemptions.* Products subject to another standard listed in 16 CFR 1130.2(a) are exempt from this part. Nursing pillows that also meet the definition of *infant lounger,* however, are not exempt from this part.

§ 1243.2 Definitions.

Conspicuous means visible, when the product is in each manufacturer's recommended use position, to a person while placing an infant into or onto the product.
Infant lounger means an infant product with a raised perimeter, a recess, or other area that provides a place for an infant to recline or to be in a supine, prone, or recumbent position.
Infant positioner means a product intended to help keep an infant in a particular position while supine or prone.
Infant support cushion means an infant product that is filled with or comprised of resilient material such as foam, fibrous batting, or granular material or with a gel, liquid, or gas, and which is marketed, designed, or intended to support an infant's weight or any portion of an infant while reclining or in a supine, prone, or recumbent position.
Occupant support surface (OSS) means the area that holds up and bears the infant or any portion of the infant.
Seat bight line means the intersection of the seat back surface with the seat bottom surface.

§ 1243.3 General requirements.

(a) *Hazardous sharp edges or points.* There shall be no hazardous sharp points or edges as defined in 16 CFR 1500.48 and 1500.49 before or after the product has been tested.
(b) *Small parts.* There shall be no small parts as defined in 16 CFR part 1501 before testing or presented as a result of testing.
(c) *Lead in paints.* All paint and surface coatings on the product shall comply with the requirements of 16 CFR part 1303.
(d) *Toys.* Toy accessories attached to, removable from, or sold with an infant pillow, as well as their means of attachment, shall comply with the applicable requirements of 16 CFR part 1250.
(e) *Side height.* The maximum side height for the product, measured from the OSS-body or test base, as appropriate, to the top of the sidewall, shall not exceed the maximum of the side heights determined in § 1243.5(d)(8).
(f) *Removal of components.* When tested in accordance with § 1243.5(k), any removal of components that are accessible to an infant while in the product or from any position around the product shall not present a small part, sharp point, or sharp edge as required in paragraphs (a) and (b) of this section.
(g) *Permanency of labeling and warnings.* (1) Warning labels, whether paper or non-paper, shall be permanent when tested in accordance with § 1243.5(b)(1) through (3).
(2) Warning statements applied directly onto the surface of the product by hot stamping, heat transfer, printing, wood burning, or any other method shall be permanent when tested in accordance with § 1243.5(b)(4).
(3) Non-paper labels shall not liberate small parts when tested in accordance with § 1243.5(b)(5).
(4) Warning labels that are attached to the fabric of the product with seams shall remain in contact with the fabric around the entire perimeter of the label when the product is in all manufacturer-recommended use positions and when tested in accordance with § 1243.5(b)(3).
(h) *Convertible products.* If the infant support cushion can be converted into another product for which a consumer product safety standard exists, the product also shall comply with the applicable requirements of that standard.

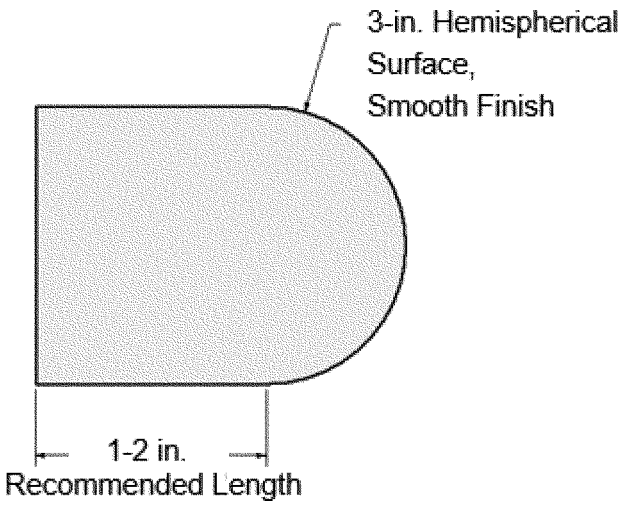
§ 1243.4 Performance requirements.

(a) *Restraint.* The product shall not include a restraint system.
(b) *Seam strength.* When tested in accordance with § 1243.5(j), fabric/mesh seams and points of attachment shall not fail such that a small part, sharp point, or sharp edge is presented, as required in § 1243.3(a) and (b).

(c) *Bounded openings.* When tested to § 1243.5(c), all completely bounded openings that exist in the front, sides, or back of the occupant lounging area, or that are created when an accessory is attached to the product, shall not allow complete passage of the small head probe unless it allows the complete passage of the large head probe.

(d) *Maximum incline angle.* The maximum incline angle shall not exceed 10 degrees when tested in accordance with § 1243.5(d).

(e) *Firmness*—(1) *Occupant support surface firmness.* When the three-inch diameter (figure 1 to this paragraph (e)(1)) hemispherical head probe is applied according to the test method for occupant support surface firmness, § 1243.5(f), the force required for a one-inch displacement shall be greater than 10 N.



(2) *Sidewall firmness.* When the three-inch diameter hemispherical head probe is applied according to the test method for sidewall firmness, § 1243.5(g), the force required for a one-inch displacement shall be greater than 10 N.

(3) *Firmness at intersection of sidewall and occupant support surface.* When the three-inch diameter hemispherical head probe is applied according to the test method for firmness at the intersection of sidewall and occupant support surface, § 1243.5(h), the force required for a one-inch displacement shall be greater than 10 N.

(f) *Sidewall angle.* Sidewall angle shall be greater than 90 degrees when determined according to the sidewall angle determination, § 1243.5(i).

§ 1243.5 Test methods.

(a) *Test conditions.* Condition the product for 48 hours at 23 °C ±2 °C (73.4 °F ±3.6 °F) and a relative humidity of 50% ±5%.

(b) *Permanence of labels and warnings.* (1) A paper label (excluding labels attached by a seam) shall be considered permanent if, during an attempt to remove it without the aid of tools or solvents, it cannot be removed, it tears into pieces upon removal, or such action damages the surface to which it is attached.

(2) A non-paper label (excluding labels attached by a seam) shall be considered permanent if, during an attempt to remove it without the aid of tools or solvents, it cannot be removed or such action damages the surface to which it is attached.

(3) A warning label attached by a seam shall be considered permanent if it does not detach when subjected to a 15-lbs (67–N) pull force applied in any direction using a 3 4-inch diameter clamp surface.

(4) Adhesion test for warnings applied directly onto the surface of the product.

(i) Apply the tape test defined in Test Method B, Cross-Cut Tape Test of ASTM D3359 (incorporated by reference, see § 1243.8), eliminating parallel cuts.

(ii) Perform this test once in each different location where warnings are applied.

(iii) The warning statements will be considered permanent if the printing in the area tested is still legible and attached after being subjected to this test.

(5) A non-paper label, during an attempt to remove it without the aid of tools or solvents, shall not be removed or shall not fit entirely within the small parts cylinder defined in 16 CFR part 1501 if it can be removed.

(c) *Head entrapment test.* For all applicable openings, rotate the small head probe (figure 2 to this paragraph (c)) to the orientation most likely to fail and gradually apply an outward force from the occupant lounging area of 25 lbs (111 N). Apply the force to the probe in the direction most likely to fail within a period of 5 seconds and maintain it for an additional 10 seconds. If the small head probe can pass entirely through the opening in any orientation, determine if the large head probe (figure 3 to this paragraph (c)) can be freely inserted through the opening.

Figure 2 to Paragraph (c)—Small Head Probe

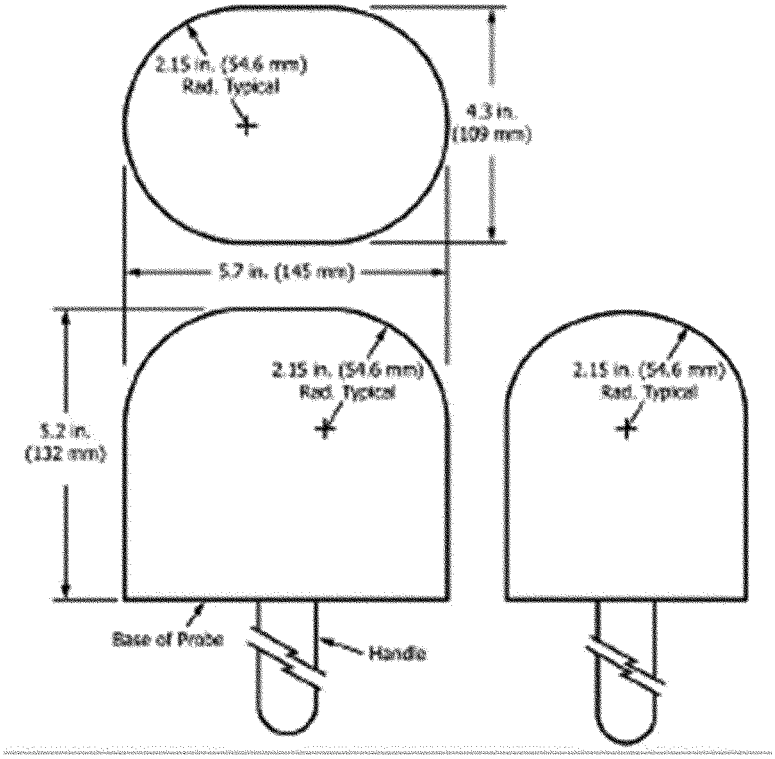
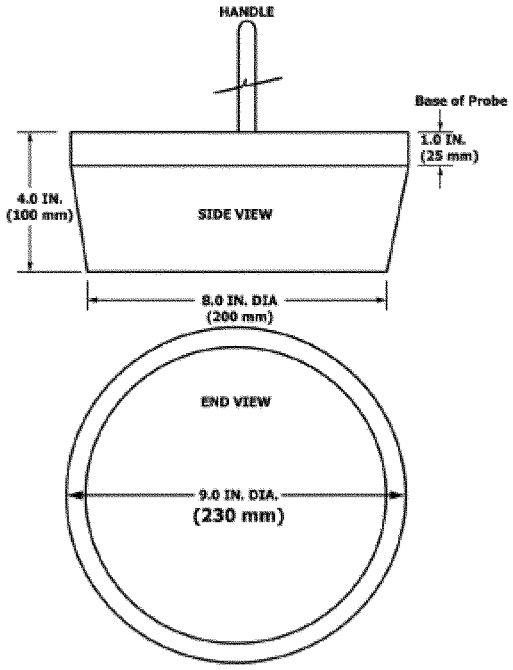


Figure 3 to Paragraph (c)—Large Head Probe



(d) *Maximum incline test.* (1) Equipment shall include:

(i) Digital protractor with accuracy +/− 1 degree;

(ii) Hinged weight gauge-newborn, requirements for part masses and

assembly (figure 4 to this paragraph (d)(1)(ii));

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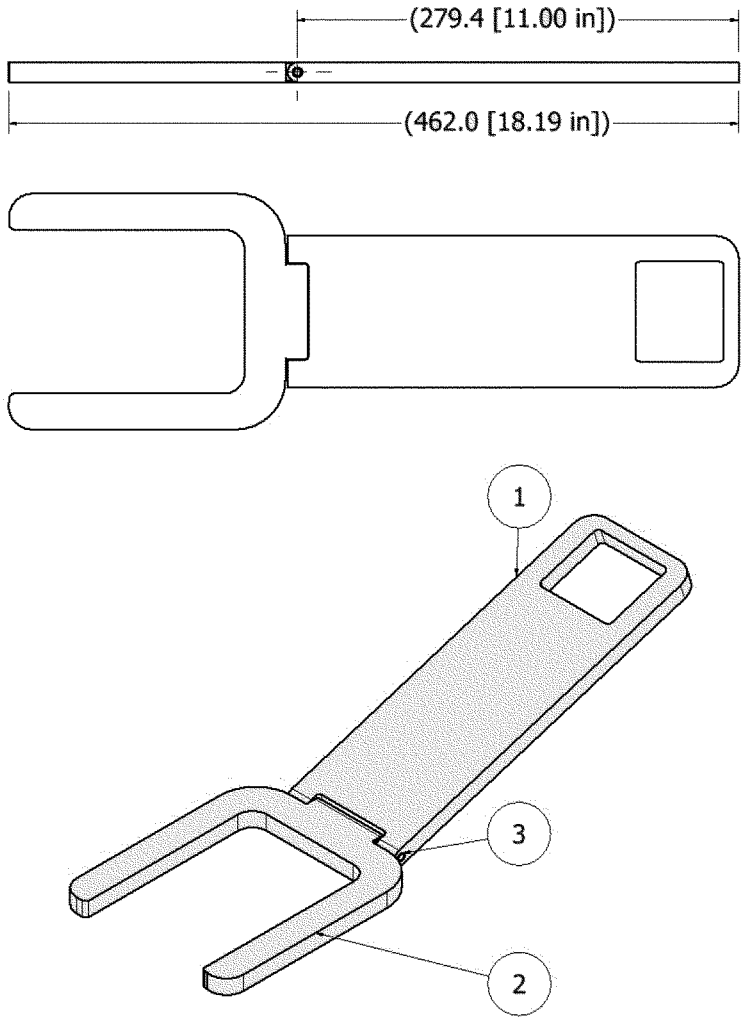
Figure 4 to Paragraph (d)(ii)—Hinged Weight Gauge-Newborn, Requirements for Part Masses and Assembly

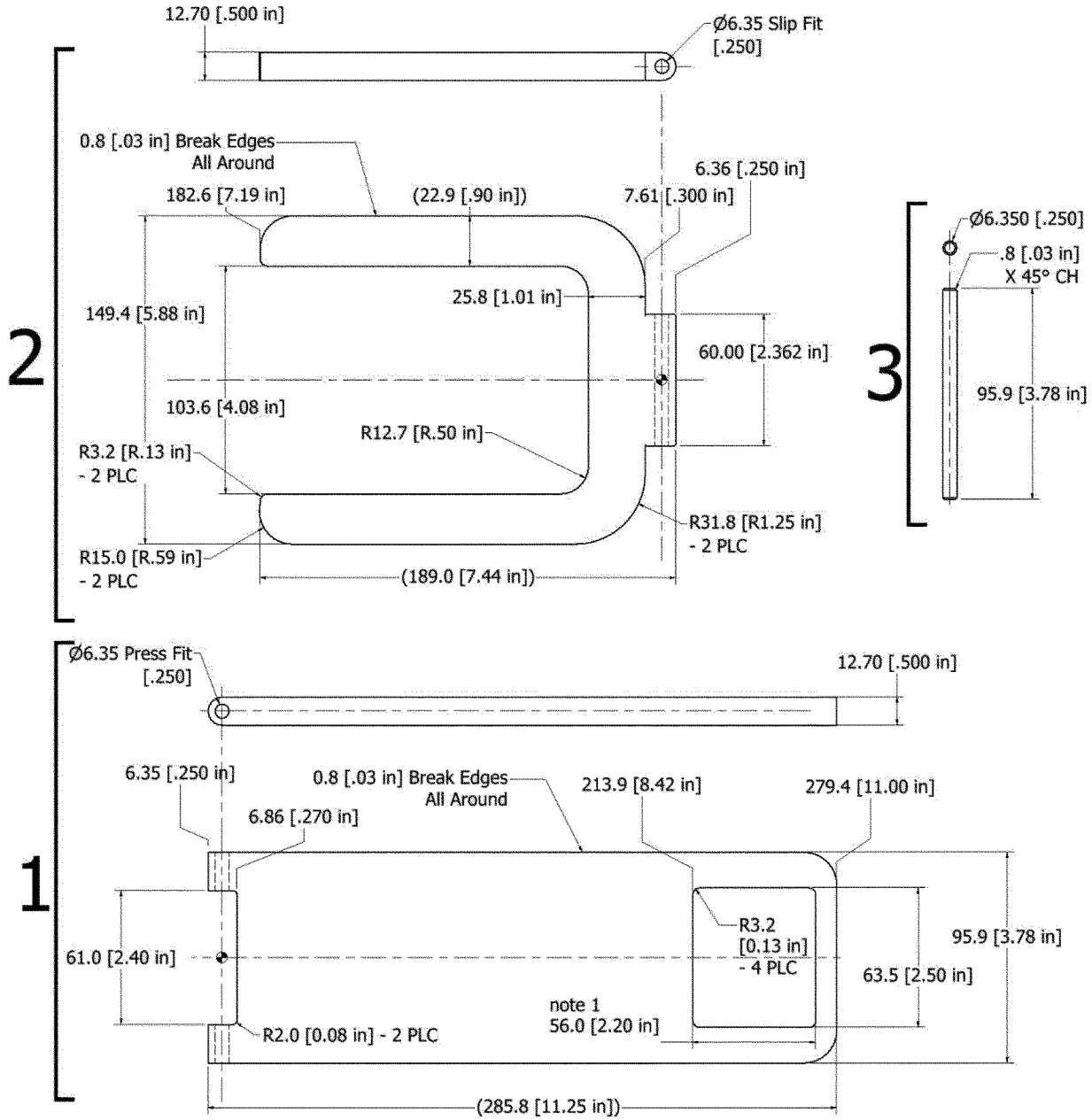
PARTS LIST			
ITEM	DESCRIPTION	MASS (1)	VOLUME
Assembly		3.378 ± .02 kg (7.447 ± .05 lb)	
1	Upper Plate	2.275 kg (5.016 lb)	289.8 cm^3 (17.68 in^3)
2	Lower Plate	1.079 kg (2.379 lb)	137.4 cm^3 (8.385 cm^3)
3	Pin	0.024 kg (0.053 lb)	3.03 cm^3 (0.185 in^3)

Note 1. Part mass is calculated as Volume divided by the density for mild steel of 7.85 g/cm^3 (0.283 lbs/in^3).



(iii) Hinged weight gauge-newborn, requirements for part dimensions (figure 5 to this paragraph (d)(1)(iii)); and

Figure 5 to Paragraph (d)(1)(iii)—Hinged Weight Gauge–Newborn, Requirements for Part Dimensions



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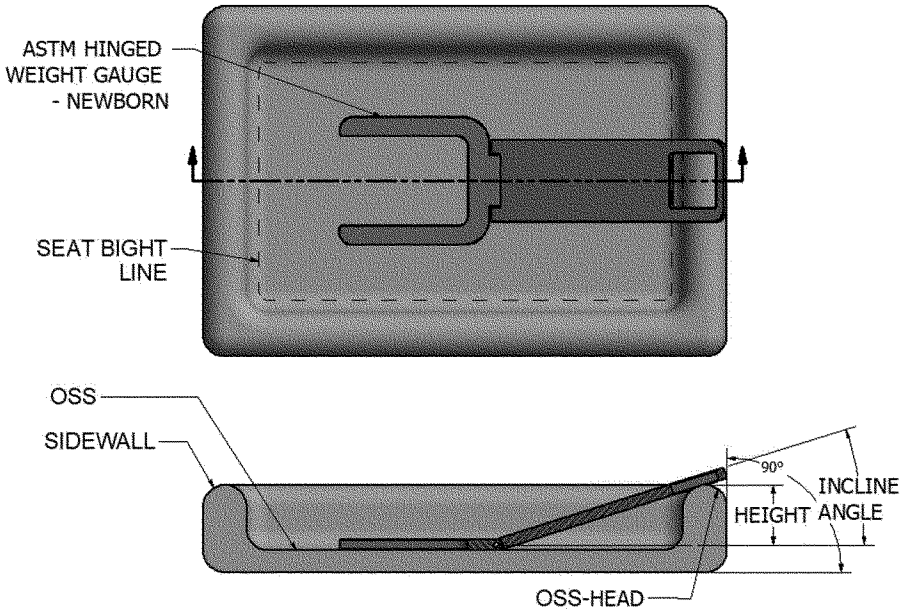
(iv) A test base that is horizontal, flat, firm, and smooth.

(2) If applicable, place the product in the manufacturer's recommended highest seat back angle position intended for lounging.

(3) If applicable, place the hinged weight gauge-newborn in the product and position the gauge with the hinge centered over the seat bight line and the upper plate of the gauge back. Place a digital protractor on the upper torso/head area lengthwise and measure the incline angle.

(4) Place the head/torso portion of the newborn hinged weight gauge on the product according to the manufacturer's recommended use position with the seat portion of the gauge, depending on the product design, allowed to lay freely on the product or on the test base (figure 6 to this paragraph (d)(4)).

Figure 6 to Paragraph (d)(4)—Test Fixture Configuration To Measure Incline Angle on an Infant Support Cushion Product



(5) Move and rotate the newborn hinged weight gauge the minimum amount necessary such that the head/torso portion rests on an OSS that could foreseeably support an infant's head, and place the head/torso portion of the gauge according to all situations that apply:

(i) In tests on products with an OSS for the infant's body, align the top edge of the head/torso portion of the gauge to coincide with a plumb line to the outermost edge of the OSS-head.

(ii) In all tests, place the seat portion of the gauge on the test base, adjust the newborn gauge to the greatest incline angle in which the top edge of the gauge maintains contact with the top surface of the product.

(6) If a product's seating bight area prevents reasonable positioning of the head/torso portion to the outermost edge, then position the seat portion of the newborn hinged weight gauge as far forward as possible towards the outermost edge and allow the head/torso portion of the gauge to rest on the product.

(7) Place a digital protractor lengthwise on the head/torso portion of the gauge and measure the incline angle.

(8) Remove the newborn gauge and determine the side height at the incline angle location, measured from the OSS-body or test base, as appropriate, to the top of the OSS-head.

(9) Measure the incline angle at the manufacturer's recommended use location(s), at feasible locations such as perpendicular to the recommended use location(s), and at least one location likely to fail in which the newborn gauge seat is supported on the test surface.

(10) Determine the maximum incline angle from the incline angle measurements.

(e) *Firmness test setup.* (1) Equipment shall include:

(i) Force gauge with accuracy +/− 0.05 N (0.01 lbs).

(ii) Distance gauge with accuracy +/− 0.01 inches (0.03 cm).

(2) Align the axis of the three-inch head probe (figure 1 to paragraph (e)(1) of § 1243.4) with a force gauge and parallel to a distance measurement device or gauge.

(3) Use a lead screw or similar device to control movement along a single direction.

(4) Support the firmness fixture to a test base such that the head probe does not deflect more than 0.01 inches (0.025 cm) under a 10.0 N (2.24 lbs) load applied in each orientation required in the test methods.

(f) *Occupant support surface firmness test method.* Perform the following steps to determine the occupant support surface firmness of the product as received from the manufacturer. *See* figure 7 to this paragraph (f).

(1) Orient the axis of the three-inch head probe perpendicular to the surface of the product at each test location that is oriented greater than five degrees relative to the test base or align the axis of the probe perpendicular to the test base (vertically) at each test location that is oriented equal to or less than five degrees to the test base.

(2) The first test location shall be at the location of maximum thickness of the surface being tested, perpendicular to the test base.

(3) Lay the product, with the occupant support surface facing up, on a test base that is horizontal, flat, firm, and smooth.

(4) Prevent movement of the product in a manner that does not affect the force or deflection measurement of the product surface under test. Provide no additional support beneath the product.

(5) Advance the probe into the product and set the deflection to 0.0 inches when a force of 0.1 N (0.02 lbs) force is reached.

(6) Continue to advance the head probe into the product at a rate not to exceed 0.1 inch per second and pause when the force exceeds 10.0 N (2.24 lbs), or the deflection is equal to 1.00 inches (2.54 cm).

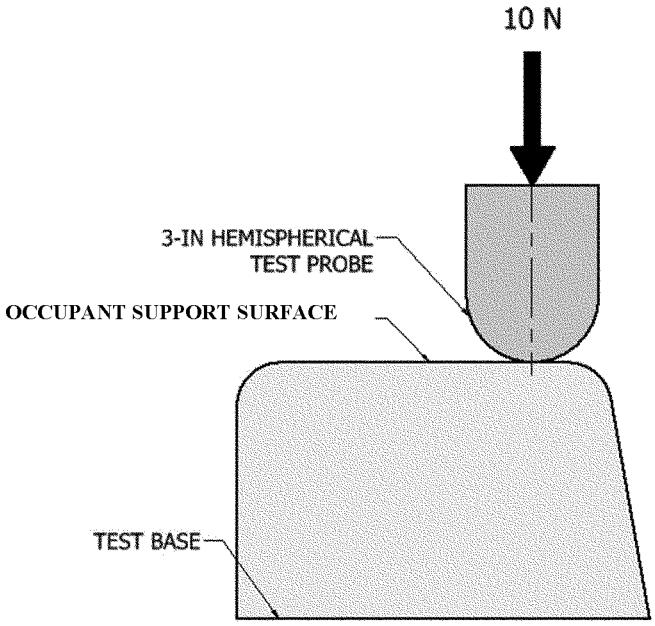
(7) Wait 30 seconds. If the deflection is less than 1.00 inches and the force is 10.0 N or less, repeat the steps in paragraphs (f)(6) and (7) of this section.

(8) Record the final force and deflection when the deflection has reached 1.00 inches or when the force has exceeded 10.0 N.

(9) If the maximum thickness of the OSS is greater than 1.0 inches (2.54 cm), perform additional tests, space permitting, at the geometric center of the OSS, at four locations along the product's longitudinal and lateral axes therefrom, 1.5 inches (3.8 cm) towards center from the intersection of the sidewall and OSS, and at one location most likely to fail.

(10) Repeat the occupant support surface firmness tests on any other occupant support surface and in all intended and feasible configurations that could affect an occupant support surface, such as the folding or layering of parts of the product.

Figure 7 to Paragraph (f)—Test Configuration for Occupant Support Surface Firmness Test



(g) *Sidewall firmness test method.* For sidewalls, perform the steps in paragraphs (f)(1) through (8) of this section to determine the sidewall firmness of the product as received from the manufacturer and then perform the following:

(1) Perform a minimum of four additional tests, located at intervals not to exceed six inches along the entire top perimeter of the sidewall, starting from the maximum side height location, and at one additional location most likely to fail.

(2) Repeat the sidewall firmness test in all the intended or feasible configurations that could affect the sidewall firmness, such as the folding or layering of parts of the product.

(h) *Intersection of sidewall and occupant support surface firmness.* Perform the following steps to determine the intersection firmness of the product as received from the manufacturer (figure 8 to this paragraph (h)).

(1) Orient the axis of the three-inch head probe perpendicular to the sidewall perimeter at an angle from horizontal that bisects the angle determined in sidewall angle determination with the axis directed at the intersection of the occupant support surface and the sidewall.

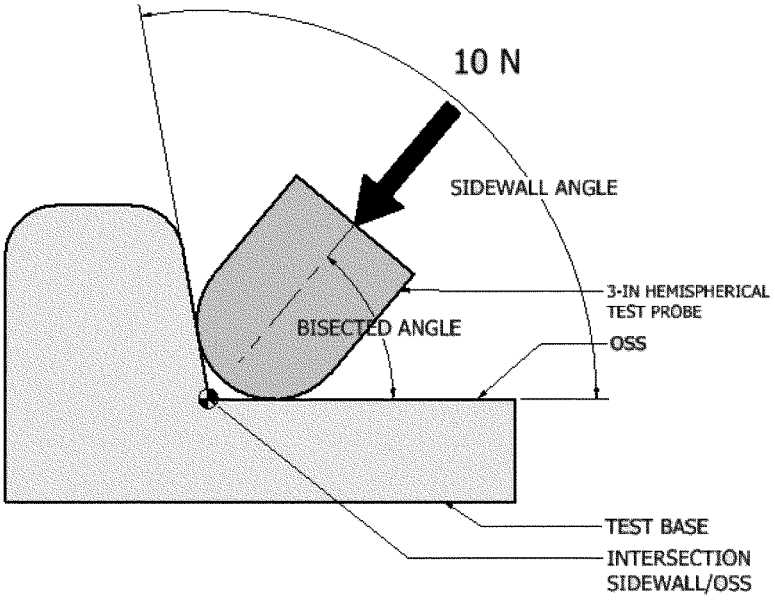
(2) The first test location shall be at the location of maximum product thickness parallel to the test base.

(3) Perform the steps in paragraphs (f)(3) through (8) of this section.

(4) Perform a minimum of four additional tests, located at intervals not to exceed six inches along the entire inside perimeter of the intersection of the sidewall and OSS, and at one additional location most likely to fail.

(5) Repeat the intersection of sidewall and occupant support surface firmness test in all the intended or feasible configurations that could affect the intersection firmness, such as the folding or layering of parts of the product.

Figure 8 to Paragraph (h)—Test Configuration for Intersection of Sidewall and Occupant Support Surface Firmness



(i) *Sidewall angle determination.* Perform the following steps to determine if the angle between the sidewall and OSS is 90 degrees or less, or to measure the angle above 90 degrees. *See* figure 9 to this paragraph (i).

(1) Orient the three-inch (7.62 cm) diameter hemispherical head probe vertically and place it over the OSS with the cylindrical surface of the probe tangent to the intersection of the sidewall and the OSS. Advance the probe into the product until a downward force of 10 N (2.2 lbs) force is reached.

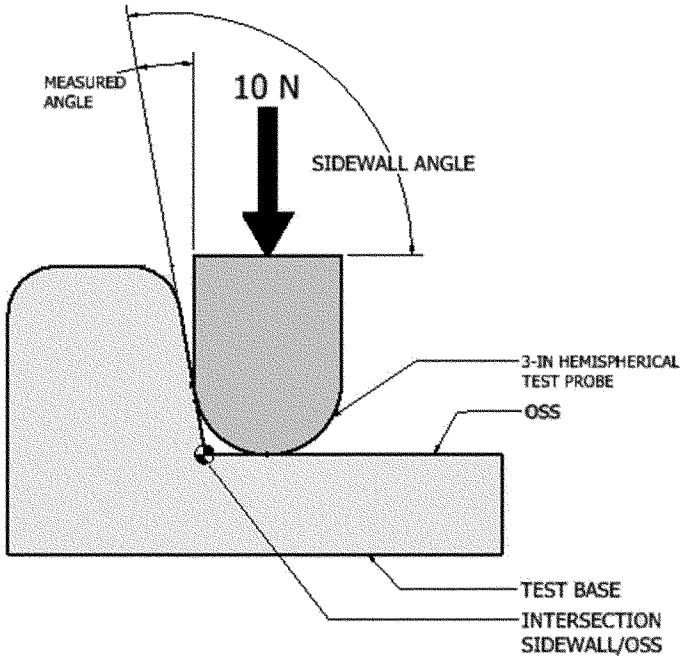
(2) After 30 seconds, determine whether the sidewall is in contact with the cylindrical side of the three-inch head probe. If the sidewall contacts the cylindrical part of the probe, the sidewall angle is equal to or less than 90 degrees.

(3) For sidewall angles greater than 90 degrees, calculate the sidewall angle as 90 degrees plus the measured angle between the cylindrical side of the three-inch head probe and the sidewall.

(4) Determine a minimum of four sidewall angles at locations not to exceed six inch (15.2 cm) intervals along the intersection of the sidewall and OSS.

(5) Measure the angle with a protractor or gauge placed to the depth of and in contact with the cylindrical side of the three-inch probe side and the sidewall.

Figure 9 to Paragraph (i)—Test Fixture Configuration for Sidewall Angle Measurement



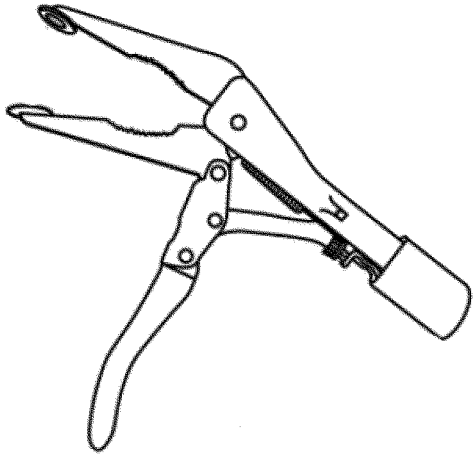
(j) *Seam strength test method.* (1) Equipment shall include:

(i) Clamps with 0.75 inches (1.9 cm) diameter clamping surfaces capable of holding fabric and with a means to

attach a force gauge. *See* figure 10 to this paragraph (j)(1), or equivalent.

(ii) A force gauge, accuracy +/− 0.5 lbs (1.1 N).

Figure 10 to Paragraph (j)(1)—Seam Clamp



(2) Clamp the fabric of the infant support cushion on each side of the seam under test with the 0.75 inches clamping surfaces placed not less than 0.5 inches (1.2 cm) from the seam.

(3) Apply a tension of 15 lbs (67 N) evenly over five seconds and maintain for an additional 10 seconds.

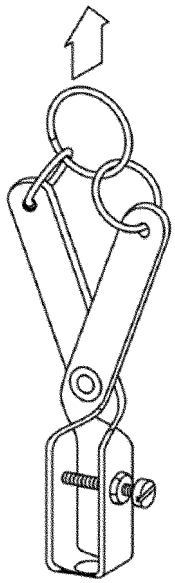
(4) Repeat the test on every distinct seam and every 12 inches (15 cm) along each seam.

(k) *Removal of components test method.* (1) For torque and tension tests, any suitable device may be used to grasp the component that does not interfere with the attachment elements that are stressed during the tests.

(2) Gradually apply a four lbs-inch (0.4 N-m) torque over five seconds in a clockwise rotation to 180 degrees or until four lbs-inch has been reached. Maintain for 10 seconds. Release and allow component to return to relaxed state. Repeat the torque test in a counterclockwise rotation.

(3) For components that can reasonably be grasped between thumb and forefinger, or teeth, apply a 15 lbs (67 N) force over five seconds, in a direction to remove the component. Maintain for 10 seconds. A clamp such as shown in figure 11 to this paragraph (k)(3) may be used if the gap between the back of the component and the base material is 0.04 inches (0.1 cm) or more.

Figure 11 to Paragraph (k)(3)—Tension Test Adapter Clamp



§ 1243.6 Marking and labeling.

(a) *General markings.* Each product and its retail package shall be marked or labeled clearly and legibly to indicate the following:

(1) The name, place of business (city, state, and mailing address, including zip code), and telephone number of the manufacturer, distributor, or seller.

(2) A code mark or other means that identifies the date (month and year as a minimum) of manufacture.

(3) The marking or labeling in paragraphs (a)(1) and (2) of this section are not required on the retail package if they are on the product and are visible in their entirety through the retail package. When no retail packaging is used to enclose the product, the information provided on the product shall be used for determining compliance with paragraphs (a)(1) and

(2) of this section. Cartons and other materials used exclusively for shipping the product are not considered retail packaging.

(b) *Permanency.* The marking and labeling on the product shall be permanent.

(c) *Upholstery labeling.* Any upholstery labeling required by law shall not be used to meet the requirements of this section.

(d) *Warning design for product.* (1) The warnings shall be easy to read and understand and be in the English language at a minimum.

(2) Any marking or labeling provided in addition to those required by this section shall not contradict or confuse the meaning of the required information or be otherwise misleading to the consumer.

(3) The warnings shall be conspicuous and permanent.

(4) The warnings shall conform to ANSI Z535.4–2011 (incorporated by reference, see § 1243.8) sections 6.1–6.4, 7.2–7.6.3, and 8.1, with the following changes.

(i) In sections 6.2.2, 7.3, 7.5, and 8.1.2, replace ''should'' with ''shall.''

(ii) In section 7.6.3, replace ''should (when feasible)'' with ''shall.''

(iii) Strike the word ''safety'' when used immediately before a color (for example, replace ''safety white'' with ''white'').

Note 1 to paragraph (d)(4)(iii): For reference, ANSI Z535.1, American National Standard for Safety Colors, provides a system for specifying safety colors.

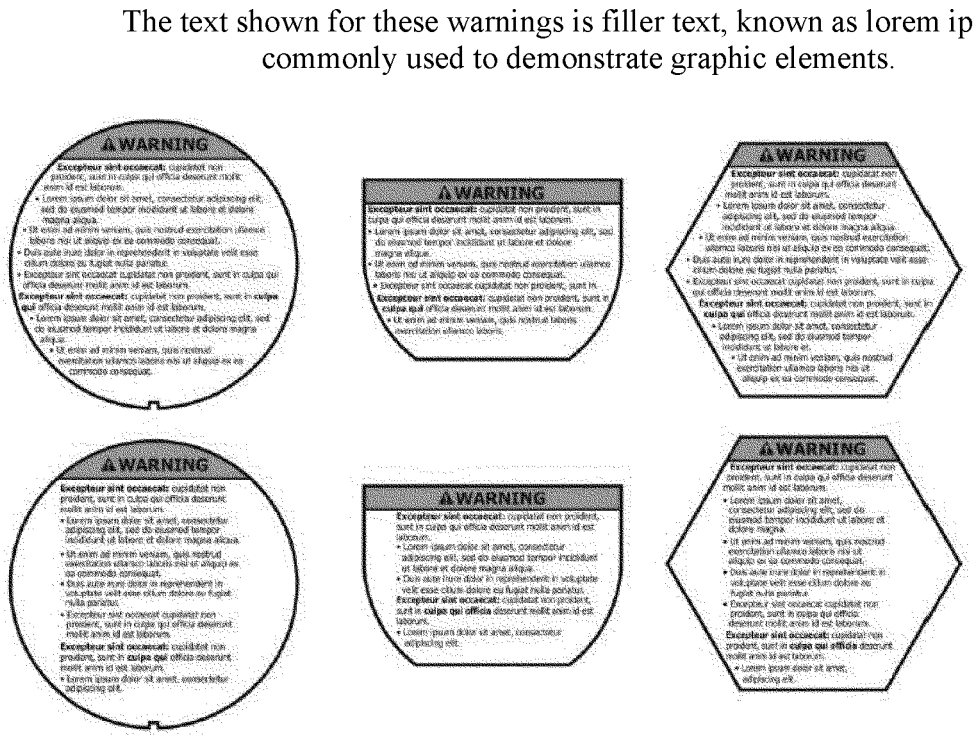
(5) The safety alert symbol and the signal word ''WARNING'' shall be at least 0.2 inches (five mm) high. The remainder of the text shall be in characters whose upper case shall be at least 0.1 inches (2.5 mm), except where otherwise specified.

Note 2 to paragraph (d)(5): For improved warning readability, typefaces with large height-to-width ratios, which are commonly identified as ''condensed,'' ''compressed,'' ''narrow,'' or similar should be avoided.

(6) The message panel text should have the following layout:

(i) The text shall be left-aligned, ragged-right for all but one-line text messages, which can be left-aligned or centered. *See* figure 1 to this paragraph (d)(6) for examples of left-aligned text.

Figure 1 to Paragraph (d)(6)—Examples of Left-Aligned Text



The text shown for these warnings is filler text, known as lorem ipsum, commonly used to demonstrate graphic elements.

Note 3 to paragraph (d)(6)(i): Left-aligned means that the text is aligned along the left margin, and in the case of multiple columns of text, along the left side of each individual column.

(ii) The text in each column should be arranged in list or outline format, with precautionary (hazard avoidance) statements preceded by bullet points. Multiple precautionary statements shall be separated by bullet points if paragraph formatting is used.

(7) An example warning in the format described in this section is shown in figure 2 to this paragraph (d)(7).

Figure 2 to Paragraph (d)(7)—Example of Warning

(e) *Warning statements.* Each product shall address the warning statements shown on figure 13 to paragraph (d)(7) of this section, at a minimum.

Note 4 to paragraph (e): ''Address'' means that verbiage other than what is shown can be used as long as the meaning is the same or information that is product-specific is presented.

§ 1243.7 Instructional literature.

(a) Instructions shall be provided with the product and shall be easy to read and understand and shall be in the English language at a minimum. These instructions shall include information on assembly, maintenance, cleaning, and use, where applicable.

(b) The instructions shall address the following additional warnings:

(1) Read all instructions before using this product.

(2) Keep instructions for future use.

(3) Do not use this this product if it is damaged or broken.

(4) Instructions shall indicate the manufacturer's recommended maximum weight, height, age, developmental level, or combination thereof, of the occupant for which the infant support cushion is intended. If this product is not intended for use by a child for a specific reason, the instructions shall state this limitation.

(c) The cautions and warnings in the instructions shall meet the requirements specified in § 1243.6(d)(4) though (6), except that sections 6.4 and 7.2–7.6.3 of ANSI Z535.4—2011 need not be applied. However, the signal word and safety alert symbol shall contrast with the background of the signal word panel, and the cautions and warnings shall contrast with the background of the instructional literature.

Note 1 to paragraph (c): For example, the signal word, safety alert symbol, and the warnings may be black letters on a white background, white letters on a black background, navy blue letters on an off-white background, or some other high-contrast combination.

(d) Any instructions provided in addition to those required by this section shall not contradict or confuse the meaning of the required information or be otherwise misleading to the consumer.

§ 1243.8 Incorporation by reference.

Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved incorporation by reference (IBR) material is available for inspection at the U.S. Consumer Product Safety Commission and at the National Archives and Records Administration (NARA). Contact the U.S. Consumer Product Safety Commission at: the Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; phone (301) 504–7479; email: *cpsc-os@cpsc.gov.* For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.* The material may be obtained from the following sources:

(a) American National Standards Institute (ANSI), 25 West 43rd Street, 4th Floor, New York, NY 10036, USA; phone: (212) 642–4900; website: *www.ansi.org* (*https://ibr.ansi.org/Standards/nema.aspx*).

(1) ANSI Z535.4–2011, *American National Standard for Product Safety Signs and Labels,* approved October 20, 2017; approved for § 1243.6.

(2) [Reserved]

(b) ASTM International, 100 Barr Harbor Drive, P.O. Box CB700, West Conshohocken, Pennsylvania 19428–2959; phone: (800) 262–1373; website: *www.astm.org.*

(1) ASTM D3359–23, Standard Test Methods for Rating Adhesion by Tape Test, approved [TBD]; approved for § 1243.5.

(2) [Reserved]

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2023–27324 Filed 1–12–24; 8:45 am]

BILLING CODE 6355–01–P

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 23

RIN 3038–AF33

Capital and Financial Reporting Requirements for Swap Dealers and Major Swap Participants

AGENCY: Commodity Futures Trading Commission.

ACTION: Proposed rule.

SUMMARY: The Commodity Futures Trading Commission (''Commission'' or

EXHIBIT 12

United States
Consumer Product Safety Commission

THIS DOCUMENT HAS BEEN ELECTRONICALLY APPROVED AND SIGNED

Vote Sheet

TO: The Commission
Alberta E. Mills, Secretary

DATE: November 8, 2023

THROUGH: Austin C. Schlick, General Counsel
Jason K. Levine, Executive Director

FROM: Daniel R. Vice, Assistant General Counsel, Regulatory Affairs
Elisabeth Layton, Attorney, Regulatory Affairs

SUBJECT: Notice of Proposed Rulemaking: Safety Standard for Infant Support Cushions

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THIS MATTER IS NOT SCHEDULED FOR A BALLOT VOTE.

A DECISIONAL MEETING FOR THIS MATTER IS SCHEDULED ON: November 29, 2023.

Pursuant to the Danny Keysar Child Product Safety Notification Act, section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), 15 U.S.C. § 2056a, which requires the Commission to promulgate consumer product safety standards for durable infant or toddler products, the Office of the General Counsel is forwarding for the Commission's consideration a staff briefing package recommending publication in the *Federal Register* of the attached draft notice of proposed rulemaking to establish a Safety Standard for Infant Support Cushions. To implement the requirements of section 104, the draft proposed rule includes mandatory performance and labeling requirements that address suffocation, entrapment, and fall hazards associated with infant support cushions.

Please indicate your vote on the following options:

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

_____ _____
(Signature) (Date)

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

National Product Testing and Evaluation Center
5 Research Place
Rockville, MD 20850

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

_____

_____

_____

_____ _____
(Signature) (Date)

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

_____ _____
(Signature) (Date)

IV. Take other action specified below.

_____

_____

_____

_____

_____ _____
(Signature) (Date)

Attachment: Notice of Proposed Rulemaking: Safety Standard for Infant Support Cushions.

Billing Code 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1112, 1130, and 1243

[CPSC Docket No. 2023-XXXX]

Safety Standard for Infant Support Cushions

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Danny Keysar Child Product Safety Notification Act, section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), requires the U.S. Consumer Product Safety Commission (Commission or CPSC) to promulgate consumer product safety standards for durable infant or toddler products. Under this statutory direction, the Commission is proposing a safety standard for infant support cushions. The Commission is also proposing to amend CPSC's consumer registration requirements to identify infant support cushions as durable infant or toddler products and proposing to amend CPSC's list of notices of requirements (NORs) to include infant support cushions.

DATES: Submit comments by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Comments related to the Paperwork Reduction Act aspects of the marking, labeling, and instructional literature requirements of the proposed rule should be directed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: CPSC Desk Officer, FAX: 202-395-6974, or emailed to oira_submission@omb.eop.gov.

Other comments, identified by Docket No. CPSC-2023-XXXX, may be submitted electronically or in writing, as follows:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: https://www.regulations.gov. Follow the instructions for submitting comments. Do not submit through this website: confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. CPSC typically does not accept comments submitted by email, except as described below.

Mail/Hand Delivery/Courier/Confidential Written Submissions: CPSC encourages you to submit electronic comments by using the Federal eRulemaking Portal. You may, however, submit comments by mail, hand delivery, or courier to: Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone: (301) 504–7479.

Instructions: All submissions received must include the agency name and docket number for this proposed rulemaking. CPSC may post all comments without change, including any personal identifiers, contact information, or other personal information provided, to: www.regulations.gov. If you wish to submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public, you may submit such comments by mail, hand delivery, or courier, or you may email them to: cpsc-os@cpsc.gov.

Docket: For access to the docket to read background documents or comments received, go to: http://www.regulations.gov, insert the docket number, CPSC- 2023-XXXX, into the "Search" box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Stefanie Marques, Ph.D., Project Manager, Directorate for Health Sciences, U.S. Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; email: smarques@cpsc.gov; telephone: (301) 987-2581.

SUPPLEMENTARY INFORMATION:

I. Background and Statutory Authority

Section 104(b) of the CPSIA requires the Commission to (1) examine and assess the effectiveness of voluntary consumer product safety standards for durable infant or toddler products, in consultation with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts and (2) promulgate consumer product safety standards for durable infant and toddler products. 15 U.S.C. 2056a(b)(1). The Commission must continue to promulgate standards for all categories of durable infant or toddler products "until the Commission has promulgated standards for all such product categories." 15 U.S.C. 2056a(b)(2).

The Commission is issuing this notice of proposed rulemaking (NPR) to establish a consumer product safety rule for infant support cushions to further implement section 104 of the CPSIA. The proposed rule defines an "infant support cushion" as "an infant product that is filled with or comprised of resilient material such as foam, fibrous batting, or granular material or with a gel, liquid, or gas, and which is marketed, designed, or intended to support an infant's weight or any portion of an infant while reclining or in a supine, prone, or recumbent position." This includes infant pillows, infant loungers, nursing pillows with a lounging function, infant props or cushions used to support an infant for activities such as "tummy time," and other similar products.

CPSC staff identified at least 79 reported fatalities involving infant support cushions from January 1, 2010 through December 31, 2022, as well as 125 nonfatal incidents or reports involving these products within the same time period. There were 17 deaths in 2020, and at least 17 more in the potentially incomplete data from 2021. More than 80 percent of the fatalities

associated with these products involved infants three months old and younger. In more than 60 percent of the fatalities, the official cause of death was either asphyxia or probable asphyxia, and these incidents typically involved use of an infant support cushion placed in or on a sleep-related consumer product such as an adult bed, futon, crib, bassinet, play yard, or a on a couch. For the nonfatal incidents, the most common circumstances involved an infant falling from an infant support cushion placed on a raised surface such as a bed or a sofa or the threat of asphyxia or entrapment.

This proposed rule addresses the risk of death and injury associated with infant support cushions primarily due to suffocation, entrapment, and fall hazards. The proposed rule would address positional asphyxiation hazards by requiring that all surfaces be sufficiently firm that they are unlikely to conform to an infant's face and occlude the airways, and by setting a maximum incline angle that would prevent hazardous positioning of an infant's head and neck along the surfaces of the product. The proposed rule would set a side angle requirement that addresses the risk of entrapment between the sidewall and the occupant support surface. It addresses fall hazards by effectively limiting sidewall height to discourage caregivers from mistakenly believing these products to be safe for unattended infants. The proposed rule also requires a strongly worded, conspicuous, and permanent on-product warning.

Consistent with section 104(b)(1)(A) of the CPSIA, CPSC consulted with manufacturers, retailers, trade organizations, laboratories, consumer advocacy groups, consultants, and the public to develop this rule, including through participation in the juvenile products subcommittee

meetings of ASTM.[1] Currently, however, no voluntary or mandatory safety standard for infant support cushions exists to address the hazards posed by these products.

Infant support cushions are a durable infant or toddler product under section 104(f) of the CPSIA. Section 104(f)(1) defines the term "durable infant or toddler product" as "a durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years." 15 U.S.C. 2056a(f)(1). Section 104(f)(2) of the CPSIA provides a non-exhaustive list of product categories within the definition of "durable infant or toddler products." Although infant support cushions are not specifically listed in section 104(f)(2), they are "durable infant or toddler products" because (as explained in Part II, below) they are: not disposable; have a useful life of up to several years and often are used by multiple children successively; are similar to other durable infant and children's products such as crib mattresses and sling carriers; and are primarily intended to be used by children five years old or younger.

Section 104(d) of the CPSIA requires manufacturers of durable infant or toddler products to establish a product registration program and comply with CPSC's rule for product registration cards, 16 CFR part 1130. The Commission proposes to amend part 1130 to include infant support cushions in the list of durable infant or toddler products that must comply with these product registration requirements. *See* 16 CFR 1130.2(a).

Manufacturers of children's products also must comply with product registration requirements, as well as testing and certification requirements for children's products that are codified in 16 CFR parts 1107 and 1109. Section 14(a)(3) of the Consumer Product Safety Act

[1] CPSC formally began the consultation process for this rulemaking in December 2021, via a letter from CPSC staff requesting that ASTM form a working group to develop a voluntary standard to reduce the risk of death and injury from hazards associated with infant pillow products, including nursing pillows. In response, ASTM formed two subcommittees intended to develop two separate voluntary standards: the F15.16 Infant Feeding Supports subcommittee, intended to develop a standard for nursing pillows; and the F15.21 Infant Loungers subcommittee. CPSC staff has been actively participating in both ASTM subcommittees to develop voluntary standards that address hazards associated with these products.

(CPSA) requires the Commission to publish an NOR for the accreditation of third party conformity assessment bodies (test laboratories) to assess conformity with a children's product safety rule to which a children's product is subject. The proposed rule would be a children's product safety rule that requires issuance of an NOR.

II. The Product Category

A. Infant Support Cushions

Infant support cushions include products that support an infant for lounging, meaning reclining or lying in a supine, prone, or recumbent position. Infant products within this category may or may not contain infants with perimeter walls. Most infant support cushions on the market today are filled with cushy foam or soft fibrous batting, covered by flexible fabric. Some infant support cushions are marketed for use in a crib or other infant sleep product, notwithstanding warnings from the Commission and others, including the American Academy of Pediatrics (AAP), that soft objects, such as pillows and excess bedding, should not be placed in an infant's sleep environment.

Illustrative pictures of infant support cushions can be found in Tab C of staff's briefing package for this proposed rule.[2] A non-exhaustive list of examples of infant support cushions includes:

- head positioner pillows;
- flat baby loungers;
- crib pillows;
- wedge pillows for infants;
- infant sleep positioners, unless regulated by the Food and Drug Administration (FDA) as medical devices;
- stuffed toys marketed for use as an infant support cushion;
- infant "tummy time" or "lounging" pillows, whether flat or inclined;
- multi-purpose pillows marketed for both nursing and lounging;

[2] Staff Briefing Package: Staff's Draft Proposed Rule for Infant Support Cushions, (November __2023) (Staff's NPR Briefing Package), available at: [INSERT LINK]

- anti-rollover pillows with or without straps that fasten the pillow to the infant;
- infant "self-feeding" pillows that hold a bottle in front of the face of a reclining or lying infant;
- pads and mats; and
- accessory pillows and other padded accessories, often marketed for use with an infant car seat, stroller, or bouncer, but not sold with that product and therefore not included in the mandatory safety standard for those products.

These in-scope products would be required to meet the performance standards of this rule. To avoid potentially duplicative or conflicting obligations, however, the scope of products that would be subject to this proposed rule does not include durable infant products that are already regulated by the Commission and included in the list of products at 16 CFR 1130.2(a).

Illustratively, the following products are not infant support cushions within the scope of this proposed rule:

- Pillows not marketed or intended for use by infants, such as adult bed and throw pillows;
- nursing pillows if subject to Commission's proposed nursing pillow rule 88 FR 65865 (Sept. 26, 2023) if that rule is finalized, unless they are also marketed for lounging;
- crib and play yard mattresses that are in scope of the play yard and crib mattress standard in 16 CFR part 1241;
- purely decorative nursery pillows, such as those personalized with a baby's name and birthdate, that are not for infant use;
- stuffed toys (unless they meet the definition of an infant support cushion in this proposed rule);
- padded seat liners that are sold with a rocker, stroller, car seat, infant carrier, swing, highchair, or bouncer that are specifically designed to fit that product; and
- sleeping accommodations, which are regulated under the Commission's infant sleep product rule at 16 CFR part 1236.

B. Market Description

Most types of new infant support cushions are sold online, including from general online retailers, online sites for "big box" stores, online baby products sites, and online marketplaces for hand-crafted items. A few types of infant support cushions, however, are also available from brick-and-mortar baby specialty stores and general retail stores, particularly crib pillows and

baby loungers. Prices for new infant support cushions average roughly $30 and range from less than $15 for a simple head positioner pillow or crib pillow to more than $250 for a lounger with a removable cover or a large stuffed toy marketed for sleep. Several thousand manufacturers and importers, including hundreds of handcrafters and direct foreign shippers, supply infant support cushions to the U.S. market. *See* Staff's NPR Briefing Package, Tab E.

Infant support cushions may be re-used for multiple children or sold for use after an infant outgrows the product. Commission staff observed that used infant support cushions are widely available on secondary marketplaces such as eBay and Mercari. In June 2023, for example, staff found listings on Mercari for used changing pads, large stuffed toys marketed for infant sleep, crib wedge pillows, baby neck pillows, baby sleep positioners, baby loungers, baby sleep mats, baby "pillow chairs," infant "self-feeding" pillows, baby/toddler bean bag chairs, and crib pillows.

C. Infant Cushion/Pillow Ban

In 1992, pursuant to the Commission's authority under the Federal Hazardous Substances Act (FHSA), 15 U.S.C. 1261-1278, the Commission issued a ban on certain infant cushions and pillows filled with foam, plastic beads, or other granular material. 57 FR 27912 (June 23, 1992). That ban prohibits "infant cushions," "infant pillows," and similar articles that are:

- made with a flexible fabric covering;
- loosely filled with granular material, including but not limited to, polystyrene beads or pellets;
- easily flattened;
- capable of conforming to the body or face of an infant; and
- intended or promoted for use by children under one year of age.

16 CFR 1500.18(a)(16). This proposed rule for infant support cushions does not change the FHSA ban. That ban was limited to products with the specific hazard presented by loosely filled granular material such as polystyrene beads or pellets, and those products will continue to be

banned under the FHSA. Infant support cushions that are not subject to the ban are within the scope of this proposed rule and would be required to comply with the performance requirements of this proposed rule.[3]

III. Incident Data and Hazard Patterns

CPSC staff searched the Consumer Product Safety Risk Management System (CPSRMS)[4] and National Electronic Injury Surveillance System (NEISS)[5] databases for fatalities, incidents, and concerns associated with infant support cushions and involving infants up to 12 months old, reported to have occurred between January 1, 2010 and December 31, 2022. Tab A of Staff's NPR Briefing Package describes the incident and hazard patterns associated with infant support cushions.

Commission staff identified 79 fatal incidents and 125 nonfatal incidents and consumer concerns reported to CPSC from 2010-2022. Of the 125 non-fatal reports. 22 consisted of emergency-department-treated injuries, three involved hospital admissions, 46 reports involved

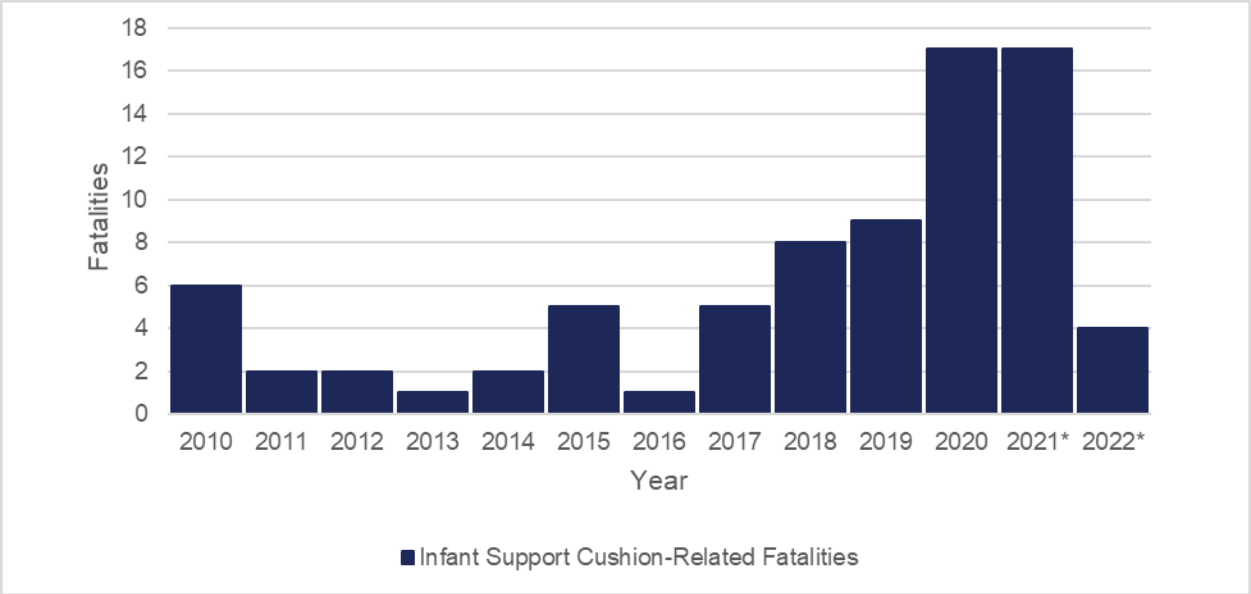
[3] An exemption to the infant pillow ban applies to Boston Billow nursing pillows and substantially similar nursing pillows that are designed to be used only as nursing aids for breastfeeding mothers. 16 CFR 1500.86(a)(9). The exemption applies specifically to the FHSA ban and is not applicable to this proposed rule or to the proposed standard for nursing pillows.

[4] CPSRMS is the epidemiological database that houses all anecdotal reports of incidents received by CPSC, "external cause"-based death certificates purchased by CPSC, all in-depth investigations of these anecdotal reports, as well as investigations of select NEISS injuries. CPSRMS documents include hotline reports, online reports, news reports, medical examiner's reports, death certificates, retailer/manufacturer reports, and documents sent by state and local authorities, among others.

[5] NEISS is a statistically valid surveillance system for collecting injury data. NEISS is based on a nationally representative probability sample of hospitals in the U.S. and its territories. Each participating NEISS hospital reports patient information for every emergency department visit associated with a consumer product or a poisoning to a child younger than five years of age. The total number of product-related hospital emergency department visits nationwide can be estimated from the sample of cases reported in the NEISS. *See* https://www.cpsc.gov/Research--Statistics/NEISS-Injury-Data.

no injury, and for 52 reports the disposition was either unknown or unspecified. Table 1 provides the distribution of fatal incidents by year.

Table 1: Infant Support Cushion-Related Fatalities Reported by Year for Children 12 Months of Age or Younger: 2010-2022



Source: CPSRMS and NEISS databases.
Asterisks (*) indicate that reporting is ongoing for CPSRMS; the years 2021–2022 are considered incomplete.

Table 2 summarizes the number of reported fatalities related to infant support cushions for victims 12 months and younger by age in months and by gender. As reflected in Table 2, 80 percent of the fatalities with a known age were infants in the zero to three month age range. Among the 76 fatalities for which the sex is known, half were male and half were female.

Table 2: Infant Support Cushion-Related Fatalities for Victims Ages 12 Months and Younger and Sex: 2010 -2022

Age (In Months)	Total (% of Total)	Male (% of Total)	Female (% of Total)	Unknown (% of Total)
Total	79 (100%)	38 (48%)	38 (48%)	3 (4%)
1	26 (33%)	12 (15%)	14 (18%)	0
2	19 (24%)	10 (13%)	9 (11%)	0
3	18 (23%)	8 (10%)	10 (13%)	0
4	7 (9%)	4 (5%)	3 (4%)	0
5	3 (4%)	1 (1%)	0	2 (3%)
6	1 (1%)	0	1 (1%)	0

7	2 (3%)	1 (1%)	1 (1%)	0
8	0	0	0	0
9	0	0	0	0
10	1 (1%)	1 (1%)	0	0
11	1 (1%)	1 (1%)	0	0
12	0	0	0	0
Unknown	1 (1%)	0	0	1 (1%)

Source: CPSRMS and NEISS databases. Percentages may not add to 100 due to rounding; the years 2021–2022 are considered incomplete.

The official cause of death reported by the medical examiner in the majority of the 79 reported fatalities 49 (62 percent) was asphyxia or probable asphyxia; 13 (17 percent) were determined to be due to sudden unexpected infant death (SUID) events; 12 (15 percent) had an undetermined cause of death; and for five (six percent), no medical examiner's report was available. Nearly all reported fatalities (75 of 79) involved placement of the infant support cushion on another sleep-related consumer product. For the remaining four fatalities, the placement of the infant support cushion was either undetermined or unknown.

In the 125 nonfatal incidents associated with infant support cushions that involved children ages 12 months and younger and occurred between January 1, 2010 and December 31, 2022, three infants were admitted to the hospital and 22 infants were reported to have been treated and released from an emergency department. In 52 of these nonfatal incidents, the severity of the injury was unspecified or unknown, and in 46 of the incidents no injury was reported. Table 3 summarizes the disposition of the nonfatal incident reports associated with infant support cushions and victims ages 12 months and younger.

Table 3: Infant Support Cushion-Related Nonfatal Reports by Severity for Victims Ages 12 Months and Younger: 2010-2022

Severity	Total Reports (% of Total)
Total Non-Fatal Reports	**125 (100%)**
Hospital Admissions	3 (2%)
Emergency Department Treated	22 (18%)

Left without being seen	1 (1%)
Seen by a Medical Professional	1 (1%)
Unspecified/Unknown	52 (42%)
No Injury Reported	46 (37%)

Source: CPSRMS and NEISS databases. Percentages may not add to 100 due to rounding; the years 2021–2022 are considered incomplete.

For the 46 reports for which no injury was reported, many of the descriptions in the incident reports indicated the potential for serious injury or death. Staff's analysis of the narratives associated with these incident reports indicated that in 29 reports (23 percent) of the incidents, an infant support cushion occupied by an infant had been place on an elevated surface (such as an adult bed or couch) and the infant had fallen off; 27 (22 percent) specified threatened asphyxia; and 17 incidents (14 percent) involved various types of rashes caused by the product. Table 4 summarizes the hazard patterns for infant support cushion-related nonfatal incidents.

Table 4: Infant Support Cushion-Related Non-Fatal Reports by Hazard Pattern for Victims Ages 12 months and Younger: 2010-2022

Event	Number of Non-Fatal Reports (% of Total)
	Children (0 to 12 Months)
Fall	29 (23%)
Threatened Asphyxia	27 (22%)
Rash	17 (14%)
Limb Entrapment	1 (1%)
Mold	1 (1%)
Choking	1 (1%)
Near Strangulation	1 (1%)
Vomiting	1 (1%)
Consumer Complaints	47 (38%)
Total Non-Fatal Reports	**125 (100%)**

Source: CPSRMS and NEISS databases. Percentages may not add to 100 due to rounding; the years 2021–2022 are considered incomplete.

Staff, based on review of nonfatal incident and report data, identified falls and threatened asphyxia as the two major nonfatal hazard patterns associated with infant support cushions. In the case of falls, the reports revealed that in most incidents infant support cushions had been

placed on elevated surfaces including adult beds and couches. The injuries associated with falls include concussions, facial injuries, and scalp injuries.

In the case of threatened asphyxia, the narratives described scenarios of infants being rescued after being found hanging partially or completely off of the infant support cushion with their mouths and noses obstructed, with their heads wedged between sleep positioner side cushions, or having rolled to a face-down position that put them at risk of an obstructed airway.

IV. International Standards for Infant Support Cushions

The Commission is aware of two international standards, both British, that contain performance requirements that address suffocation and asphyxiation hazards associated with infant pillows. BS 1877-8:1974, *Specification for Domestic bedding —Part 8: Pillows and bolsters for domestic use (excluding cellular rubber pillows and bolsters)* (BS 1877-8:1974) and BS 4578:1970, *Specification for Methods of test for hardness of, and for air flow through, infants' pillows* (BS 4578:1970). The scope of BS 1877-8:1974 includes both adult and cot pillows (infant pillows), and recommends that cot pillows be filled firmly enough to prevent infants' heads from sinking into the products and that the pillow covering not be loose enough to be drawn into an infant's mouth. BS 1877-8:1974 has requirements for cot pillow size, filling, and covering. Cot pillows must be 58 x 38 cm (23 x 15 inches) and their covering must be of open construction to allow air permeability. Both the filling and covering must meet performance requirements described in BS 4578:1970 for "hardness" (*i.e.*, firmness) and air permeability.

The hardness test in BS 4578:1970 requires that a 100 mm diameter probe be placed in the center of the product with 10 newtons (N) of force for one minute. BS 1877-8:1974 requires that displacement of the pillow when the force is applied shall not exceed 25 percent of the

thickness. Staff assesses that the proportional approach used in this standard allows thicker pillows to have a greater displacement than thinner pillows, which does not sufficiently protect against the suffocation and asphyxia hazards associated with infant support cushions because that greater displacement could allow the product to obstruct the infant's airways.

V. Boise State University Contractor Report

CPSC awarded a contract to Boise State University (BSU) for infant biomechanics and suffocation research and consultancy services. This research included an analysis of the risk of injury or death to infants associated with the use of nursing pillows and infant support cushions during activities such as feeding, nursing, sleeping, propping, and lounging. *See* Staff's NPR Briefing Package, Tab C.

BSU delivered its final report on June 30, 2022 (the BSU Final Report).[6] The BSU Final Report provides recommendations and conclusions related to the performance and design of infant support cushions, including the following.

Firmness Testing. The BSU Final Report recommends that all infant support cushions be required to undergo firmness testing because products that lack firmness are more likely to conform around an infant's nose and mouth and present a suffocation hazard. The report recommended testing all infant pillows for firmness using a three-inch diameter, anthropometry-based hemispheric probe that is geometrically similar to, and sized to represent the breadth of, an infant's face. The report recommends that the probe should be applied to the product at three locations: the location of maximum thickness, the location of minimum thickness, and a subjective location of interest (*i.e.*, another soft location most likely to result in failure). The

[6] Mannen, E. M., Davis, W., Goldrod, S., Lujan, T., Siddicky, S. F., Whitaker, B., & Carroll, J. (2022). *Pillows Product Characterization and Testing*. Prepared for the U.S. Consumer Product Safety Commission under contract no. 61320620D0002, task order no. 61320621F1015. Available at: https://www.cpsc.gov/content/Pillows-Product-Characterization-and-Testing.

force required to displace the probe one inch into the product at each location must exceed 10 N. Meeting this requirement would mean that the product has firmness comparable to crib mattresses.

Airflow Testing. The BSU Final Report recommends that products that do not pass firmness testing be required to pass an airflow test. Passing the airflow test would mean that the product has airflow characteristics comparable to current mesh crib liners, which the BSU researchers concluded would mitigate the suffocation hazard. However, the report recommends against requiring that airflow testing for products that pass the BSU Final Report's proposed firmness testing, because a firm product is unlikely to form a seal around an infant's nose and mouth.

Sagittal-Plane Testing. BSU developed prototype sagittal-plane testing devices to allow for more comprehensive assessments of infant positioning in and on infant support cushions.[7] The BSU Final Report recommends further research to determine appropriate worst-case positions for testing and to set threshold values for acceptable body positions that would not negatively impact infant breathing.

Tab C of Staff's NPR Briefing Package contains staff's summary of how the Commission's proposed rule reflects the conclusions and recommendations of the BSU Final Report.

VI. ASTM's Working Draft Standard

There are no published U.S. voluntary standards for infant support cushions. ASTM is working toward a voluntary standard for infant loungers under Subcommittee F15.21 on Infant

[7] The sagittal plane is an anatomical plane that runs vertically through the human body, dividing it into left and right sections. It can be thought of as viewing the human body in profile.

Carriers, Bouncers, and Baby Swings.[8] In the draft voluntary standard, an "infant lounger" is a product "with a raised perimeter, a recess, or other area that is intended to be placed on the floor and to provide a place for an infant to sit, lie, recline, or rest, while supervised by an adult." That draft definition would govern only a subset of the products covered by this proposed rule, which includes infant positioners, nursing products with dual use for lounging, infant cushions, and other infant pillow-like products, as well as the infant loungers being considered by ASTM. Staff has been working with ASTM to develop performance requirements intended to address the primary hazards associated with infant loungers, but to date ASTM has not issued a ballot on a standard for infant loungers.

ASTM's draft voluntary standard includes general requirements typically found in other ASTM juvenile product standards, such as requirements addressing lead content, small parts, hazardous sharp edges or points, and toy accessories that are attached to, removable from, or sold with the products. The ASTM draft also specifies that if the lounger can be converted to another product it shall comply with the applicable requirements of that product's standard. The general requirements of the draft infant lounger standard also state that the sidewall height of the product shall be less than four inches when measured according to the sidewall height measurement test method specified in the draft standard. The draft voluntary standard further includes the following performance requirements:

- *Stability:* The product shall not tip over and shall retain the CAMI dummy[9] when tested in all manufacturers' use positions.
- *Infant Restraints*: The product shall not have a restraint system.
- *Fabric/Mesh Integrity*: This requirement is intended to address product integrity issues such as seam failures and material breakage.

[8] *See* Staff's NPR Briefing Package, Tab B. This ASTM standard is still in draft form and has not completed the full consensus process to be an approved standard and the draft language is subject to change.
[9] CAMI (Civil Aeromedical Institute) dummies, which are designated ASTM test devices, are based on child anthropometric data and come in multiple sizes. ASTM's working draft references the six-month-old size.

- *Bounded Openings:* This requirement is intended to address potential entrapment hazards associated with openings in the product.
- *Occupant Support Surface*: This requirement is intended to address the thickness of, dimensions of, and potential gaps in the occupant support surface.
- *Occupant Support Surface Firmness*: This requirement uses an eight-inch diameter, disc-shaped "firmometer" probe and requires that there shall be no point where the feeler arm of the device, which hangs over the edge of a disc, comes in contact with the occupant support surface.
- *Sidewall Firmness*: The top of the sides of the product cannot be displaced more than one inch when a three-inch diameter hemispheric probe is applied to the product with 10 N of force.
- *Side Angle and Deflection:* To address potential entrapment hazards at the intersection of the side wall and occupant support surface, the angle between the sidewall and the occupant support surface of the infant support cushion shall be greater than 90 degrees.

The draft voluntary standard also includes marking, labeling, and instructional literature requirements, such as warning the consumer on the product about not using the product for sleep or naps, only using the product when the occupant baby is supervised, only using the product on the floor, keeping soft bedding out of the product, not using the product on raised surfaces, and not using the product to carry or move an infant. The draft standard requires the warnings to be "permanent" and "conspicuous."

The product's instructions must, among other requirements, indicate the manufacturer's recommended maximum weight, height, age, developmental level, or combination of these attributes for any infant using the product, as well as any limitation on use of the product by a child for any specific unintended use.

VII. Description of the Proposed Mandatory Standard for Infant Support Cushions[10]

To address established risks of death and injury associated with infant suffocations, asphyxiations, entrapments, and falls, and as section 104 of the CPSIA requires, the Commission

[10] *See* Staff's NPR Briefing Package, Tab C

is issuing this proposed rule to establish mandatory performance and labeling requirements for infant support cushions.

The text of the proposed rule is based on an evaluation of incident data associated with infant support cushions, the ASTM working draft standard for infant loungers that is under development, and the recommendations of the BSU Final Report. The proposed rule is summarized below and explained in more detail in Tabs C and F of Staff's NPR Briefing Package.

A. Scope and Definitions

Section 1243.1 of the proposed rule explains that the rule would apply to infant support cushions, including infant positioners, nursing products with a dual use for lounging, infant loungers, infant props, or cushions used to support an infant for activities such as "tummy time," and other infant pillow-like products. It would exclude, however, products already regulated by other Commission mandatory standards for durable infant products, which are listed in 16 CFR 1130.2(a). The proposed rule would apply to all infant support cushions manufactured after the effective date of the rule.

Section 1243.2 of the proposed rule defines "infant support cushion" as:

> an infant product that is filled with or comprised of resilient material such as foam, fibrous batting, or granular material or with a gel, liquid, or gas, and which is marketed, designed, or intended to support an infant's weight or any portion of an infant while reclining or in a supine, prone, or recumbent position.

The scope of "infant support cushions" is intended to encompass the products described in Part II above.

As noted previously, this proposed definition of "infant support cushions" includes, but is not limited to, the infant loungers that would be subject to ASTM's draft voluntary standard. The proposed rule would define "infant lounger" as "a product with a raised perimeter or recess

that provides a place for an infant to sit, lie, recline or rest." Because, however, incident data show that the suffocation, asphyxiation, and fall hazards this rule seeks to address are posed by other infant pillow-like products, in addition to those with a raised perimeter or recess, the proposed broader definition more effectively addresses the hazards posed by these products. For example, the proposed rule would apply to "infant positioners," defined as a product intended to help keep an infant in a particular position while supine or prone.

As discussed above, ASTM is working concurrently on developing voluntary standards for both "infant feeding supports" and "infant loungers." The draft ASTM standards address hazards posed by "dual use" products intended to be used both to feed an infant and to support a lounging infant by requiring such products to comply with both standards. Adopting ASTM's approach, the proposed rule would apply to nursing pillows with a dual use for lounging, while excluding those nursing pillows that are solely intended to be used for nursing or feeding, along with other products already regulated by other Commission mandatory standards for durable infant products.

The Commission invites public comment on the scope of the proposed rule, including whether it addresses all products that pose the identified hazards and whether it is sufficiently clear and administrable. For example, the Commission invites public comment on whether it is appropriate to subject "dual use" products to both the proposed nursing pillow rule and the proposed infant support cushion rule (assuming that both are finalized), and what nursing products should be considered "dual use."

B. General Requirements

The proposed rule includes many of the general requirements included in the ASTM draft standard for infant loungers to address sharp edges or points, small parts, and lead in paints. It

also requires that toy accessories that are attached to, removable from, or sold with the products comply with 16 CFR part 1250, which establishes a mandatory safety standard for toys, as well as requirements for the permanency of labels and warnings. However, while ASTM's draft standard for infant loungers would allow a maximum sidewall height of four inches, the Commission is concerned that this height may give consumers the mistaken impression that an infant can safely be left unattended in or on the product. For that reason, the proposed rule addresses the positional asphyxia hazard with a maximum incline requirement that effectively sets a lower limit on sidewall height, rather than the maximum side height requirement currently favored by ASTM. The Commission invites public comment on side height limit and incline angle requirements.

C. Proposed Performance Requirements

1. Firmness

The Commission's proposed firmness requirements and associated test methods are consistent with those applicable to crib mattresses and more stringent than those currently included in ASTM's draft standard for infant loungers. As explained in Tab C of Staff's NPR Briefing Package, based upon the findings and recommendations in the BSU Final Report as well as staff's analysis of the incidents and hazard patterns associated with facial occlusion into infant support cushions, the proposed rule requires firmness testing at three locations: the

occupant support surface, the sidewall, and the intersection of the occupant support surface with the sidewall, as follows:

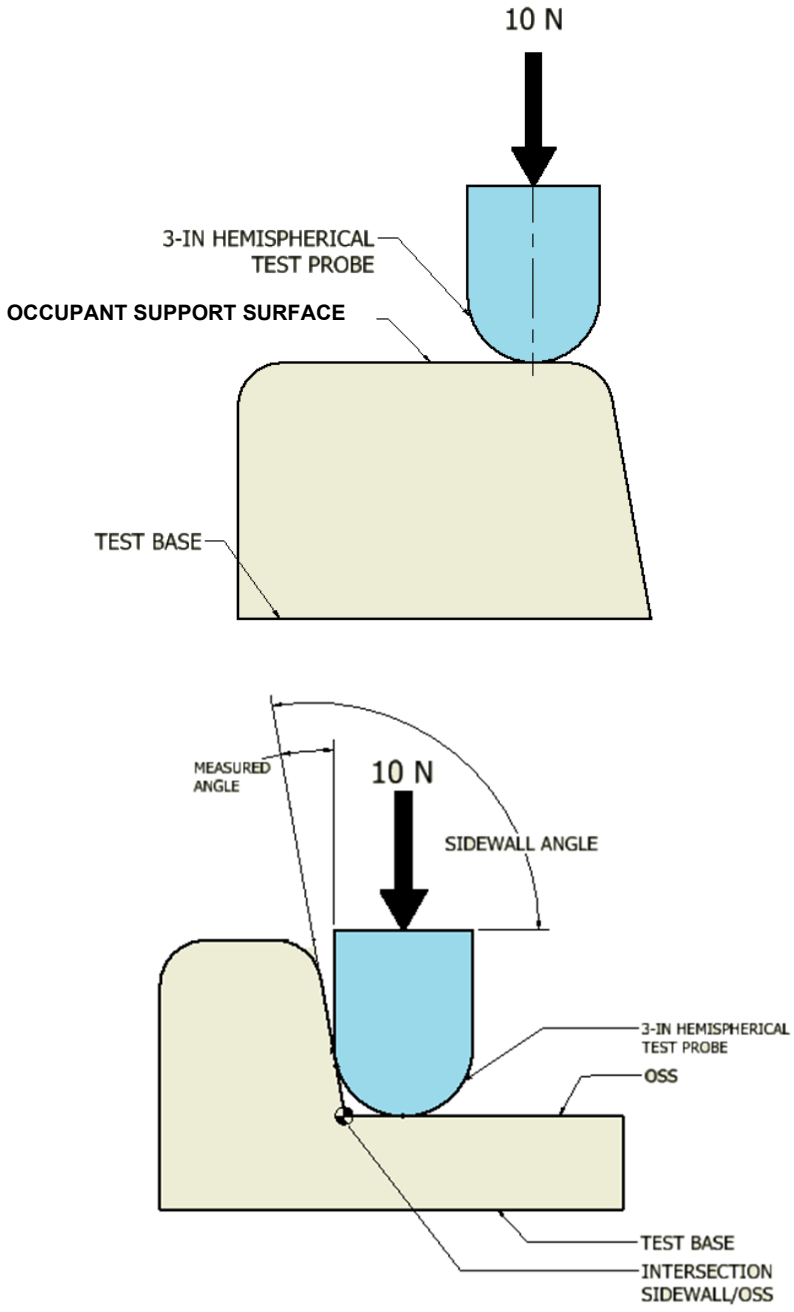
a. Occupant Support Surface (OSS) Firmness

The proposed rule includes a firmness test for the occupant support surface[11] that is based on the BSU Final Report, with modifications to improve the test methodology. The firmness test is intended to reduce the likelihood that the OSS can conform to an infant's face and cause suffocation. The proposed rule requires that OSS firmness be tested using the three-inch diameter hemispheric probe developed by BSU, rather than the eight-inch firmometer probe in the ASTM draft standard. The three-inch probe is more consistent, in both size and shape, with the size and dimensions of an infant's head, enabling it to more accurately detect any material deformations and surface features that an infant's face may come in contact with on an infant support cushion. In addition, staff's testing showed that an eight-inch disc probe may not be as accurate as a three-inch hemispheric probe when used on certain models of infant support cushions with smaller dimensions or an OSS surface that is not completely flat, so that the eight-inch firmometer cannot fit well enough in the product to provide accurate measurement.

To meet the proposed rule's firmness requirement, the force required to displace the probe one inch into the OSS test location (as well as the two other test locations) must exceed 10 N (about 2.25 pounds), which indicates product firmness that is at least comparable to a crib mattress. Figure 1, below, illustrates the firmness test being applied to the OSS of an infant support cushion.

[11] The proposed rule uses ASTM's draft definition of an infant support cushion's "occupant support surface" or OSS as "the area that holds up and bears the infant or any portion of the infant."

Figure 1: Firmness Test Applied to OSS or Sidewall



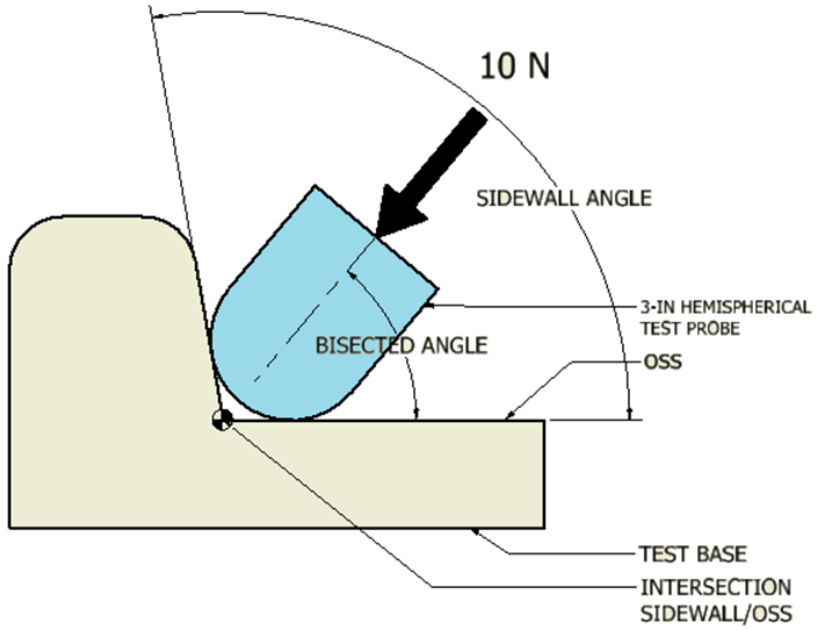
Because an infant's head or face may rest on the sidewall of a product, as well as on the product's OSS, the proposed rule includes firmness requirements for any product sidewall. While the ASTM working draft also requires firmness testing of sidewalls, the proposed rule

requires testing a minimum of four sidewall locations, including the location of maximum sidewall height, and requires that the test locations include at least one location most likely to fail, rather than requiring that sidewalls be tested in six-inch increments around the product as stated in ASTM's draft. The differences from ASTM in testing protocol are intended to provide more accurate testing for both smaller head pillows and larger lounger products.

b. Intersection of OSS with Sidewall

To address the hazard of suffocation when an infant's face is surrounded on two sides by the OSS and a sidewall, the proposed rule includes firmness requirements based on testing the angle at which the two surfaces intersect, to ensure sufficient firmness to prevent the product from conforming to the infant's mouth or face and obstructing airways. It requires testing of firmness with the three-inch hemispherical probe positioned to bisect the angle formed where the two surfaces intersect, as shown in Figure 2.

Figure 2: Test Configuration for Intersection of Sidewall and Occupant Support Surface Firmness



The proposed rule's firmness requirements for the OSS/Sidewall intersection are similar to those in

ASTM's draft standard.

2. Sidewall Angle

The proposed rule, like ASTM's draft, requires that the angle formed between the product's OSS and any sidewall be greater than 90 degrees to reduce potential entrapment hazards between the sidewall and the occupant support surfaces. The proposed rule requires a slightly different methodology for measuring this angle than does ASTM's draft. While ASTM's draft requires that this angle be measured with a protractor or similar tool at four-inch intervals along the product's interior, the proposed rule specifies assessing this angle with the cylindrical side of the three-inch probe, with a 10 N force applied to the probe. The probe, which is designed to simulate the size and shape of an infant's head, is used to determine whether there is any contact between the sidewall and the probe's side when the "face" of the probe is pressed against the OSS/sidewall intersection. If there is such contact, indicating an entrapment risk, that indicates that the angle is less than 90 degrees and the product would fail. Conversely, if there is no contact between the sidewall and the side of the probe, the angle is greater than 90 degrees and the product meets this requirement.

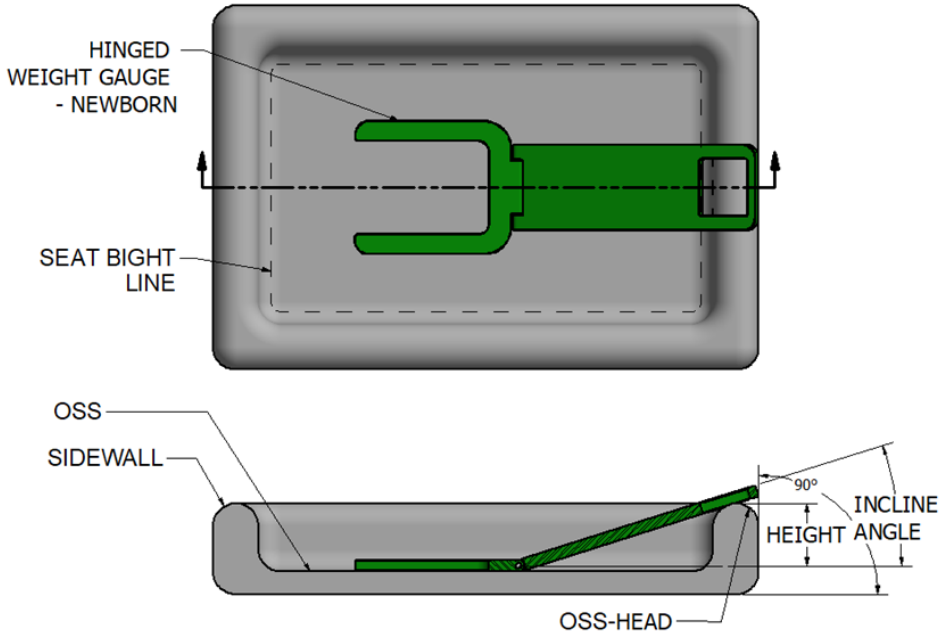
3. Maximum Incline Angle

The proposed rule, like ASTM's draft, requires that any incline of the OSS of an infant support cushion not exceed 10 degrees. This requirement is consistent with incline test of CPSC's *Safety Standard for Infant Sleep Products*, 16 CFR part 1236, and the ban of inclined sleepers for infants in the Safe Sleep for Babies Act, 15 U.S.C. 2057d, and similarly it addresses the hazards associated with inclined sleep products.

The proposed rule, however, differs from ASTM's maximum incline angle requirements and test procedures in order to improve test consistency across all infant support cushion

products and to address additional locations of potential inclined lounging, reclining, and sleep. The three ways in which the proposed rule modifies ASTM's proposed testing protocol are: (1) setting a maximum incline angle that applies not only to all of a manufacturer's recommended use positions, but also to all other infant cushion surfaces that can feasibly support an infant's head, including, for example, the angle from any sidewall to the OSS or from the sidewall to the floor; (2) use of a newborn hinged weight gauge, rather than an infant gauge; and (3) positioning the gauge differently throughout testing. Figure 3 below, shows the use of a hinged weight gauge to measure the incline on an infant support cushion with a sidewall. The proposed rule requires use of a newborn hinged weight gauge, rather than the heavier infant gauge specified in the ASTM draft, because infant support cushions are commonly used for newborns, who are at higher risk of suffocation.

Figure 3: Test Fixture Configuration to Measure Incline Angle on an Infant Lounger



4. Sidewall Height

The proposed rule limits the height of any sidewall of an infant support cushion, as does ASTM's draft. However, the proposed rule addresses the hazards associated with relatively high sidewalls in a manner that is more closely tailored to the hazards, and applies to all of the products that fall within the scope of the proposed rule. These hazards are that caregivers may judge that an infant support cushion with relatively high sidewalls can safely contain an infant without supervision and is suitable for use on top of an adult bed or in a crib notwithstanding any contrary warnings, and that high sidewalls can cause hazardous positioning of the infant's neck when an infant's head is placed on top of the sidewall while their body is on a lower surface either inside or outside of the product. *See* Staff's NPR Briefing Package, Tabs B and C. While ASTM's draft sets a four-inch limit on sidewall height, the proposed rule addresses these hazards by limiting the maximum incline angle and provides testing protocols based on the type of product (for example, lounger-type products or head cushions). Using the test methodology prescribed in the proposed rule, sidewall heights, for products that have sidewalls, would be limited to approximately 1.9 inches.

The Commission invites public comments on the proposed rule's method for addressing hazards posed by sidewall heights via measurement of maximum incline angle and what methodology would most effectively address the identified fall and positional asphyxia hazards.

D. Warning and Instructional Requirements

Compared to the performance requirements described above, warnings are less effective in eliminating or adequately reducing exposure to hazards associated with infant support cushions. Nevertheless, prominent and well-designed warnings can provide consumers with important information about the hazards associated with these products and appropriate

behaviors to avoid the hazards. Thus, the proposed rule includes requirements for on-product warnings that address the primary hazards associated with infant support cushions.

The proposed rule includes warning content and format requirements similar to those in the ASTM draft standard. Figure 4 shows the warning statements and format that would be required on infant support cushions:

Figure 4: Example of Infant Support Cushion Warning

The proposed rule, like ASTM's draft, requires on-product warning labels to be "conspicuous," defined as "visible, when the product is in each manufacturer's recommended use position, to a person while placing an infant into or onto the product." Also, like ASTM's draft, the proposed rule requires such warning labels to be "permanent," with permanence requirements based on ASTM's draft but better addressing the potential for consumers to attempt to remove on-product warning labels. The draft ASTM warning label for infant loungers indicates that the product should only be used on the floor, "with baby face-up on back." This proposed rule would adopt ASTM's draft language. However, this proposed rule for infant support cushions includes products that can be used for "tummy time," for which infants are on their stomach. The Commission invites public comments in answer to the following questions:

Should manufacturers have flexibility to remove or change the "with baby face-up on back" language in the warning label? If so, in what circumstances?

The proposed rule incorporates by reference the following provisions of the American National Standards Institute (ANSI) warning format requirements published in sections 6.1–6.4 of ANSI Z535.4, *Product Safety Signs and Labels*, which include requirements related to safety alert symbol use, signal word selection, and warning panel format, arrangement, and shape; sections 7.2–7.6.3 of ANSI Z535.4, which include color requirements for each panel; and section 8.1 of ANSI Z535.4, which addresses letter style. *See* Staff's NPR Briefing Package, Tab D, 80-81.

In addition to on-product warnings, the ASTM draft standard includes basic warning requirements for instructional literature that are the same as those in ASTM's draft.

VIII. Proposed Amendment to 16 CFR Part 1112 to Include NOR for Infant Support Cushions

Products subject to a consumer product safety rule under the CPSA, or to a similar rule, ban, standard, or regulation under any other act enforced by the Commission, must be certified as complying with all applicable CPSC-enforced requirements. 15 U.S.C. 2063(a). Certification of children's products subject to a children's product safety rule must be based on testing conducted by a CPSC-accepted third-party conformity assessment body. 15 U.S.C. 2063(a)(2). The Commission must publish an NOR for the accreditation of testing laboratories as third party conformity assessment bodies to assess conformity with a children's product safety rule. 15 U.S.C. 2063(a)(3). The proposed standard for infant support cushions would be a children's product safety rule that requires the issuance of an NOR.

The Commission's rules, at 16 CFR part 1112, establish requirements for accreditation of third party conformity assessment bodies to test for conformance with a children's product safety rule in accordance with section 14(a)(2) of the CPSA. Part 1112 also lists the NORs that the CPSC has published. The Commission proposes to amend part 1112 to include the *Safety Standard for Infant Support Cushions* in the list of children's product safety rules for which the CPSC has issued NORs.

Laboratories applying for acceptance as a CPSC-accepted third party conformity assessment body to test to the new standard are required to meet the third party conformity assessment body accreditation requirements in part 1112. When a laboratory meets the requirements as a CPSC-accepted third party conformity assessment body, the laboratory can apply to the CPSC to have the *Safety Standard for Infant Support Cushions* included in its scope of accreditation as reflected on the CPSC Web site at: www.cpsc.gov/labsearch.

IX. Product Registration Rule Amendment

In addition to requiring the Commission to issue safety standards for durable infant or toddler products, section 104 of the CPSIA directed the Commission to issue a rule requiring that manufacturers of durable infant or toddler products establish a program for consumer registration of those products. 15 U.S.C. 2056a(d). Section 104(f) of the CPSIA defines the term "durable infant or toddler product" as "a durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years," and lists 12 distinct product categories. 15 U.S.C. 2056a(f). The product categories listed in section 104(f)(2) of the CPSIA represent a non-exhaustive list of durable infant or toddler product categories. Infant support cushions are not included in the statutory list of durable infant or toddler products.

In 2009, the Commission issued a rule implementing the consumer registration requirement. 74 FR 68668 (Dec. 29, 2009) (establishing 16 CFR part 1130). As section 104(d) of the CPSIA directs, the consumer registration rule requires each manufacturer of a durable infant or toddler product to provide a postage-paid consumer registration form with each product; keep records of consumers who register their products with the manufacturer; and permanently place the manufacturer's name and certain other identifying information on the product.

When issuing the consumer registration rule, the Commission identified six additional products as durable infant or toddler products: children's folding chairs; changing tables; infant bouncers; infant bathtubs; bed rails; and infant slings. 74 FR at 68669. The Commission explained that the specified statutory categories are not exclusive, and that the Commission is charged with identifying the product categories that are covered. "Because the statute has a broad definition of a durable infant or toddler product but also includes 12 specific product categories," the Commission noted, "additional items can and should be included in the definition, but should also be specifically listed in the rule." *Id.* at 68670.

The Commission proposes in this NPR to amend part 1130 to include "Infant Support Cushions" as durable infant or toddler products. Infant support cushions are a category of "durable infant or toddler product" for purposes of CPSIA section 104 because they: (1) are intended for use, and may be reasonably expected to be used, by children under the age of five years; (2) are products similar to other products listed in section 104(f)(2), such as crib mattresses and sling carriers; and (3) are commonly resold or "handed down" for use by other children over a period of years.

X. Incorporation by Reference

Section 1243.6(d)(4) of the proposed rule incorporates by reference ANSI Z535.4–2011, *American National Standard for Product Safety Signs and Labels*, sections 6.1–6.4, 7.2–7.6.3, and 8.1, with modifications to further reduce the risk of injury associated with infant support cushions. In accordance with regulations of the Office of the Federal Register (OFR), 1 CFR part 51, Part VII.D of this preamble summarizes the provisions of ANSI Z535.4–2011 that the Commission proposes to incorporate by reference. The ANSI standard is reasonably available to interested parties in several ways. By permission of ANSI, the standard can be viewed as a read-only document during the comment period on this NPR, at: https://www.surveymonkey.com/r/DQVJYMK. To download or print the standard, interested persons may purchase a copy of ANSI Z535.4–2011 from ANSI via its website, https://www.ansi.org, or by mail from ANSI, 25 West 43rd Street, 4th Floor, New York, NY 10036, telephone: (212)-642-4900. Alternatively, interested parties may inspect a copy of the standard at CPSC's Office of the Secretary by contacting Alberta E. Mills, Commission Secretary, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone: (301) 504-7479; email: cpsc-os@cpsc.gov.

XI. 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). The Commission proposes an effective date of 180 days after publication of the final rule in the *Federal Register*, such that the requirements of the rule would apply to all infant support cushions manufactured after that date. This amount of time is typical for rules issued under section 104 of the CPSIA. It is also the period that the Juvenile Products Manufacturers Association (JPMA) typically allows

for products in their certification program to shift to a new standard once that new standard is published. Therefore, juvenile product manufacturers are accustomed to adjusting to new standards within this time. A 180-day effective date should also be sufficient for manufacturers to comply with this rule because the proposed requirements do not demand significant preparation by testing laboratories. For example, no new complex testing instruments or devices would be required to test infant support cushions for compliance with the proposed rule. The Commission invites comments, particularly from small businesses, that provide specific data addressing whether the proposed 180-day effective date period is appropriate.

XII. Regulatory Flexibility Act

The Regulatory Flexibility Act ((RFA); 5 U.S.C. 601-612) requires that agencies review a proposed rule's potential economic impact on U.S. small entities, including small businesses. Section 603 of the RFA generally requires that agencies make an initial regulatory flexibility analysis (IRFA) available to the public for comment when the NPR is published. The IRFA must describe the impact of the proposed rule on small entities and identify significant alternatives that accomplish the statutory objectives and minimize any significant economic impact of the proposed rule on small entities. Staff prepared an IRFA for this rulemaking that appears at Tab E of the Staff's NPR Briefing Package. We summarize the IRFA below.

A. Reasons and Legal Basis for the NPR

Part I of this preamble describes the reasons and legal basis for this NPR. As discussed in Parts VII-IX of this preamble, and detailed in Tab B of Staff's NPR Briefing Package, the proposed rule sets out mandatory requirements for infant support cushions to address the suffocation, entrapment, and fall hazards associated with these products; adds infant support

cushions to the list of products for which a registration card is required; and adds infant support cushions to the list of durable infant products for which an NOR is required.

B. Small Entities to Which the Proposed Rule Would Apply

As explained in Tab E to Staff's NPR Briefing Package, Commission staff has identified more than 2,000 suppliers of infant support cushions to the U.S. market, including manufacturers, importers, and foreign direct shippers. The majority of these suppliers are small businesses.

C. Impact of the Proposed Rule on Small Manufacturers and Importers

Most in-scope products on the market will require redesign to meet the requirements in the proposed rule, and redesign costs would be potentially significant for a substantial number of small firms, particularly small-volume home crafters, for the first year that a rule is effective. Staff considers a "significant" impact to be at least one percent of annual revenue, which is consistent with the regulatory flexibility analyses of other federal agencies. With an estimated 2,000 models to be redesigned, the total cost of redesign to the industry in the first year could be up to $27 million. However, as discussed in Tab E of Staff's Briefing Package, suppliers may be able to cover these costs by implementing modest retail price increases which would reduce the rule's impact on individual small entities. For example, a firm supplying 5,000 infant support cushions per year could cover the entire cost of redesign by raising the retail price by $2.70.

If issued, a final rule would require all manufacturers and importers of infant support cushions to meet additional third party testing requirements under section 14 of the CPSA. As specified in 16 CFR part 1109, entities that are not manufacturers of children's products, such as importers and wholesalers, may rely on the certificates of compliance provided by others.

However, manufacturers could pass on at least some of the cost of testing for compliance to U.S. importers and wholesalers.

Third party testing costs for infant support cushions are estimated to be $500 to $1,000 per model. The annual cost of samples for testing is estimated at around $100, bringing the overall annual testing cost to an estimated $600 to $1,100 per model. The costs of testing per model would be similar for suppliers of all sizes, although larger firms may be more likely to qualify for volume discounts. As with redesign costs, these testing costs could largely be covered by modest retail price increases.

The hand crafters of infant support cushions with the smallest sales volumes may not have sufficient sales volume to cover these costs and may exit the market. However, consumers would likely not experience a significant loss of utility as there are many different products available from different suppliers.

D. Other Federal Rules That May Duplicate, Overlap, or Conflict with the Proposed Rule

The Commission has not identified any federal rules that duplicate, overlap with, or conflict with the proposed rule.

E. Alternatives Considered to Reduce the Impact on Small Entities

The Commission considered the following alternatives to the proposed rule to reduce the impact on small businesses. The Commission requests comments on these alternatives and other alternatives that could reduce the potential burden on U.S. small entities.

1. Not Establishing a Safety Standard

The Commission considered not establishing a safety standard for infant support cushions. While this alternative would result in no regulatory impact on small entities, deaths

and injuries from the use of infant support cushions would likely continue to occur at similar rates as those observed during the period from 2010 through 2022. In 2020 alone, there were 17 fatalities involving infant support cushions. Another 17 fatalities have been recorded in the potentially incomplete data for 2021. *See* Staff NPR Briefing Package, Tab A.

2. Delay To Await Publication of a Voluntary Standard

The Commission considered delaying the draft proposed rule to allow possible publication of a voluntary standard. Although this alternative would delay any impact on small businesses, it would also allow the hazard to continue indefinitely, as there is no clear date at which ASTM or any other voluntary standards organization will adopt a relevant standard, nor any assurance that a voluntary standard, if published, would be complied with by industry or adequately address the identified hazards.

3. Earlier or Later Effective Date

The Commission is proposing an effective date 180 days after publication of the final rule in the *Federal Register*. An earlier effective date would achieve the safety benefits of the rule more quickly, but it would also increase the burden on small businesses to quickly redesign and test their products. In addition, a significantly earlier effective date could result in temporary shortages of infant support cushions due to a potential lack of availability of testing laboratory resources.

The Commission is not proposing a later effective date, which would somewhat reduce burdens on small suppliers, because 180 days has generally been sufficient time for suppliers to come into compliance with durable infant or toddler product rules. Additionally, six months from the change in a voluntary standard is the period that JPMA uses for its certification program, so compliant manufacturers are used to this time frame to comply with a modified

standard. Testing laboratories should have no difficulty preparing to test to the proposed new mandatory standards within a 180-day period.

F. Impact on Testing Labs

The proposed rule should not have a significant adverse impact on testing laboratories. Laboratories will not need to acquire complex or costly testing instruments or devices to test infant support cushions for compliance, and laboratories will decide for themselves, based on expected demand for their testing services, whether to offer testing services for infant support cushion compliance.

XIII. Environmental Considerations

Certain categories of CPSC actions normally have "little or no potential for affecting the human environment" and therefore do not require an environmental assessment or an environmental impact statement. Safety standards providing requirements for consumer products come under this categorical exclusion. 16 CFR 1021.5(c)(1). The proposed rule for infant support cushions falls within the categorical exclusion.

XIV. Paperwork Reduction Act

This proposed rule contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA; 44 U.S.C. 3501–3521). In this document, pursuant to 44 U.S.C. 3507(a)(1)(D), we set forth:

- a title for the collection of information;
- a summary of the collection of information;
- a brief description of the need for the information and the proposed use of the information;
- a description of the likely respondents and proposed frequency of response to the collection of information;
- an estimate of the burden that shall result from the collection of information; and
- notice that comments may be submitted to the OMB.

Title: Safety Standard for Infant Support Cushions.

Description: The proposed rule would require each infant support cushion within the scope of the rule to meet the rule's performance and labeling requirements. It would require suppliers to conduct third party testing to demonstrate compliance and provide the specified warning label and instructions. These requirements fall within the definition of a "collection of information," as defined in 44 U.S.C. 3502(3).

Description of Respondents: Persons who manufacture or import infant support cushions.

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

Table 7: Estimated Annual Reporting Burden

Burden Type	Number of Respondents	Frequency of Response	Total Annual Responses	Hours per Response	Total Burden Hours
Labeling and instructions	2,000	1	2,000	2	4,000

While some infant support cushion products currently have labels, all of these products would have to meet the specific labeling requirements and instructions specified in the proposed rule, which provides the text and graphics for the required labels and instructions. Specialized expertise in graphics design would not be required to develop the warnings and instructions. Most reporting and recordkeeping requirements in this proposed rule would be new for all suppliers.

CPSC estimates there are 2,000 entities that would respond to this collection annually, the majority of which would be small entities. We estimate that the time required to create and/or modify labeling and instructions is about two hours per response. Therefore, the estimated burden associated with this collection is 2,000 responses × one response per year × two hours per response = 4,000 hours annually.

We estimate the hourly compensation for the time required to respond to the collection is $37.88 (U.S. Bureau of Labor Statistics, "Employer Costs for Employee Compensation," June 2023, Table 4, total compensation for all sales and office workers in goods-producing private industries: https://www.bls.gov/news.release/archives/ecec_09122023.pdf. Therefore, the estimated annual cost of the collection is $151,520 ($37.88 per hour x 4,000 hours = $151,520).

Based on this analysis, the proposed standard for infant support cushions would impose a burden to industry of 4,000 hours at a cost of $151,520.

Comments. CPSC has submitted the information collection requirements of this proposed rule to OMB for review in accordance with PRA requirements. 44 U.S.C. 3507(d). CPSC requests that interested parties submit comments regarding information collection to the Office of Information and Regulatory Affairs, OMB (see the **ADDRESSES** section at the beginning of this NPR). Pursuant to 44 U.S.C. 3506(c)(2)(A), the Commission invites comments on:

- whether the collection of information is necessary for the proper performance of CPSC's functions, including whether the information will have practical utility;
- the accuracy of CPSC's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- ways to enhance the quality, utility, and clarity of the information to be collected;
- ways to reduce the burden of the collection of information on respondents, including the use of automated collection techniques when appropriate and other forms of information technology; and
- the estimated burden hours associated with label modification, including any alternative estimates.

XV. Preemption

Section 26(a) of the CPSA, 15 U.S.C. 2075(a), provides that when a consumer product safety standard is in effect and applies to a product, no state or political subdivision of a state may either establish or continue in effect a standard or regulation that prescribes requirements for the performance, composition, contents, design, finish, construction, packaging, or labeling of such product dealing with the same risk of injury unless the state requirement is identical to the

federal standard. Section 26(c) of the CPSA also provides that states or political subdivisions of states may apply to the Commission for an exemption from this preemption under certain circumstances. Section 104(b) of the CPSIA refers to the rules to be issued under that section as "consumer product safety rules." Therefore, if finalized, the preemption provision of section 26(a) of the CPSA would apply to this rule for infant support cushions.

XVI. Request for Comments

The Commission seeks public comment on all aspects of the proposed rule. In particular, the Commission seeks comments on the scope of the proposed rule, with respect to both in scope and out of scope products, including comments on whether the proposed definition of "infant support cushion" is sufficient to include all infant support cushions that are not subject to the FHSA infant pillow ban, 16 CFR 1500.18(a)(16). The Commission would also welcome comments on the wording of proposed warning label as well as on whether the on-product warning label requirement included in the proposed rule should be applied to replacement covers for infant support cushions in addition to the cushions themselves. In addition, the Commission invites public comment on the proposed limit on sidewall height and whether the proposed rule's incline angle requirements provide appropriate protection against positional asphyxiation. Finally, the Commission requests comments on the proposed effective date and the costs of compliance with, and testing to, the proposed rule.

Submit comments in accordance with the instructions in the **ADDRESSES** section at the beginning of this notice.

List of Subjects

16 CFR Part 1112

Administrative practice and procedure, Audit, Consumer protection, Reporting and recordkeeping requirements, Third party conformity assessment body.

16 CFR Part 1130

Administrative practice and procedure, Business and industry, Consumer protection, Reporting and recordkeeping requirements.

16 CFR Part 1243

Consumer protection, Imports, Incorporation by reference, Infants and children, Labeling, Law enforcement, Pillows, Toys.

For the reasons discussed in the preamble, the Commission proposes to amend Title 16 of the Code of Federal Regulations as follows:

PART 1112—REQUIREMENTS PERTAINING TO THIRD PARTY CONFORMITY ASSESSMENT BODIES

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

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

2. Amend § 1112.15 by adding paragraph (b)(57) to read as follows:

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

* * * * *

(b) * * *

(57) 16 CFR part 1243, Safety Standard for Infant Support Cushions.

* * * * *

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

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

4. Amend § 1130.2 by adding paragraph (a)(21) to read as follows:

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

§ 1130.2 Definitions.

* * * * *

(a) * * *

(21) Infant Support Cushions.

* * * * *

5. Add part 1243 to read as follows:

PART 1243—SAFETY STANDARD FOR INFANT SUPPORT CUSHIONS

Sec.
1243.1 Scope, purpose, application, and exemptions.
1243.2 Definitions.
1243.3 General requirements.
1243.4 Performance requirements.
1243.5 Test methods.
1243.6 Marking and labeling.
1243.7 Instructional literature.
1243.8 Incorporation by reference.

Authority: 15 U.S.C. 2056a.

§ 1243.1 Scope, purpose, application, and exemptions.

(a) *Scope and Purpose*. This consumer product safety standard prescribes requirements to reduce the risk of death and injury from hazards associated with *infant support cushions*, as defined in § 1243.2. This includes but is not limited to *infant positioners*, nursing products with a dual use for lounging, *infant loungers*, and infant props or cushions used to support an infant. All *infant support cushions* must be tested according to the requirements of § 1243.5 and comply with all requirements of this part 1243.

(b) *Application*. All infant support cushions manufactured after [insert effective date of

the final rule], are subject to the requirements of this part 1243.

(c) *Exemptions*. Products subject to another standard listed in 16 CFR 1130.2(a) are exempt from this part 1243. Nursing pillows that also meet the definition of *infant lounger*, however, are not exempt from this part 1243.

§ 1243.2 Definitions.

Conspicuous means visible, when the product is in each manufacturer's recommended use position, to a person while placing an infant into or onto the product.

Infant lounger means an infant product with a raised perimeter, a recess, or other area that provides a place for an infant to recline or to be in a supine, prone, or recumbent position.

Infant positioner means a product intended to help keep an infant in a particular position while supine or prone.

Infant support cushion means an infant product that is filled with or comprised of resilient material such as foam, fibrous batting, or granular material or with a gel, liquid, or gas, and which is marketed, designed, or intended to support an infant's weight or any portion of an infant while reclining or in a supine, prone, or recumbent position.

Occupant support surface (OSS) means the area that holds up and bears the infant or any portion of the infant.

Seat bight line means the intersection of the seat back surface with the seat bottom surface.

§ 1243.3 General requirements.

(a) *Hazardous Sharp Edges or Points*. There shall be no hazardous sharp points or edges as defined in 16 CFR 1500.48 and 16 CFR 1500.49 before or after the product has been tested.

(b) *Small Parts.* There shall be no small parts as defined in 16 CFR 1501 before testing or presented as a result of testing.

(c) *Lead in Paints*. All paint and surface coatings on the product shall comply with the requirements of 16 CFR 1303.

(d) *Toys.* Toy accessories attached to, removable from, or sold with an infant pillow, as well as their means of attachment, shall comply with the applicable requirements of 16 CFR 1250.

(e) *Side Height*. The maximum side height for the product, measured from the OSS-body or test base, as appropriate, to the top of the sidewall, shall not exceed the maximum of the side heights determined in § 1243.5(d)(8).

(f) *Removal of Components*. When tested in accordance with § 1243.5(k), any removal of components that are accessible to an infant while in the product or from any position around the product shall not present a small part, sharp point, or sharp edge as required in § 1243.3(a) and § 1243.3(b).

(g) *Permanency of Labeling and Warnings.* (1) Warning labels, whether paper or non-paper, shall be permanent when tested in accordance with § 1243.5(b)(1)-(3).

(2) Warning statements applied directly onto the surface of the product by hot stamping, heat transfer, printing, wood burning, or any other method shall be permanent when tested in accordance with § 1243.5(b)(4).

(3) Non-paper labels shall not liberate small parts when tested in accordance with § 1243.5(b)(5).

(4) Warning labels that are attached to the fabric of the product with seams shall remain in contact with the fabric around the entire perimeter of the label when the product is in all manufacturer-recommended use positions and when tested in accordance with § 1243.5(b)(3).

(h) *Convertible Products.* If the infant support cushion can be converted into another product for which a consumer product safety standard exists, the product also shall comply with the

applicable requirements of that standard.

§ 1243.4 Performance requirements.

(a) *Restraint*. The product shall not include a restraint system.

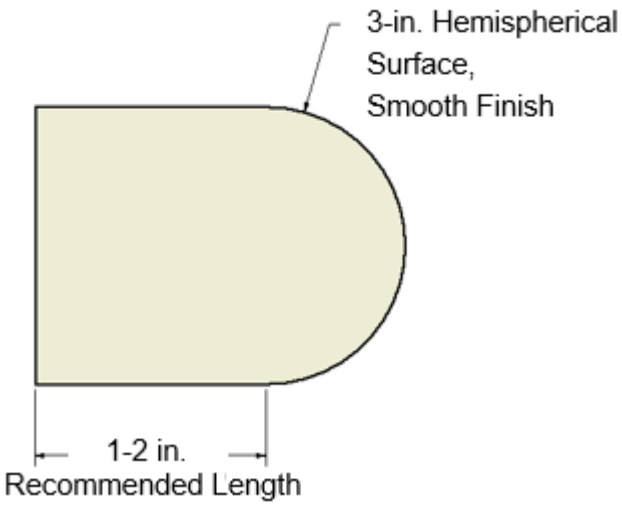
(b) *Seam Strength*. When tested in accordance with § 1243.5(j), fabric/mesh seams and points of attachment shall not fail such that a small part, sharp point, or sharp edge is presented, as required in § 1243.3(a) and § 1243.3(b).

(c) *Bounded Openings*. When tested to § 1243.5(c), all completely bounded openings that exist in the front, sides, or back of the occupant lounging area, or that are created when an accessory is attached to the product, shall not allow complete passage of the small head probe unless it allows the complete passage of the large head probe.

(d) *Maximum Incline Angle*. The maximum incline angle shall not exceed 10 degrees when tested in accordance with § 1243.5(d).

(e) *Firmness.* (1) *Occupant support surface firmness.* When the three-inch diameter (Figure 1 to paragraph (e)(1)) hemispherical head probe is applied according to the test method for occupant support surface firmness, § 1243.5(f), the force required for a one-inch displacement shall be greater than 10 N.

Figure 1 to paragraph (e)(1) - 3-in Head Probe



(2) *Sidewall firmness*. When the three-inch diameter hemispherical head probe is applied according to the test method for sidewall firmness, § 1243.5(g), the force required for a one-inch displacement shall be greater than 10 N.

(3) *Firmness at intersection of sidewall and occupant support surface*. When the three-inch diameter hemispherical head probe is applied according to the test method for firmness at the intersection of sidewall and occupant support surface, §1243.5(h), the force required for a one-inch displacement shall be greater than 10 N.

(f) *Side Wall Angle*. Sidewall angle shall be greater than 90 degrees when determined according to the Sidewall Angle Determination, § 1243.5(i).

§ 1243.5 Test Methods.

(a) *Test Conditions.* Condition the product for 48 hours at 23 °C +/- 2 °C (73.4 °F +/- 3.6 °F) and a relative humidity of 50 % +/- 5 %.

(b) *Permanence of Labels and Warnings.* (1) A paper label (excluding labels attached by a seam) shall be considered permanent if, during an attempt to remove it without the aid of tools or solvents, it cannot be removed, it tears into pieces upon removal, or such action damages the

surface to which it is attached.

(2) A non-paper label (excluding labels attached by a seam) shall be considered permanent if, during an attempt to remove it without the aid of tools or solvents, it cannot be removed or such action damages the surface to which it is attached.

(3) A warning label attached by a seam shall be considered permanent if it does not detach when subjected to a 15-lbs (67-N) pull force applied in any direction using a 3⁄4-inch diameter clamp surface.

(4) Adhesion test for warnings applied directly onto the surface of the product.

(i) Apply the tape test defined in Test Method B, Cross-Cut Tape Test of ASTM Test Methods D3359, eliminating parallel cuts.

(ii) Perform this test once in each different location where warnings are applied.

(iii) The warning statements will be considered permanent if the printing in the area tested is still legible and attached after being subjected to this test.

(5) A non-paper label, during an attempt to remove it without the aid of tools or solvents, shall not be removed or shall not fit entirely within the small parts cylinder defined in 16 CFR part 1501 if it can be removed.

(c) *Head Entrapment Test*. For all applicable openings, rotate the small head probe (Figure 2 to paragraph (c)) to the orientation most likely to fail and gradually apply an outward force from the occupant lounging area of 25 lbs (111 N). Apply the force to the probe in the direction most likely to fail within a period of 5 seconds and maintain it for an additional 10 seconds. If the small head probe can pass entirely through the opening in any orientation, determine if the large head probe (Figure 3 to paragraph (c)) can be freely inserted through the opening.

Figure 2 to paragraph (c) - Small Head Probe

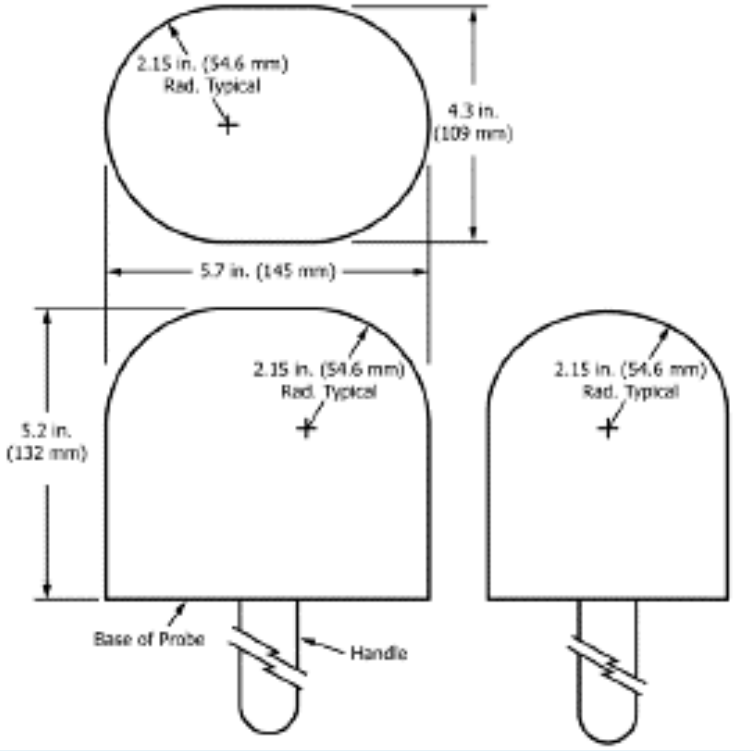
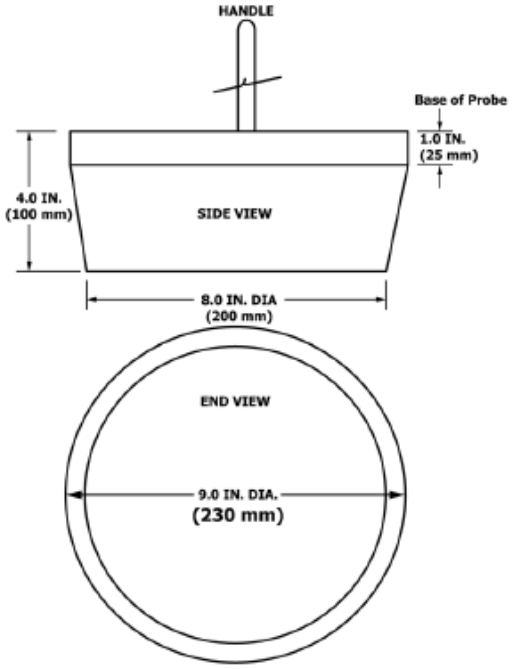


Figure 3 to paragraph (c) - Large Head Probe



(d) *Maximum Incline Test*. (1) *Equipment*: (i) Digital Protractor with accuracy +/- 1 degree;

(ii) Hinged Weight Gauge–Newborn, requirements for part masses and assembly (Figure 4 to this paragraph 5(d)(1)(ii)); (iii) Hinged Weight Gauge-Newborn, requirements for part dimensions (Figure 5 to this paragraph 5(d)(1)(iii)); and (iv) A test base that is horizontal, flat, firm, and smooth.

Figure 4 to paragraph 5(d)(1)(ii) - Hinged Weight Gauge–Newborn, Requirements for Part Masses and Assembly

PARTS LIST			
ITEM	DESCRIPTION	MASS (1)	VOLUME
Assembly		3.378 ± .02 kg (7.447 ± .05 lb)	
1	Upper Plate	2.275 kg (5.016 lb)	289.8 cm^3 (17.68 in^3)
2	Lower Plate	1.079 kg (2.379 lb)	137.4 cm^3 (8.385 cm^3)
3	Pin	0.024 kg (0.053 lb)	3.03 cm^3 (0.185 in^3)

Note 1. Part mass is calculated as Volume divided by the density for mild steel of 7.85 g/cm^3 (0.283 lbs/in^3).

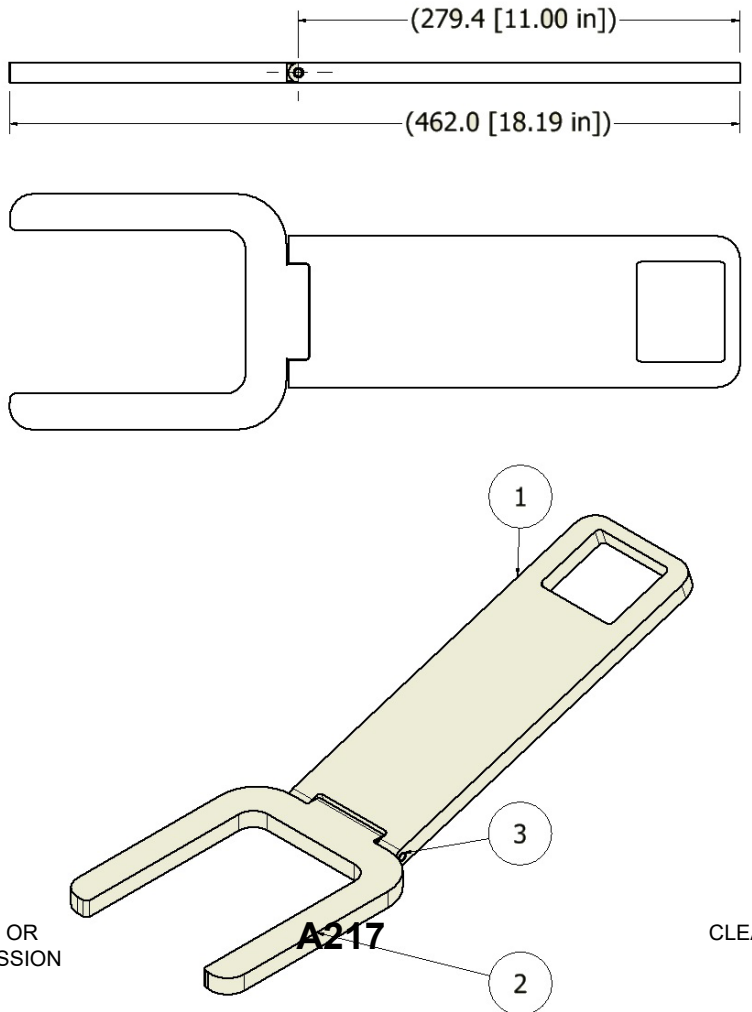
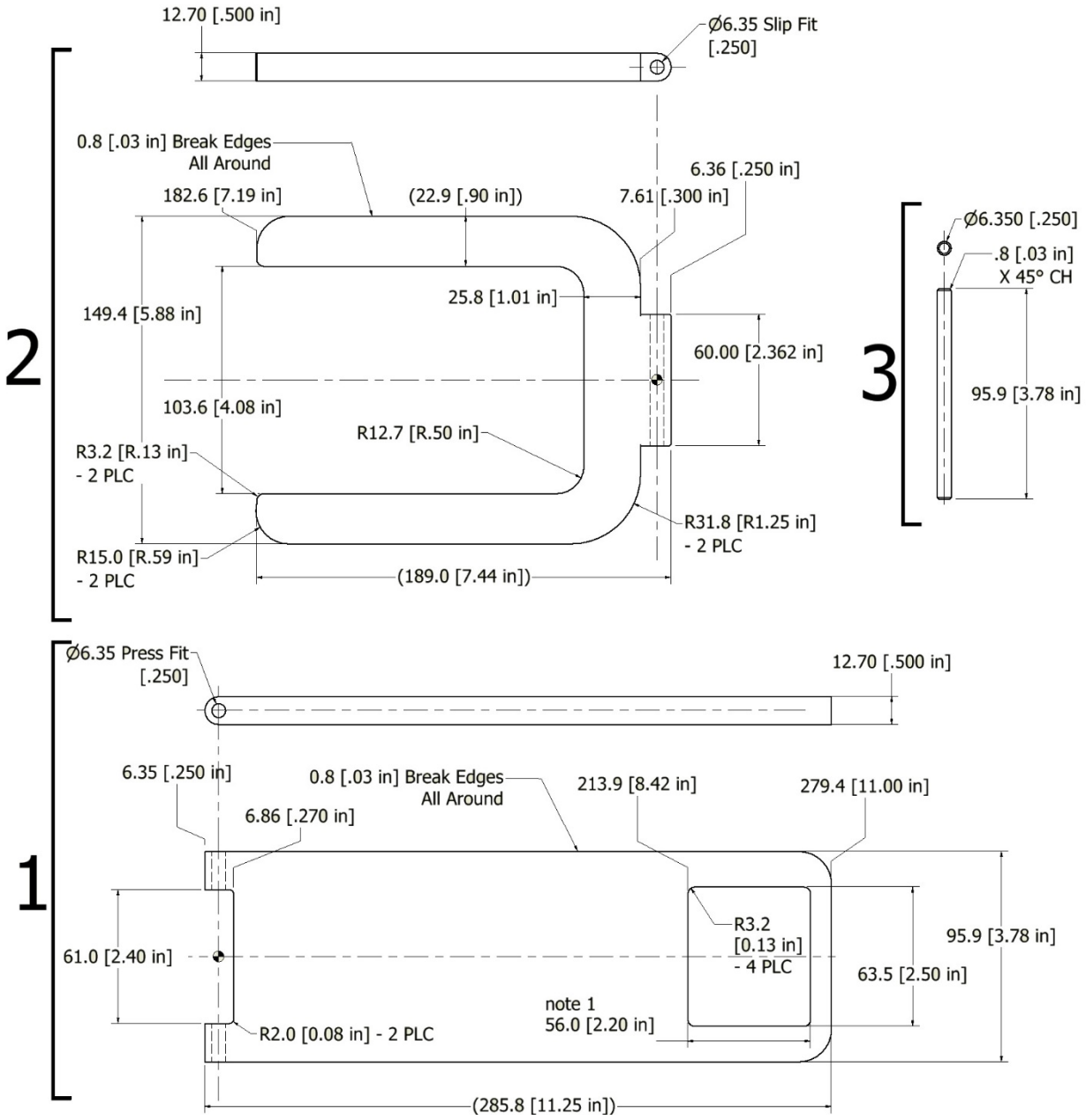


Figure 5 to paragraph 5(d)(1)(iii) - Hinged Weight Gauge–Newborn, Requirements for Part Dimensions

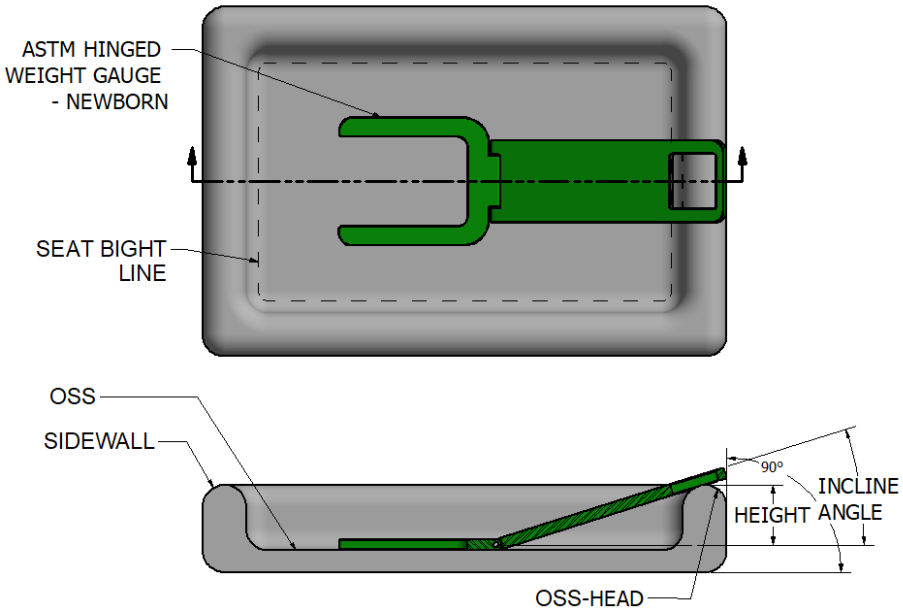


(2) If applicable, place the product in the manufacturer's recommended highest seat back angle position intended for lounging.

(3) If applicable, place the hinged weight gauge–newborn in the product and position the gauge with the hinge centered over the seat bight line and the upper plate of the gauge back. Place a digital protractor on the upper torso/head area lengthwise and measure the incline angle.

(4) Place the head/torso portion of the newborn hinged weight gauge on the product according to the manufacturer's recommended use position with the seat portion of the gauge, depending on the product design, allowed to lay freely on the product or on the test base (Figure 6 to paragraph (d)(4)).

Figure 6 to paragraph (d)(4) - Test Fixture Configuration to Measure Incline Angle on an Infant Support Cushion Product



(5) Move and rotate the newborn hinged weight gauge the minimum amount necessary such that the head/torso portion rests on an OSS that could foreseeably support an infant's head, and place the head/torso portion of the gauge according to all situations that apply: (i) In tests on products with an OSS for the infant's body, align the top edge of the head/torso portion of the gauge to coincide with a plumb line to the outermost edge of the OSS-head.

(ii) In all tests, place the seat portion of the gauge on the test base, adjust the newborn gauge to the greatest incline angle in which the top edge of the gauge maintains contact with the top surface of the product.

(6) If a product's seating bight area prevents reasonable positioning of the head/torso portion

to the outermost edge, then position the seat portion of the newborn hinged weight gauge as far forward as possible towards the outermost edge and allow the head/torso portion of the gauge to rest on the product.

(7) Place a digital protractor lengthwise on the head/torso portion of the gauge and measure the incline angle.

(8) Remove the newborn gauge and determine the side height at the incline angle location, measured from the OSS-body or test base, as appropriate, to the top of the OSS-head.

(9) Measure the incline angle at the manufacturer's recommended use location(s), at feasible locations such as perpendicular to the recommended use location(s), and at least one location likely to fail in which the newborn gauge seat is supported on the test surface.

(10) Determine the maximum incline angle from the incline angle measurements.

(e) *Firmness Test Setup*. (1) *Equipment*. (i) Force gauge with accuracy +/- 0.05 N (0.01 lbs); (ii) Distance gauge with accuracy +/- 0.01 inches (0.03 cm).

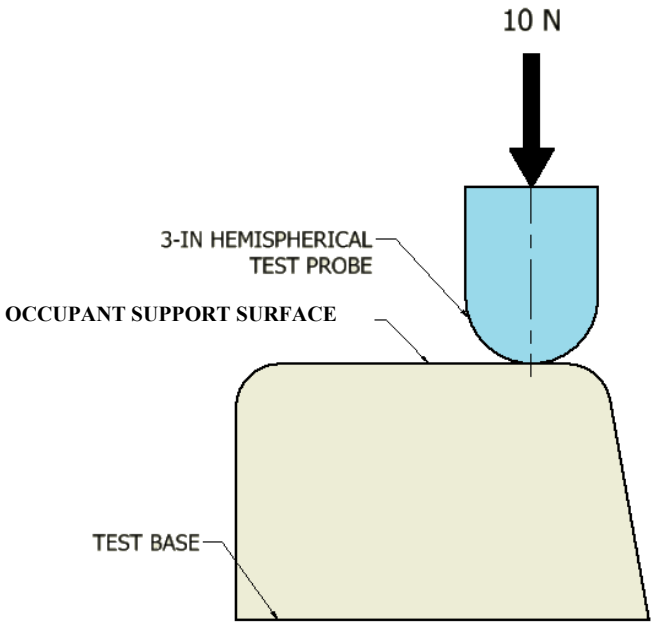
(2) Align the axis of the three-inch head probe (Figure 1 to paragraph (e)(1) of § 1243.4) with a force gauge and parallel to a distance measurement device or gauge.

(3) Use a lead screw or similar device to control movement along a single direction.

(4) Support the firmness fixture to a test base such that the head probe does not deflect more than 0.01 inches (0.025 cm) under a 10.0 N (2.24 lbs) load applied in each orientation required in the test methods.

(f) *Occupant Support Surface Firmness Test Method*. Perform the following steps to determine the occupant support surface firmness of the product as received from the manufacturer. *See* Figure 7 to paragraph (f).

Figure 7 to paragraph (f) – Test Configuration for Occupant Support Surface Firmness Test



(1) Orient the axis of the three-inch head probe perpendicular to the surface of the product at each test location that is oriented greater than five degrees relative to the test base or align the axis of the probe perpendicular to the test base (vertically) at each test location that is oriented equal to or less than five degrees to the test base.

(2) The first test location shall be at the location of maximum thickness of the surface being tested, perpendicular to the test base.

(3) Lay the product, with the occupant support surface facing up, on a test base that is horizontal, flat, firm, and smooth.

(4) Prevent movement of the product in a manner that does not affect the force or deflection measurement of the product surface under test. Provide no additional support beneath the product.

(5) Advance the probe into the product and set the deflection to 0.0 inches when a force of 0.1 N (0.02 lbs) force is reached.

(6) Continue to advance the head probe into the product at a rate not to exceed 0.1 inch per second and pause when the force exceeds 10.0 N (2.24 lbs), or the deflection is equal to 1.00 inches (2.54 cm).

(7) Wait 30 seconds. If the deflection is less than 1.00 inches and the force is 10.0 N or less, repeat steps § 1243.5(f)(6) and § 1243.5(f)(7)).

(8) Record the final force and deflection when the deflection has reached 1.00 inches or when the force has exceeded 10.0 N.

(9) If the maximum thickness of the OSS is greater than 1.0 inches (2.54 cm), perform additional tests, space permitting, at the geometric center of the OSS, at four locations along the product's longitudinal and lateral axes therefrom, 1.5 inches (3.8 cm) towards center from the intersection of the sidewall and OSS, and at one location most likely to fail.

(10) Repeat the occupant support surface firmness tests on any other occupant support surface and in all intended and feasible configurations that could affect an occupant support surface, such as the folding or layering of parts of the product.

(g) *Sidewall Firmness Test Method*. For sidewalls, perform the steps in § 1243.5(f)(1)-(8) to determine the sidewall firmness of the product as received from the manufacturer and then perform the following:

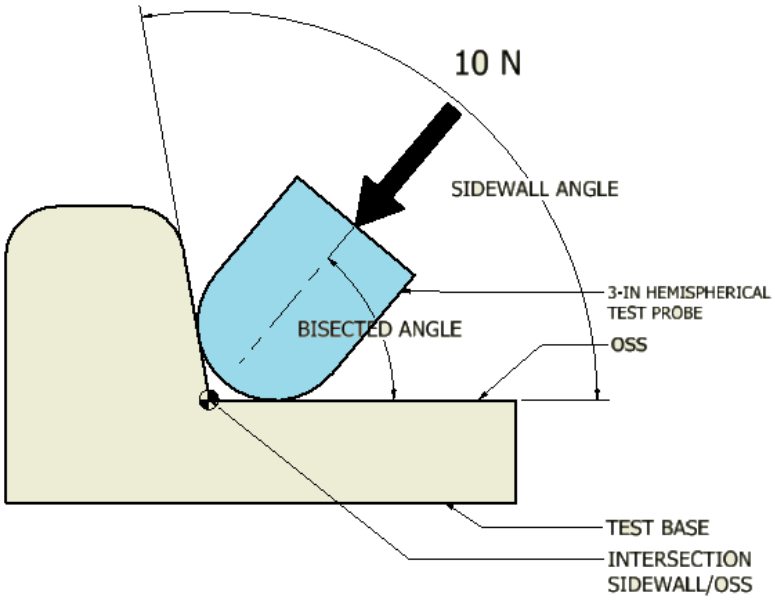
(1) Perform a minimum of four additional tests, located at intervals not to exceed six inches along the entire top perimeter of the sidewall, starting from the maximum side height location, and at one additional location most likely to fail.

(2) Repeat the sidewall firmness test in all the intended or feasible configurations that could affect the sidewall firmness, such as the folding or layering of parts of the product.

(h) *Intersection of Sidewall and Occupant Support Surface Firmness*. Perform the following

steps to determine the intersection firmness of the product as received from the manufacturer (Figure 8 to paragraph (h)).

Figure 8 to paragraph (h) - Test Configuration for Intersection of Sidewall and Occupant Support Surface Firmness



(1) Orient the axis of the three-inch head probe perpendicular to the sidewall perimeter at an angle from horizontal that bisects the angle determined in Sidewall Angle Determination with the axis directed at the intersection of the occupant support surface and the sidewall.

(2) The first test location shall be at the location of maximum product thickness parallel to the test base.

(3) Perform the steps in § 1243.5(f)(3)-(8).

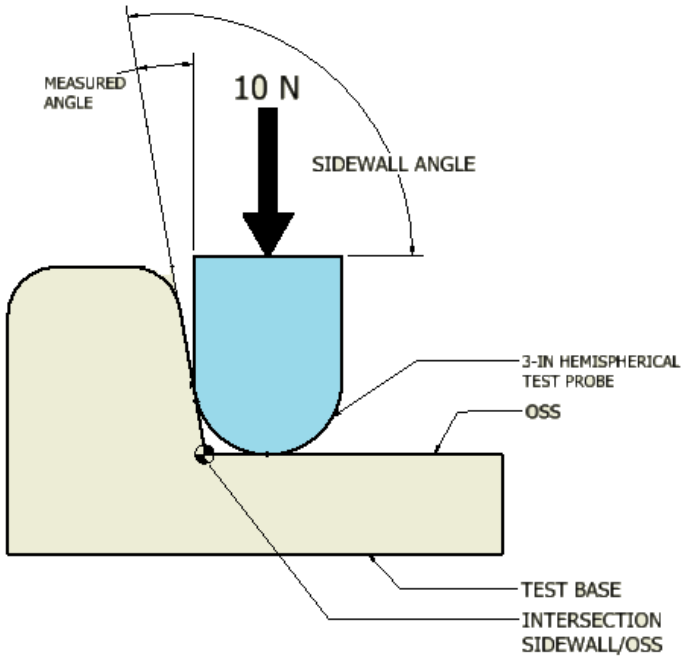
(4) Perform a minimum of four additional tests, located at intervals not to exceed six inches along the entire inside perimeter of the intersection of the sidewall and OSS, and at one additional location most likely to fail.

(5) Repeat the intersection of sidewall and occupant support surface firmness test in all the intended or feasible configurations that could affect the intersection firmness, such as the folding

or layering of parts of the product.

(i) *Sidewall Angle Determination.* Perform the following steps to determine if the angle between the sidewall and OSS is 90 degrees or less, or to measure the angle above 90 degrees. *See* Figure 9 to paragraph (i).

Figure 9 to paragraph (i) – Test Fixture Configuration for Sidewall Angle Measurement



(1) Orient the three-inch. (7.62 cm) diameter hemispherical head probe vertically and place it over the OSS with the cylindrical surface of the probe tangent to the intersection of the sidewall and the OSS. Advance the probe into the product until a downward force of 10 N (2.2 lbs) force is reached.

(2) After 30 seconds, determine whether the sidewall is in contact with the cylindrical side of the three-inch head probe. If the sidewall contacts the cylindrical part of the probe, the sidewall angle is equal to or less than 90 degrees.

(3) For sidewall angles greater than 90 degrees, calculate the sidewall angle as 90 degrees plus the measured angle between the cylindrical side of the three-inch head probe and the

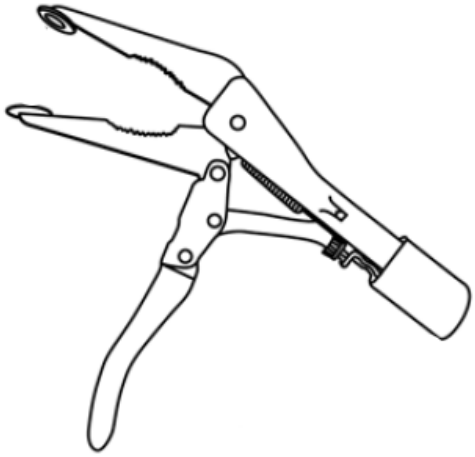
sidewall.

(4) Determine a minimum of four sidewall angles at locations not to exceed six inch (15.2 cm) intervals along the intersection of the sidewall and OSS.

(5) Measure the angle with a protractor or gauge placed to the depth of and in contact with the cylindrical side of the three-inch probe side and the sidewall.

(j) *Seam Strength Test Method*. (1) *Equipment*. (i) Clamps with 0.75 inches (1.9 cm) diameter clamping surfaces capable of holding fabric and with a means to attach a force gauge. *See* figure 10 to paragraph (j), or equivalent; (ii) A force gauge, accuracy +/- 0.5 lbs (1.1 N).

Figure 10 to paragraph (j) – Seam Clamp



(2) Clamp the fabric of the infant support cushion on each side of the seam under test with the 0.75 inches clamping surfaces placed not less than 0.5 inches (1.2 cm) from the seam.

(3) Apply a tension of 15 lbs (67 N) evenly over five seconds and maintain for an additional 10 seconds.

(4) Repeat the test on every distinct seam and every 12 inches (15 cm) along each seam.

(k) *Removal of Components Test Method*. (1) For torque and tension tests, any suitable device may be used to grasp the component that does not interfere with the attachment elements that are stressed during the tests.

(2) *Torque Test*. Gradually apply a four lbs-inch (0.4 N-m) torque over five seconds. in a clockwise rotation to 180 degrees or until four lbs-inch has been reached. Maintain for 10 seconds. Release and allow component to return to relaxed state. Repeat the torque test in a counterclockwise rotation.

(3) *Tension Test*. For components that can reasonably be grasped between thumb and forefinger, or teeth, apply a 15 lbs (67 N) force over five seconds, in a direction to remove the component. Maintain for 10 seconds. A clamp such as shown in Figure 11 to paragraph (k)(3) may be used if the gap between the back of the component and the base material is 0.04 inches (0.1 cm) or more.

Figure 11 to paragraph (k)(3) - Tension Test Adapter Clamp

§ 1243.6 Marking and Labeling.

(a) Each product and its retail package shall be marked or labeled clearly and legibly to indicate the following:

(1) The name, place of business (city, state, and mailing address, including zip code), and

telephone number of the manufacturer, distributor, or seller.

(2) A code mark or other means that identifies the date (month and year as a minimum) of manufacture.

(3) The marking or labeling in § 1243.6(a)(1) and (2) are not required on the retail package if they are on the product and are visible in their entirety through the retail package. When no retail packaging is used to enclose the product, the information provided on the product shall be used for determining compliance with § 1243.6(a)(1) and (2). Cartons and other materials used exclusively for shipping the product are not considered retail packaging.

(b) The marking and labeling on the product shall be permanent.

(c) Any upholstery labeling required by law shall not be used to meet the requirements of this section.

(d) *Warning Design for Product*. (1) The warnings shall be easy to read and understand and be in the English language at a minimum.

(2) Any marking or labeling provided in addition to those required by this section shall not contradict or confuse the meaning of the required information or be otherwise misleading to the consumer.

(3) The warnings shall be conspicuous and permanent.

(4) The warnings shall conform to ANSI Z535.4–2011, American National Standard for Product Safety Signs and Labels, sections 6.1–6.4, 7.2–7.6.3, and 8.1, with the following changes.

(i) In sections 6.2.2, 7.3, 7.5, and 8.1.2, replace “should” with “shall.”

(ii) In section 7.6.3, replace “should (when feasible)” with “shall.”

(iii) Strike the word "safety" when used immediately before a color (for example, replace "safety white" with "white").

Note 1 to paragraph (d)(4)(iii) — For reference, ANSI Z535.1, American National Standard for Safety Colors, provides a system for specifying safety colors.

(5) The safety alert symbol and the signal word "WARNING" shall be at least 0.2 inches (five mm) high. The remainder of the text shall be in characters whose upper case shall be at least 0.1 inches (2.5 mm), except where otherwise specified.

Note 2 to paragraph (d)(5) — For improved warning readability, typefaces with large height-to- width ratios, which are commonly identified as "condensed," "compressed," "narrow," or similar should be avoided.

(6) Message Panel Text Layout. (i) The text shall be left-aligned, ragged-right for all but one-line text messages, which can be left-aligned or centered. *See* Figure 12 to paragraph (d)(6) for examples of left-aligned text.

Figure 12 to paragraph (d)(6) - Examples of Left-Aligned Text.
The text shown for these warnings is filler text, known as lorem ipsum, commonly used to demonstrate graphic elements.

Note 3 to paragraph (d)(6)(i) — Left-aligned means that the text is aligned along the left margin, and in the case of multiple columns of text, along the left side of each individual column.

(ii) The text in each column should be arranged in list or outline format, with precautionary (hazard avoidance) statements preceded by bullet points. Multiple precautionary statements shall be separated by bullet points if paragraph formatting is used.

(7) An example warning in the format described in this section is shown in Figure 13 to paragraph (d)(7).

Figure 13 to paragraph (d)(7) – Example of Warning

(e) *Warning Statements* — Each product shall address the warning statements shown on Figure 13 to paragraph (d)(7), at a minimum.

Note 4 to paragraph (e) — "Address" means that verbiage other than what is shown can be used as long as the meaning is the same or information that is product-specific is presented.

§ 1243.7 Instructional Literature.

(a) Instructions shall be provided with the product and shall be easy to read and understand and

shall be in the English language at a minimum. These instructions shall include information on assembly, maintenance, cleaning, and use, where applicable.

(b) The instructions shall address the following additional warnings:

(1) Read all instructions before using this product.

(2) Keep instructions for future use.

(3) Do not use this this product if it is damaged or broken.

(4) Instructions shall indicate the manufacturer's recommended maximum weight, height, age, developmental level, or combination thereof, of the occupant for which the infant support cushion is intended. If this product is not intended for use by a child for a specific reason, the instructions shall state this limitation.

(c) The cautions and warnings in the instructions shall meet the requirements specified in § 1243.6(d)(4)-(6), except that sections 6.4 and 7.2–7.6.3 of ANSI Z535.4 – 2011, *American National Standard for Product Safety Signs and Labels*, need not be applied. However, the signal word and safety alert symbol shall contrast with the background of the signal word panel, and the cautions and warnings shall contrast with the background of the instructional literature.

Note five to paragraph (c) —For example, the signal word, safety alert symbol, and the warnings may be black letters on a white background, white letters on a black background, navy blue letters on an off-white background, or some other high-contrast combination.

(d) Any instructions provided in addition to those required by this section shall not contradict or confuse the meaning of the required information or be otherwise misleading to the consumer.

§ 1243.8 Incorporation by Reference

ANSI Z535.4-2011, *American National Standard for Product Safety Signs and Labels*, approved October 20, 2017, is incorporated by reference. The Director of the Federal Register

approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. This material is available for inspection at the U.S. Consumer Product Safety Commission and at the National Archives and Records Administration (NARA). Contact the U.S. Consumer Product Safety Commission at: the Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814, telephone (301) 504-7479, email: cpsc-os@cpsc.gov. For information on the availability of this material at NARA, email fr.inspection@nara.gov, or go to: www.archives.gov/federal-register/cfr/ibr-locations.html. A free, read-only copy of the standard is available for viewing on the ANSI website at https://ibr.ansi.org/Standards/nema.aspx. You may also obtain a copy from American National Standards Institute (ANSI), 25 West 43rd Street, 4th Floor, New York, NY 10036, USA, telephone: (212) 642-4900, www.ansi.org.

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Alberta E. Mills, Secretary
Consumer Product Safety Commission

United States
Consumer Product Safety Commission

Staff Briefing Package

Staff's Draft Proposed Rule for Infant Support Cushions

November 8th, 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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Briefing Memorandum

United States
Consumer Product Safety Commission

Memorandum

TO: The Commission
Alberta E. Mills, Secretary
Austin C. Schlick, General Counsel
Jason Levine, Executive Director
DeWane Ray, Deputy Executive Director of Operations

DATE: November 8, 2023

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

Stefanie Marques, Infant Support Cushions Rulemaking Project Manager,
Directorate for Health Sciences

SUBJECT: Staff's Draft Proposed Rule for Infant Support Cushions

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I. Introduction

This briefing package presents staff's draft proposed rule for infant support cushions under the Danny Keysar Child Product Safety Notification Act, *i.e.*, section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA). Infant support cushions are products marketed, designed, or intended to support an infant's weight or any portion of an infant while reclining or in a supine, prone, or recumbent position. Some of these products are marketed for use inside a crib or other sleep product but are not sleeping accommodations themselves.

Staff has identified 79 fatal incidents and 125 nonfatal incidents and consumer concerns reported to the U.S. Consumer Product Safety Commission (CPSC) from January 1, 2010, through December 31, 2022, associated with infant support cushions and involving infants up to 12 months of age.

Section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), requires the U.S. Consumer Product Safety Commission (CPSC) to:

1) examine and assess voluntary safety standards for certain infant or toddler products; and

2) promulgate mandatory consumer product safety standards that are substantially the same as the voluntary standards or more stringent than the voluntary standards, if the Commission determines that more stringent standards would further reduce the risk of injury associated with these products.

15 U.S.C. § 2056a(b). The Commission must continue promulgating safety standards for infant and toddler products until it "has promulgated standards for all such product categories." 15 U.S.C. § 2056a(b)(2).

Section 104(f) of the CPSIA defines "durable infant or toddler products" as "durable products intended for use, or that may be reasonably expected to be used, by children under the age of 5 years." 15 U.S.C. § 2056a(f). Section 104(f)(2) sets forth a non-exhaustive list of durable infant or toddler products that fall within the definition. 15 U.S.C. § 2056a(f)(2). Although infant support cushions are not specifically listed, they are "durable infant or toddler products" because they are durable products used by infants to support their weight while reclining or in a supine, prone, or recumbent position.

Section 104 of the CPSIA requires the Commission to consult with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts to examine and assess the effectiveness of any relevant voluntary standards. This consultation process has been ongoing with CPSC staff's participation in the juvenile product subcommittee meetings of ASTM International. ASTM subcommittee members represent producers, users, consumers, government, and academia.[1] Staff began the consultation process that led to this rulemaking in December 2021, in a letter to ASTM requesting that ASTM form a working group under the F15 committee to develop a voluntary standard containing performance requirements to reduce the risk of death and injury from hazards associated with infant support cushions, including nursing pillows. ASTM formed two subcommittees to develop two separate voluntary standards:

3) the F15.16 Infant Feeding Supports subcommittee,[2] intended to develop a standard for nursing pillows and other infant feeding supports, and

4) the F15.21 Infant Loungers subcommittee, intended to develop a standard for infant loungers, including nursing pillows intended for lounging.

Since then, staff has been actively participating with both ASTM subcommittees to develop voluntary standard requirements that address the associated hazards; however, neither subcommittee has published their respective standards.

Staff considers infant loungers to be a type of infant support cushion, therefore this briefing package summarizes staff's assessment of the performance and other requirements under consideration by the ASTM F15.21 Infant Loungers subcommittee for its voluntary standard as well as staff's work to develop requirements for infant support cushions.

This Briefing Package presents staff's recommendations for a draft proposed rule for infant support cushions, provides staff's analysis of the draft ASTM standards, and discusses the impact of this proposed rule on small businesses as required by the Regulatory Flexibility Act. Staff recommends updating 16 C.F.R. part 1130 to include infant support cushions as "durable infant or toddler products" requiring consumer registration cards under section 104(b) of the

[1] ASTM International website: www.astm.org, About ASTM International.
[2] The ASTM F15.16 Infant Feeding Supports subcommittee was initially called the Feeding and Infant Support Products subcommittee.

CPSIA and updating 16 C.F.R. part 1112 to include a Notice of Requirements (NOR) for infant support cushions.[3,4]

II. Background

A. Infant Pillow Ban

In 1992, pursuant to the Commission's authority under the Federal Hazardous Substances Act (FHSA), the Commission banned certain infant cushions and infant pillows. Specifically, 16 C.F.R. § 1500.18(a)(16) bans any article known as an "infant cushion" or "infant pillow," and any other similar article, which has *all* of the following characteristics:

- Has a flexible fabric covering;
- Is loosely filled with granular material, including but not limited to, polystyrene beads or pellets;
- Is easily flattened;
- Is capable of conforming to the body or face of an infant; and
- Is intended or promoted for use by children under 1 year of age.

The ban was intended to address a specific type of product; an infant bean bag cushion designed in the 1980s that, due to its size and shape, was being used as a mattress during a time when the recommended position for infant sleep was to place infants face down, prone. Therefore, the characteristics of pillows that fall under the ban were oriented to a particular product. For at least some period, this rule kept pillows that conformed to infants' faces and presented a suffocation hazard off the market. However, staff's assessment is that the infant pillow ban is not sufficient to remove potentially hazardous products available in today's market. In recent years, CPSC staff has become concerned about the increase in products promoted as infant support cushions that do not fall within the scope of the infant pillow ban, particularly those using non-granular fill materials, and the potential suffocation hazards that these products present to infants. Staff's proposed rulemaking does not disturb the FHSA infant pillow ban, but instead proposes performance standards for infant support cushions pursuant to section 104 of the CPSIA.

B. Products and the Market

Most infant support cushions on the market today are "loosely filled" or simply "filled" with some type of cushy foam or soft fibrous batting, rather than a "granular material," and are therefore not within the scope of the FHSA ban. As a result, many soft products marketed as infant support cushions have been used in infant sleep environments where they create asphyxiation and suffocation hazards.

The proposed rule defines an "infant support cushion" as "an infant product that is filled with or comprised of resilient material such as foam, fibrous batting, or granular material or with a gel,

[3] Staff's assessment of the performance and other requirements under consideration by the ASTM F15.16 Infant Feeding Supports subcommittee for its voluntary standard, and staff's recommendations for a draft proposed rule for nursing pillows intended to position and support an infant during supervised feeding, such as breastfeeding, nursing, or bottle feeding are addressed under a separate rulemaking activity, and separate staff briefing package for nursing pillows.

[4] https://www.regulations.gov/document/CPSC_FRDOC_0001-1332

liquid, or gas, and which is marketed, designed, or intended to support an infant's weight or any portion of an infant while reclining or in a supine, prone, or recumbent position. (Figure 1). This includes products such as infant loungers that may have walls around their perimeters, infant positioners, nursing products used for lounging, infant cushions and props. The proposed rule would not apply to removable padding or padded seat liners sold as part of products primarily used to transport, entertain, or feed infants. It also would not apply to infant products subject to other infant product rules listed at 16 CFR 1130.2(a), including infant sleeping accommodations, which are already regulated by CPSC's infant sleep products standard, 16 C.F.R. part 1236. In other words, if an infant cushion product is not subject to another CPSC durable infant product rule and is marketed, designed, or intended to support an infant's weight or any portion of an infant for reclining or lying in a supine, prone, or recumbent position, it would be required to comply with the proposed infant support cushions rule.

Figure 1. Examples of the various types of infant support cushions

The products in scope would include but are not limited to:

- Head positioner pillows
- Flat baby loungers
- Crib pillows
- Wedge pillows for infants
- Infant sleep positioners, unless regulated by the FDA as medical devices[5]
- Stuffed toys marketed for use as infant support cushions
- Infant "tummy time" or "lounging" pillows, whether flat or inclined
- Multi-purpose pillows marketed for both nursing and lounging

[5] The FDA discourages the use of infant sleep positioners and has not approved pillow products for preventing sudden infant death syndrome (SIDS). See https://www.fda.gov/consumers/consumer-updates/do-not-use-infant-sleep-positioners-due-risk-suffocation

- Anti-rollover pillows with or without straps that fasten the pillow to the infant
- Infant "self-feeding" pillows that hold a bottle in front of the face of reclining or lying infant[6].
- Pads and mats
- Accessory pillows and other padded accessories, often marketed for use with an infant car seat, stroller, or bouncer, but not sold with that product and therefore, not included in the mandatory safety testing for those products.

Some of these products are currently marketed for use inside a crib or other infant sleep product, notwithstanding the American Academy of Pediatrics' (AAP's) recommendation that soft objects, such as pillows and excess bedding, should not be placed in an infant's sleep environment.[7] In addition, the CPSC and FDA have warned against using infant positioning products in an infant's sleep environment, out of concern for the potential suffocation hazards these products pose. Based on the AAP, CPSC, and FDA's consistent recommendations regarding infants, pillows, and soft bedding, the draft proposed rule does not encourage infant support cushions to be used for sleep or in a sleep environment. However, because infants sleep a majority of the day and tend to fall asleep in products intended for lounging or periods of rest, and based on the incident data, staff concludes it reasonably foreseeable that caregivers will continue to use infant support cushions in an infant sleep environment. Therefore, staff proposes a performance standard to reduce the asphyxiation and suffocation hazards that, based on incident data, these products pose.

The following products are out of scope:

- Pillows not marketed or intended for use by infants, such as adult bed pillows
- Nursing pillows that are marketed only for feeding and are not marketed, intended, or foreseeably used for lounging, if they meet the requirements of the Commission's proposed nursing pillow rule 88 FR 65865 (Sept. 26, 2023) if that rule is finalized
- Crib and play yard mattresses that are in scope of the play yard and crib mattress standard in 16 C.F.R. part 1241
- Purely decorative nursery pillows, such as those personalized with the baby's name and birthdate, if they are not intended, or marketed for infant use.
- Stuffed toys (unless they meet the definition of an infant support cushion in this proposed rule)
- Padded seat liners that are sold with a rocker, stroller, car seat, infant carrier, swing, highchair or bouncer that are specifically designed to fit that product
- Sleeping accommodations, which are regulated under the Commission's infant sleep product rule at 16 CFR part 1236.

In general, products that are clearly intended to keep an infant engaged while awake or that can only be used when supervised by a caregiver would be considered out of scope of this proposed rule. In addition, free-standing products marketed or intended to provide sleeping accommodations for infants up to five months of age are within the scope of the "Safety

[6] These products are banned in the UK due to suffocation and pneumonia hazards. https://www.gov.uk/product-safety-alerts-reports-recalls/product-safety-alert-baby-self-feeding-pillows-slash-prop-feeders-psa3

[7] American Academy of Pediatrics, Sleep-Related Infant Deaths: Updated 2022 Recommendations for Reducing Infant Deaths in the Sleep Environment., https://publications.aap.org/pediatrics/article/150/1/e2022057990/188304/Sleep-Related-Infant-Deaths-Updated-2022

Standard for Infant Sleep Products" (16 C.F.R. part 1236), and therefore do not fall within the scope of this proposed safety standard. Staff recommends that the Commission invite comments from the public on whether the scope of this proposed rule is appropriate, or instead should be expanded or narrowed.

Staff cannot precisely determine the annual sales volume of infant support cushions, given the variety of products in scope of this rule and the large number of suppliers. Most types of infant support cushions are sold primarily online, rather than primarily in brick-and-mortar stores. Prices for new infant support cushions range from less than $15 for a simple head positioner pillow or crib pillow to more than $250 for a lounger with a removable cover or a large stuffed toy marketed for sleep, with the average price at roughly $30. Infant support cushions are supplied by several thousand manufacturers and importers, including hundreds of handcrafters and direct foreign shippers. There is also a considerable market in secondhand items, particularly for the more expensive items such as loungers and large stuffed toys marketed for sleep. In addition, caregivers frequently save and reuse infant support cushions for more than one child, and manufacturers of some infant support cushions sell replacement covers that facilitate use over many years.

III. Incident Data

As staff of CPSC's Directorate for Epidemiology, Division of Hazard Analysis (EPHA) discusses in Tab A, staff's search of the Consumer Product Safety Risk Management System (CPSRMS) and National Electronic Injury Surveillance System (NEISS) databases identified 79 fatal incidents and 125 nonfatal incidents and concerns reported to CPSC from January 1, 2010, through December 31, 2022—a period of 13 years—associated with infant support cushions as defined above, and involving infants up to 12 months of age (i.e. 365 days old). The data obtained from NEISS did not meet the minimum criteria to enable staff to compute a national estimate of the number of emergency department-treated injuries to infants involving infant support cushions. Thus, these cases are included with the other reported incident data. Because reporting is ongoing, the number of reported fatalities and nonfatal incidents and concerns during the specified timeframe might change in the future, especially for years 2021 and 2022. More detailed analyses of the incident data can be found in the EPHA staff memorandum in Tab A, as well as the memoranda in Tabs B and D, prepared by staff of the Directorate for Health Sciences (HS), and staff of the Directorate for Engineering Sciences, Division of Human Factors (ESHF), respectively.

A. Fatalities

CPSC staff identified 79 reported fatalities involving infant support cushions from January 1, 2010, through December 31, 2022. Given the anecdotal and incomplete nature of the data, staff discourages inferences based on year-over-year changes. However, more than three times as many fatalities occurred in the 2016-2022 period (61 fatalities) compared to the 2010-2015 period (18 fatalities), which is a concerning reporting trend, especially considering incident data from 2021 and 2022 may be incomplete.

Although staff reviewed incident data for children 12 months and younger, almost 81% of the infant pillow-related fatalities involved infants 3 months old and younger, a vulnerable age bracket. In 49 of the fatalities (62%), the official cause of death was asphyxia/probable

asphyxia. The decedent was placed on an infant support cushion in the following scenarios typically involving another sleep-related consumer product: 34 fatalities (43%) in an adult bed, 1 fatality in an air mattress (1%), 11 fatalities (14%) in a crib, 13 incidents in a bassinet or the bassinet portion of a play yard (15%), 8 fatalities (10%) inside a play yard or non-full sized crib, 3 fatalities (4%) on top of a couch/futon, 4 fatalities (5%) on either a mat or on the floor, and 1 fatality (1%) inside a toddler bed. Four (4) fatalities (5%) involved an undetermined or unknown scenario.

B. Non-Fatalities

CPSC staff identified 125 nonfatal incidents or reports involving infant support cushions for children 12 months old and younger that occurred from January 1, 2010, through December 31, 2022. Three of these incidents (2%), resulted in hospital admission, and 22 incidents (18%). were Emergency Department treated. Using reported information, that varied widely due to the self-reporting nature of the reports, staff was able to further characterize the nonfatal incidents into the following scenarios: 29 reports (23%), involved the victim falling off the infant support cushion that was placed on raised surfaces (e.g. beds and sofas) 27 reports (22%) involved the victim having a threatened asphyxia event while using the infant support cushion, 17 reports (14%) involved the victim developing a rash after using the infant support cushion; reports of limb entrapment, mold, choking, entanglement /entrapment and vomiting associated with the use of the infant support cushion all had one report each (each 1%). Forty-seven of the nonfatal reports were consumer complaints (38%).

IV. Hazard Pattern Identification.

As staff of CPSC's Directorate of Health Sciences (HS) discusses in Tab B, positional asphyxia/suffocation is a serious risk factor associated with the use of infant support cushions. HS staff identified four major types of positional asphyxia/suffocation hazards associated with infant support cushions:

Remaining on product with nose and mouth occluded- HS staff identified 23 (29%) fatal incidents where the victim remained on the infant pillow and suffocated due to their nose and mouth being occluded. The narratives in those incidents indicate that the victim was placed supine on the infant pillow, or in an unstable side position and later found prone on the infant pillow with nose and mouth occluded by the infant pillow and/or by other soft bedding present in the sleep setting. These incidents suggest that the infants' unexpected movement on the infant pillow resulted in the occlusion of their nose and mouth either by the infant pillow itself or other soft bedding. An infant can suffocate/asphyxiate against an object that partially or fully obstructs the nose and mouth and prevents breathing. Death as the result of asphyxia can occur in as little as 3 minutes.

Use as an in-bed sleeper/bassinet to facilitate bedsharing hazard- HS staff identified 27 fatal incidents (34%) where the victim was sharing a sleeping environment such as an adult bed, couch, or air mattress with caregivers and/or siblings. Bedsharing exposes the infant to a potentially fatal asphyxia hazard from overlay of the caregiver or suffocation from extraneous adult bedding; however, many narratives specifically describe scenarios where the infant pillow was being used as an in-bed sleeper/bassinet to facilitate bedsharing. Due to the complexity of

this unsafe sleep environment, victims were found in a variety of positions while using the infant pillow, including prone and supine on the pillow, partially off the infant pillow, completely off the infant pillow and wedged between the adult bed and the wall/or the outside surface of another children's product.

Hyperextension hazard- HS staff identified 2 fatal incidents (3%) where the victim's neck was hyperextended. Neck hyperextension is a hazardous position that can result if an infant's unsupported head is tilted backwards over the top of the product; if sustained in this position and the infant's head is below the level of the infant's heart, respiration will be significantly impaired which could lead to oxygen desaturation and death. In one incident the victim was found to have moved further up on the infant pillow, resulting in the infant's head falling off the pillow and resting on a comforter while the infant's body remained on the pillow. In the second incident, the infant partially rolled off the pillow which resulted in their head over the back of the pillow with their neck hyperextended.

Rolling off product into hazardous setting- HS staff identified 14 fatal incidents (18%) not associated with the bedsharing incidents described above where the infant rolled or slid off the infant pillow into a hazardous environment, such as wedge entrapment hazard or soft bedding hazard. Several incidents involved the victim using the infant pillow on an adult bed, rolling off the infant pillow and becoming wedged between parts of an adult bed or wedged between the adult bed and a wall; other wedging incidents resulted from the victim using the infant pillow in an infant sleep product such as a crib, bassinet, or play yard, rolling off the infant pillow and becoming wedged between the infant pillow and the side of the infant sleep product. In other incidents, the victims rolled off infant support cushions face down onto soft bedding that was placed in the sleep setting; in two incidents involving soft bedding the victims slid off the infant support cushions and remained supine (face up) but were suffocated by adult pillows placed in the sleep setting that covered the victims' nose and mouth.

V. Contractor Report

In September 2020, Commission staff awarded a contract to Boise State University (BSU) for infant biomechanics and suffocation research and consultancy services.[8] One task order under this contract was for research on pillows intended for infant care and use and included an analysis of the risk of injury or death to infants associated with the use of infant pillows, including nursing pillows and other types of pillows marketed as aiding infants during activities such as feeding, nursing, sleeping, propping, and lounging.[9] On June 30, 2022, BSU delivered their final report which included development and testing on an appropriate test probe and performance requirements recommendations for infant pillows[10].

A. Test probe development

BSU compared the effectiveness of 11 different probes for potential use in implementing their recommended performance requirements. The goal of this probe development process was to

[8] Contract No. 61320620D0002.The key personnel for performance under this contract are Dr. Erin M. Mannen, Ph.D. (Principal Investigator), and Dr. John Carroll, MD (Co-Investigator).
[9] Task Order No. 61320621F1015.
[10] Pillows Product Characterization and Testing | CPSC.gov

identify a probe that could produce consistent and accurate airflow measurements. The probes ranged in complexity from simple disc probes to different sized hemispheric probes, to probes modeled on an infant's airway. Ultimately BSU recommended a 3-inch hemispheric probe, because it was geometrically similar to an infant's face, relatively easier to manufacture, and produced air flow rates that were consistent with physiological values reported in previous infant research. Although selection of the appropriate probe was based mainly on its airflow measurements, BSU determined that this probe was also appropriate for firmness testing.

B. Firmness testing

Based on its characteristics, described above, BSU recommended that all infant pillows be tested for firmness using the 3-inch hemispheric probe. The recommended test involves using the probe in three different locations: the location of maximum thickness, the location of minimum thickness, and a subjective location of interest (*i.e.*, another soft location that seems most likely to result in failure). At each location the probe is lowered onto the product and displaces the product surface by 1 inch; the resulting force measured from this displacement must exceed 10 Newtons (N) (which is approximately 2.25 pounds force). This requirement is consistent with the firmness requirement currently applicable to crib mattresses[11] in order to reduce a suffocation hazard. BSU tested 13 infant pillow products using this recommended firmness performance test, and none of them exceeded 10 N (2.25 pounds) force to cause a 1-inch displacement on any of the three locations tested. Thus, each pillow failed to meet this proposed requirement.

C. Other Recommended Requirements

In their final report, BSU also discussed requirements for airflow testing, and sagittal-plane[12] testing for infant pillows. BSU developed an airflow test that would determine whether a product had airflow characteristics comparable to mesh crib liners, however BSU suggested that this test should not be required if a product passes BSU's recommended firmness test. BSU also developed a novel multi-hinged sagittal-plane testing device, which they determined provides a better visual representation of infants positioning on an infant pillow than a single-hinged gauge testing fixture; however, consistent placement of the sagittal plane testing device was a concern, and BSU concluded that further research was needed to determine appropriate worst-case positioning of the testing device.

VI. International Standards for Infant Pillows

Other than CPSC's Infant Pillow Ban under the FHSA discussed above, the only other current standards that address infant pillows are the following British Standards:

[11] BSU found that sample crib mattresses tested using the hemispheric probe required more than 10 N (2.25 pounds) to displace the probe 1 inch. A force of 10 N also approximates the weight of an infant's head.
[12] The sagittal plane is the plane that runs lengthwise the body, dividing it into right and left.

- **BS 1877-8:1974, Specification for domestic bedding —Part 8: pillows and bolsters for domestic use (excluding cellular rubber pillows and bolsters)**
- **BS 4578:1970, Specification for methods of test for hardness of, and for air flow through, infants' pillows**

The scope of BS 1877-8:1974 includes both adult pillows and cot pillows (infant pillows) and recommends that cot pillows be filled firmly enough to prevent infants' heads from sinking into the products and that the pillow covering not be loose enough to be drawn into the infant's mouth. BS 1977-8:1974 has requirements for cot pillow size, filling, and covering. Cot pillows must be 58 x 38 cm (23 x 15inches) and filled with curled hair, and their covering must be of open construction to allow air permeability. Both the filling and covering must meet performance requirements described in BS 4578:1970 for hardness and air permeability.

BS 4578:1970 sets out performance requirements for hardness and air permeability in addition to describing how to wash those pillows. The hardness test requires that a 100mm diameter probe be placed in the center of the product with 10N of force for 1 minute. BS 1877-8:1974 requires that displacement of the pillow when the force is applied shall not exceed 25% of the thickness. Staff's concern with this requirement is that the proportional approach used in this requirement allows thicker pillows to have a greater displacement than thinner pillows.

VII. Draft ASTM Voluntary Standard for Infant Loungers

No published voluntary standards in the U.S. cover infant support cushions; however, ASTM is in the process of developing a voluntary standard for "Infant Loungers" under Subcommittee F15.21 on Infant Carriers, Bouncers, and Baby Swings. The working definition of infant loungers is that they are products "with a raised perimeter, a recess, or other area that is intended to be placed on the floor and to provide a place for an infant to sit, lie, recline, or rest, while supervised by an adult". As such, it would be a subset of the products covered by this proposed rule, which also includes infant positioners, nursing products with dual use for lounging, infant loungers, infant cushions, and other infant pillow-like products. On May 2, 2023, the Subcommittee discussed the draft standard for infant loungers, but so far, ASTM has not issued a ballot on the draft standard for Infant Loungers. CPSC staff has been working with ASTM to develop performance requirements intended to address the primary hazards associated with infant loungers.

ASTM's draft voluntary standard includes general requirements typically found in other ASTM juvenile product standards, such as requirements related to hazardous sharp edges or points, small parts, lead in paints, resistance to collapse, scissoring shearing and pinching, openings, protective components, toys accessories that are attached to, removable from, or sold with the products, and the permanency of labels and warnings, as well as the requirement that if the lounger can be converted to another product it shall comply with the applicable requirements of that product's standard. The general requirements of the draft infant lounger standard also state that the sidewall height of the product shall be less than 4 inches when measured according to the sidewall height measurement test method.

The draft voluntary standard also includes the following performance requirements:

- *Stability:* This requirement states that the product shall not tip over and shall retain the CAMI dummy when tested in all manufacturers use positions.

- *Infant Restraints*: This requirement states the product shall not have a restraint system.

- *Fabric/Mesh Integrity*: This requirement is intended to address product integrity issues such as seam failures and material breakage.

- *Bounded openings*[13]: This requirement is intended to address potential entrapment hazards.

- *Occupant Support Surface*: This requirement is intended to address the thickness, dimensions, and potential gaps of the occupant support surface.

- *Occupant Support Surface Firmness*: This requirement uses an 8-inch diameter "Firmometer" probe[14] and requires that there shall be no point where the feeler arm, which hangs over the edge of the disc, comes in contact with the occupant support surface.

- *Sidewall Firmness*: This requirement states that the top of the sides of the product cannot be displaced more than 1-inch when a 3-inch diameter hemispheric probe is applied to the product with a 10N of force.

- *Side Angle and Deflection:* This requirement states that the angle between the sidewall and the occupant support surface shall be greater than 90 degrees; this requirement is intended to address potential entrapment hazards at the intersection of the side wall and occupant support surface.

The draft voluntary standard also includes marking and labeling and instructional literature requirements. The marking and labeling requirements include requirements for warnings that must appear on infant loungers covered by the standard, that address hazards associated with infant loungers such as warning the consumer about using the product for sleep or naps, only using with an awake baby, only using when baby is supervised, only using the product on the floor, keeping soft bedding out of the product, not using the product on raised surfaces, and not using the product to carry or move an infant while in the product. The draft standard requires the warnings to be "permanent" and "conspicuous."

In addition, the draft voluntary standard provides requirements for instructional literature to accompany products covered by the standard. These requirements state that the instructional literature that accompanies infant loungers must include warnings on the product, as well as the following additional warnings:

- Read all instructions before using this product.
- Keep instructions for future use.
- Do not use this product if it is damaged or broken.

[13] A completely bounded opening is defined as opening that exists due to the design of the product or created by accessory attached to the product that does not have any breaks in the perimeter of the opening.
[14] A Firmometer probe is a device that consists of a circular disk of a certain size and weight, with an attached "feeler arm" that extends over the edge of the disk.

The instructions also must indicate the manufacturer's recommended maximum weight, height, age, developmental level, or combination thereof, of the infant. If the product is not intended for use by a child for a specific reason, the instructions must state that limitation.

VIII. Staff's Proposed Rule

Although CPSC staff has worked closely with ASTM in the development of the loungers requirements in the standard discussed above and drawn extensively from this work to develop requirements for infant support cushions, to protect against hazard patterns observed with incidents involving infant support cushions, staff determined that additions and modifications to the draft lounger standard were warranted.

A. Scope and definition

Based on the incident data and hazards associated with infant support cushions, staff recommends the following scope and definition:

> This consumer product safety standard prescribes requirements to reduce the risk of death and injury from hazards associated with *infant support cushions*. This includes but is not limited to *infant positioners*, *nursing products* with a dual use for lounging, *infant loungers*, and infant props or cushions used to support an infant.
>
> An Infant support cushion is defined as an infant product that is filled with or comprised of resilient material such as foam, fibrous batting, or granular material, or a gel, liquid, or gas, and which is marketed, designed, or intended to support an infant's weight or any portion of an infant while reclining or in a supine, prone, or recumbent position.

B. General Requirements

Staff concludes that the general requirements included in the draft ASTM voluntary standard for infant loungers such as requirements related to hazardous sharp edges or points, small parts, lead in paints, resistance to collapse, scissoring shearing and pinching, openings, protective components, toy accessories that are attached to, removable from, or sold with the products, and the permanency of labels and warnings, as well as the requirement that if the lounger can be converted to another product it shall comply with the applicable requirements of that product's standard, would also be necessary for infant support cushions, apart from the sidewall height requirement which staff addresses in a different manner. The ASTM infant loungers draft voluntary standard allows a maximum sidewall height of 4 inches for infant loungers, however CPSC staff is concerned that this side height might give consumers the impression that the infant support cushion is intended to safely contain the infant occupant. The draft proposed rule addresses hazards associated with infant support cushion products that do not provide sleeping accommodations and are not intended to or do not safely contain the infant user of the product. CPSC staff has developed proposed performance requirements for the maximum incline angle discussed below to address positional asphyxia concerns. These requirements would effectively limit the side height of infant support cushion products (because due to geometry, it would be difficult for a lounger with high sidewalls over 2 inches to meet the incline angle

requirement), but it does not specify a maximum side height. CPSC staff recommend that the Commission invite comments from the public on what is an appropriate side height that would not give the consumer the impression that an infant support cushion is intended to safely contain the infant and whether these incline angle requirements provide sufficient protection.

The General Requirements in ASTM's draft lounger standard include warning label permanence requirements that are consistent with other ASTM juvenile product standards. However, staff also recommends that the draft proposed rule include an additional warning-permanency requirement that would address so-called "free-hanging" labels; that is, labels that attach to the product at only one end of the label. Warning labels that are attached in that way are more likely to be torn or ripped off, or otherwise altered by the consumer, which eliminates the potential safety benefit of the warning for future users of the product. Thus, staff recommends that the draft proposed rule include the following additional requirement.

> Warning labels that are attached to the fabric of infant support cushions with seams shall remain in contact with the fabric around the entire perimeter of the label, when the product is in all manufacturer-recommended use positions, when subjected to a 15-lbf (67N) pull force applied in any direction using a 3/4-in diameter clamp surface.

C. Performance requirements

CPSC staff assessed that the draft requirements in the ASTM lounger standard for restraints, seam strength, and bounded openings are appropriate for the infant support cushion standard. ASTM draft requirements for restraints would not allow an infant support cushion to have a restraint system which could potentially pose an entanglement/strangulation hazard. Because infant support cushions are not intended to safely contain the infant, not allowing restraints is consistent with this intended purpose and staff finds the requirement necessary to prevent entanglement/strangulation hazards. The seam strength requirement ensures that all the seams of the infant support cushion bear the weight of the occupant, which is appropriate for infant support cushions that are intended to support the body or even a part of the infant's body. The bounded opening requirements ensures that any bounded opening in the product does not pose a head entrapment hazard; infant support cushions range in a variety of shape and sizes and some may include openings, so it is appropriate for infant support cushions to have this requirement.

In addition to incorporating these performance standards from ASTM's infant lounger draft standard, the draft proposed rule includes additional performance standards intended to address the specific safety hazards staff have found particular infant support cushion products to pose. Tab C discusses the extensive research and testing on infant pillow products by the staff of CPSC's Directorate for Laboratory Sciences, Division of Mechanical Engineering (LSM), to develop performance requirements for infant support cushions. These proposed requirements are as follows:

i. Firmness

Staff developed firmness requirements differing from those in the ASTM draft Lounger standard. Staff proposes firmness requirements and associated test methods that are consistent with crib mattresses firmness requirements summarized below and described in greater detail in Tab C, which staff finds necessary for safety based on the work of BSU[8] and to address the incidents and hazard patterns described above with facial occlusion into infant support cushions:

Occupant Support Surface (OSS) Firmness

Staff recommends an OSS firmness requirement that the OSS of any infant pillow must require more than 10 N force to deflect one inch with a 3-inch hemispheric probe following staff's recommended test procedure. In the ASTM draft lounger standard, the 8-inch firmometer probe is used for the OSS firmness requirement; however, CPSC staff has concerns about the accuracy of using this probe to measure the firmness of the OSS. Due to the variety of infant pillow styles, LSM staff observed that in some of support cushions tested, the OSS was more curved than horizontal, had button-like stitching that made the OSS irregular, or had a thin and flexible OSS that would make consistent positioning of the firmometer difficult. In addition, LSM staff noted that some infant support cushions have smaller OSS dimensions, in which ASTM's large 8-inch disc firmometer would not fit well enough to provide accurate measurement, and the large size of the firmometer probe could possibly mask OSS features that could potentially pose a suffocation hazard Staff recommends the OSS firmness requirement for the NPR use the 3-inch hemispheric probe developed by BSU as described above, because the size and dimensions of this probe are more anthropometrically consistent with the size and dimensions of an infant's head, as compared to the 8-inch diameter firmometer, and the BSU-developed probe can more accurately detect the types of material deformations and surface features that an infant's face may come in contact with while on the infant support cushion.

To simplify and clarify test methods and to improve upon the ASTM test methodology, staff also recommends: (1) to conduct tests and measurements of loungers/support cushions vertically if the OSS is on average within 10 degrees of horizontal, and conduct tests and measurements perpendicular to the OSS if the OSS is tilted at an angle equal to or greater than 10 degrees (so that probe is always at a 90 degree angle to the OSS) ; and (2) to establish a vertical reference to the side of the 3-in probe and a horizontal reference to the top of that probe. Once the infant support cushion has been prepared for firmness testing, staff recommends performing the OSS firmness test both at the location of maximum OSS thickness and also at a location most likely to fail, using the following test procedure:

a. Using a lead screw or similar device to control movement, advance the probe onto the product and set the deflection to 0.0 in when a force of 0.1 N (0.022 lb) force is reached.

b. Continue to advance the head probe into the product at a rate not to exceed 0.1 in (0.25 cm) per second and pause when the force exceeds 10 N (2.2 lb), or the deflection is equal to 1.0 in (2.54 cm).

c. After a 30 second pause, if the force is equal to or less than 10 N (2.2 lb) and the deflection is less than 1.0 in (2.54 cm), the probe shall be advanced further in a similar manner,

d. Record the final force and deflection when the deflection has reached 1.0 in (2.54 cm) or when the force has exceeded 10 N (2.2 lb).

e. If the maximum thickness of the OSS is equal to or greater than 1.0 in (2.54 cm), perform additional tests at the geometric center of the OSS and at four locations along the product's longitudinal and lateral axes therefrom, 1.5 in (3.8 cm) towards center from the intersection of the sidewall and OSS.

Sidewall Firmness

For the sidewall firmness test, ASTM uses the 3-inch hemispheric probe developed by BSU to apply a force of 10N downwards on top of the side wall and requires that the product may not deflect 1 inch or greater under this force. This test method is similar to the one developed for firmness by BSU, and the OSS firmness test recommended by LSM staff above, because the force required for a 1-inch displacement should be greater than 10N to pass the firmness test. However, staff concludes ASTM's draft sidewall firmness test is not as accurate in measuring firmness as the test proposed in this rule. The ASTM method is the inverse of the staff proposed method; the ASTM test applies a fixed force and measures the deflection that force causes, while the staff proposed method applies force until a fixed deflection is achieved and measures the force required to reach the specified deflection, which results in a product firmness that is comparable to crib mattresses, and reduces the likelihood that the sidewalls of infant support cushions conform to infant's face and pose a suffocation hazard.

LSM staff does not consider the ASTM test requirement compatible with staff proposed test requirements. ASTM does not describe how the force is applied, and the force driving deflection method (ASTM) is not the same as deflection driving force (staff proposed) because the staff proposed test method requires a time delay before measuring deflection. A time delay is essential to allow the filling material of the infant pillow to adjust to the applied force, i.e., force decay, and relax to a stable reading, which increases the repeatability of the test method. Staff recommends for infant support cushions with sidewalls, the staff proposed test method because it accounts for the downward decay of test forces and enables precise control of deflection. After performing the OSS firmness test, LSM staff recommends also performing the sidewall surface firmness test a minimum of four times starting at the location of maximum sidewall height, and along the entire perimeter of the sidewall located at intervals not to exceed 6 in., including an additional test at a location most likely to fail using the procedure steps a. to d. from the OSS firmness test.

Intersection of Sidewall and Occupant Support Surface Firmness

Staff recommends, for infant support cushions with sidewalls, consistent with the firmness requirements for OSS and for sidewall, that the force required for a 1.0-inch displacement at the intersection of the sidewall and OSS must be greater than 10N which is the force exerted by crib mattresses in firmness tests, when a 3-in (7.62 cm) diameter hemispheric probe is directed

at an angle to that intersection that bisects the angle between the OSS and the sidewall. A minimum of four sidewall firmness tests should be conducted, and at intervals not to exceed 6 in, to account for the various sizes of infant's heads that could encounter this area. In addition, staff recommends that the test locations include at least one location most likely to fail.

LSM staff observed that for some infant support cushions the intersection of the sidewall and the OSS had clear transition from the OSS to the sidewall with distinctive angle changes; however, in other infant support cushions tested the transition between the OSS and sidewall was more curved and not easily discerned especially for infant support cushions that had a more recessed OSS with a thicker outside perimeter. Despite the potential challenge to consistently determine a definitive intersection between the OSS and the sidewall, staff determined that having a firmness requirement at this intersection is appropriate for infant support cushions, because in addition to the firmness of the two mating surfaces, a firmness requirement at the intersection also addresses hazards of suffocation in product areas or configurations where parts join, sharply transition, or overlay other parts and that form internal or concave surfaces in which the face of the infant can contact simultaneously.

ii. Sidewall angle

In the draft ASTM lounger standard, ASTM requires that the angle between the sidewall and the occupant support surface (OSS) be greater than 90 degrees to reduce potential entrapment hazards that could occur in these areas. The angle is measured with a protractor, or similar tool, every 4 in (10 cm) along the interior of the product. As discussed above, the OSS for infant support cushions is generally an irregular surface, making it challenging as an angular reference. Staff finds that for support cushions with a sidewall, a requirement of sidewall angle greater than 90 degrees is necessary to protect against entrapment of the infant between the sidewall and the OSS. In addition, staff recommends the 90-degree angle requirement for the sidewall be assessed with the cylindrical side of the 3-in probe, applied with a 10 N (2.2 lb) force and placed with the probe side tangent to the intersection of sidewall and OSS. Contact with the probe side by the product sidewall will constitute an angle equal to or less than 90 degrees and no contact will signify an angle greater than 90 degrees. Sidewall angle measurements should be taken, starting at the location of maximum sidewall height, and at intervals not to exceed 6 in (15.2 cm). to account for the various sizes of infant's heads that could encounter this area.

iii. Maximum Incline Angle

In the draft ASTM lounger standard, ASTM proposes a requirement for "Maximum Seat Back Angle," which states that the angle of the seat back along the head-to-toe axis relative to the horizontal shall not exceed 10 degrees when tested with the infant hinged weight gauge.[15] The infant hinged weight gauge is positioned with the hinge aligned over the seat bight line[16] and

[15] A two-part, hinged, metal gauge to represent the approximate form and weight of an infant when lying prostate or supine. This gauge is used in several ASTM infant safety standards.
[16] Seat bight: The intersection between the seat or occupant support surface and seatback or sidewall.

with the upper torso/head plate of the gauge on the seat back. The angle is measured with a digital protractor resting on the upper gauge area. Staff recommends that infant support cushions should have a maximum incline angle that shall not exceed 10 degrees, as in the CPSC infant sleep product rule[17], the Safe Sleep for Babies Act, and based on addressing the hazards identified for inclined sleep products. However, staff recommends several modifications to the maximum incline angle requirements and test procedures in ASTM's proposed testing protocol to improve test consistency across all infant support cushion products and to address additional locations of potential inclined sleep.

The first modification is to apply the maximum seat back angle requirement not only to all of a manufacturer's recommended use positions, but also to all other infant cushion surfaces that can feasibly support an infant's head (OSS-head), including the angle from the sidewall (if present) to the OSS or from the OSS-head to the floor when no elevated sidewall is present or from sidewall to floor when an elevated sidewall is present, see figure 9 Tab C.

The second modification is to use a newborn hinged weight gauge. This newborn gauge is lighter than the infant counterpart and presents a worse-case scenario since the lighter newborn gauge would deflect less, creating more of a seat back angle, and consumers foreseeably would use infant products for newborns.

The third modification is a change to the placement of the gauge throughout testing. The torso/head portion of the gauge should, at times, be positioned so that it rests against the top surface of the product, with the top edge of the torso/head portion positioned plumb with the outer edge of the product, even if this positioning causes the hinge of the gauge to not align with the bight line of the product. It is staff's preliminary determination that these recommendations for positioning and using the newborn hinged weight gauge and the resulting maximum incline angle measurement better represents the positioning on or in the product for the youngest occupant. These recommended modifications of the maximum seat back angle requirement would also limit the heights of OSS-head surfaces for loungers and infant support cushions, which addresses staff's concern that higher sidewall heights give the consumer the impression the infant support cushion could safely contain an infant as discussed above. Also, the floor to OSS surface and floor to sidewall angle requirement protect against inclined sleep from the angle created by having an infant's head on the side of the pillow and body on the floor and limit the height of the side of the pillow, to address incidents and hazard patterns described above of positional asphyxia seen with support cushions (including loungers) used together with other sleep products.

D. Warning and Instructional Literature Requirements

i. Marking and Labeling

The draft ASTM voluntary standard for infant loungers includes marking and labeling requirements, which include requirements for warnings that must appear on infant loungers. CPSC staff worked with the ASTM infant lounger's subcommittee to develop the on-product warning requirements, which address the primary hazards associated with infant loungers, with particular emphasis on the potentially deadly consequences of using these products for sleep or naps. As staff of CPSC's Directorate for Engineering Sciences, Division of Human Factors

[17] https://www.cpsc.gov/s3fs-public/Final-Rule-Safety-Standard-for-Infant-Sleep-Products.pdf

(ESHF) discusses in Tab D, infant support cushions under the scope of this rule would also be expected to meet this requirement.

The ASTM draft lounger standard has accepted staff's recommendations for defining "conspicuous" as staff has in the draft proposed rule:

> "visible, when the product is in each manufacturer's recommended use position, to a person while placing an infant into or onto the product."

This definition allows for consumers using the infant support cushion from any position to visibly see the warning label.

The ASTM draft lounger standard also requires the warnings to be "permanent" and includes permanence requirements among the General Requirements for infant loungers. In Tab D, staff also discusses a recommended additional permanence requirement to reduce the potential for the warnings to be torn, ripped, or cut off.

ii. Instructional Literature

The ASTM draft lounger standard includes requirements for instructional literature to accompany loungers. These requirements are based on the ASTM Ad Hoc Language Task Group recommended requirements for instructional literature and for the formatting of warnings in instructional literature, and CPSC staff worked with the ASTM Ad Hoc Language Task Group to develop these requirements. Thus, staff recommends adopting consistent instructional literature requirements in the draft proposed rule for infant support cushions.

IX. Potential Small Business Impact

As staff of CPSC's Directorate of Economics (EC) discusses in its Tab E initial regulatory flexibility analysis pursuant to the Regulatory Flexibility Act, the draft proposed rule is expected to have a significant impact on a substantial number of small entities because currently there is no mandatory or voluntary performance standard for infant support cushions, therefore all the proposed requirements would be new for any small business in this market.

There are more than 2,000 suppliers, i.e., manufacturers, importers, and foreign direct shippers of infant support cushions to the U.S. market. Based on the U.S. Small Business Administration (SBA) size standards, most of these suppliers qualify as small. Most products on the market will require redesign to meet the requirements in the draft proposed rule. Staff considers one percent of annual revenue to be a "significant" economic impact on a company, consistent with regulatory flexibility analyses conducted by other federal government agencies. The cost of redesign and testing is likely to be significant for a substantial number of small U.S. firms, including small manufacturers and small importers. Small home crafters are a subset of small manufacturers; they will likely be significantly impacted by this rule.

Manufacturers of infant support cushions would be required to comply with the standards of this draft proposed rule and demonstrate this compliance through third-party testing. As specified in

16 C.F.R. part 1109, entities that are not manufacturers of children's products, such as importers and wholesalers, may rely on the certificate of compliance provided by others. Staff assumes that manufacturers will pass on at least some of the cost of testing for compliance to importers and wholesalers. Third-party testing will be a new cost for all suppliers, because infant support cushions are not currently required to be third-party tested. The performance requirements in this draft proposed rule require that products meet certain firmness criteria and incline requirements. While any product in scope of this rule could in theory be redesigned to meet the performance requirements in this rule, some suppliers may decide to remove their products from the market rather than redesign because they anticipate that there may not be a sufficient market for their redesigned products. In terms of small businesses, the impact of removing the product from the market instead of redesigning it could be significant as a result of a potentially large volume of lost sales.

The labeling and instructions requirements constitute a burden under the Paperwork Reduction Act. CPSC staff will submit an Information Collection Request to the Office of Management and Budget of the Executive Office of the President (OMB) for their approval and obtain an OMB control number for this information collection. Certificates of Conformance are already required for all children's products under OMB Control Number 3041-0159 and are not a new requirement of this NPR.

X. Compliance Recall Information

Staff of CPSC's Office of Compliance (EXC) has not identified any recalls involving infant support cushions that are not intended to provide a sleeping accommodation, from January 1, 2010, through December 31, 2022.

XI. Product Registration Rule Amendment

In addition to requiring the Commission to issue safety standards for durable infant or toddler products, section 104 of the CPSIA directed the Commission to issue a rule requiring that manufacturers of durable infant or toddler products establish a program for consumer registration of those products. Section 104(f) of the CPSIA defines the phrase "durable infant or toddler product" and lists examples of such products.

In 2009, the Commission issued a rule, commonly known as the product registration card rule, implementing product registration as section 104 required (16 C.F.R. part 1130). As part of that rule, the Commission added six products—children's folding chairs, changing tables, infant bouncers, infant bathtubs, bed rails, and infant slings—to the list of durable infant or toddler products that the CPSIA specifically identified.

Staff's draft proposed rule would add "infant support cushions" to the list of durable infant or toddler products requiring registration under section 104(b) of the CPSIA. Infant support cushions are a durable infant or toddler product because they are not disposable and have a useful life of up to a few years and are similar to other durable nursery products including crib mattresses and sling carriers, and because they are primarily intended to be used by children five years old or younger, and in this case, 12 months old or younger.

XII. Notice of Requirements

Section 14(a) of the Consumer Product Safety Act (CPSA) requires that any children's product subject to a consumer product safety rule under the CPSA must be certified as complying with all applicable CPSC-enforced requirements. The children's product certification must be based on testing conducted by a CPSC-accepted third party conformity assessment body (test laboratory). The CPSA requires the Commission to publish a notice of requirements (NOR) for the accreditation of third-party test laboratories to determine compliance with a children's product safety rule. This proposed rule for infant support cushions, if issued as a final rule, would be a children's product safety rule that requires issuing an NOR.

The Commission rule, *Requirements Pertaining to Third Party Conformity Assessment Bodies*, 16 C.F.R. part 1112 establishes the requirements for accreditation of third-party testing laboratories to test for compliance with a children's product safety rule. The part 1112 rule also codifies all the NORs that the CPSC has published to date for children's product safety rules. All new children's product safety rules, such as the proposed rule for infant support cushions, would require an amendment to Part 1112 to create an NOR. Therefore, staff recommends that the Commission propose to amend Part 1112 to include infant support cushions in the list of children's product safety rules for which the CPSC has issued NORs.

As discussed in Tab E, EC staff concludes that there should be no adverse impact on testing laboratories as a result of the proposed rule. There are no new complex testing instruments, devices, or procedures that are required to test infant support cushions for compliance to this draft proposed rule. The testing devices include a probe, a distance measurement device, a force gauge, a hinged weight gauge, and a frame to hold the product and testing devices in place. Testing laboratories are not required to provide these testing services; only those laboratories that make the business decision to provide such services, based on expected demand for their services, will need to procure the testing devices and apply for CPSC-acceptance of their ISO accreditation.

For the same reasons, revising the NOR to add infant support cushions to the list of products subject to part 1112 would not have a significant adverse impact on small laboratories. Most laboratories are not small U.S. businesses. Companies in the lab testing industry include companies with hundreds of locations, including labs in Asia and Europe, and thousands of employees. Thus, the Commission could certify that the NOR for the infant pillow mandatory standard will not have a significant impact on a substantial number of small laboratories.

XIII. Recommended 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)). Staff recommends a 180-day, or approximately 6-month, effective date. Staff generally considers 6 months to be sufficient time for laboratories to apply for accreditation for the proposed standard and suppliers to come into compliance with the proposed standard, and this amount of time is typical for other CPSIA section 104 rules. Six months is also the period that JPMA typically allows for products in their certification program to shift to a new standard once that new standard is published. Therefore,

juvenile product manufacturers are accustomed to adjusting to new standards within this time. A significantly earlier effective date could potentially result in shortages due to testing logistics, while a longer effective date could reduce the burden on small businesses to redesign their products quickly but would delay the safety benefits of the rule. Staff invites comments, particularly from small businesses, regarding the amount of time they will need to come into compliance.

XIV. Staff Conclusion and Recommendations

Staff recommends that the Commission issue the draft proposed rule for infant support cushions that includes the requirements discussed in Section VIII, which are provided in detail in Tab F and summarized as follows:

- General requirements and associated test methods that are consistent with the draft voluntary standard for infant loungers, with the exception of a maximum side height requirement, and with an additional warning permanence requirement to prevent "free-hanging" labels.
- Performance requirements and associated test methods that:
    - Add firmness requirements that apply to all surfaces that an infant may be exposed to while using the product, e.g., occupant support surface, sidewall, and the intersection of the sidewall and occupant support surface.
    - Add a side angle requirement to reduce potential entrapment hazards between the sidewall and occupant support surface.
    - Add a maximum incline angle requirement that will: (1)l effectively limit the height of the sidewalls, discouraging the impression that the product can safely contain an infant; and (2) protect against unsafe sleep angles when the infant is within the product and when the infant's head is elevated onto the side of the product while the infant's body is on the floor.
- Warning and instructional requirements that include a strongly worded and conspicuous on-product warning.

Staff also recommends an effective date of 180 days after publication of the final rule to allow manufacturers to bring their products into compliance and to arrange for third party testing. Before labs can provide third party testing to verify conformity with the final rule, they will need to become ISO accredited to perform testing to the new standard and then apply to CPSC for acceptance of their accreditation for this rule. The draft proposed rule provided with this briefing package includes these recommended provisions.

TAB A: Infant Support Cushion-Related Fatalities, Injuries, and Noninjury Incidents, 2010 – 2022

United States
Consumer Product Safety Commission

Memorandum

TO: Stefanie Marques, Infant Support Cushions Rulemaking Project Manager,
Directorate for Health Sciences

DATE: November 8, 2023

THROUGH: Steve Hanway, Associate Executive Director,
Directorate for Epidemiology

FROM: Blake Smith, Mathematical Statistician,
Directorate for Epidemiology Division of Hazard Analysis

SUBJECT: Infant Support Cushion-Related Fatalities, Injuries and Noninjury Incidents 2010-2022

I. Introduction

This memorandum characterizes the reported fatalities and nonfatal incidents associated with infant support cushions received by CPSC staff. Staff reviewed incidents reported to have occurred between January 1, 2010, and December 31, 2022.

For the reported fatal and nonfatal incidents, staff extracted and analyzed data from both the Consumer Product Safety Risk Management System (CPSRMS)[1] as well as the National Electronic Injury Surveillance System (NEISS).[2] The number of emergency department (ED)-treated injuries reported through NEISS that were within the scope of this analysis did not meet the publication criteria.[3] As such, a separate national estimate of ED-treated injuries associated with infant support cushions is not presented in this memorandum. However, the NEISS injury cases have been combined with the anecdotal data from CPSRMS and are part of the analysis presented in this memorandum. The data presented in this memorandum represent the minimum number of incidents associated with infant support cushions within the scope of the NPR during the relevant time period.

Incident Data

CPSC staff extracted data concerning incidents that occurred between January 1, 2010, and December 31, 2022, where the victim's age was 12 months or younger. The data extraction took place on January 3, 2023, from the CPSRMS and NEISS databases for the following 12 infant support cushion-related product codes[4]: 4050 (Pillows, excluding water pillows), 1513 (Playpens and play yards), 1529 (Portable cribs),1537 (Bassinets or cradles), 1542 (baby

[1] CPSRMS is the epidemiological database that houses all anecdotal reports of incidents received by CPSC, external cause-based death certificates purchased by CPSC, all in-depth investigations of these anecdotal reports, as well as investigations of select NEISS injuries. Examples of documents in CPSRMS include hotline reports, Internet reports, news reports, medical examiner's reports, death certificates, retailer/manufacturer reports, and documents sent by state/local authorities, among others.
[2] Data from the NEISS is based on a nationally representative probability sample of about 100 hospitals in the United States and its territories. The NEISS data can be used to derive national estimates of emergency department-treated injuries associated with infant pillows.
[3] Reporting criteria for NEISS require that the estimated number of injuries be 1,200 or higher, the sample size be 20 or larger, and the coefficient of variation be less than 33 percent.

mattresses or pads), 1543 (Cribs), 1552 (Cribs, Nonportable or Not specified), 1545 (Cribs, Not specified), 4010 (Mattresses, not specified), 4082 (Toddler beds), 1562 (Other soft baby carriers), and 4002 (Bedding, not specified). Staff also separately extracted a generic code (9101) because the reports under code 9101 are not clerically coded, and the products are not clearly identified. Reports under these codes required staff to search the narrative text using specific keywords. Staff excluded all incidents occurring outside of the U.S. except for incidents occurring at U.S. military bases in foreign countries. To prevent any double counting, when multiple reports of the same incident were identified, staff consolidated and counted them as one incident.

CPSC staff then reviewed the data to ensure each product involved in an incident met the criteria of an infant support cushion as described in the draft proposed rule.[5] The emergency department treated injuries (NEISS) and non-fatal incidents (CPSRMS) were then combined to form one non-fatal incidents dataset. The same was done for emergency department fatalities (NEISS) and fatal incidents (CPSRMS) to form a fatalities dataset. CPSC staff removed any duplicate reports to avoid double counting.

Staff identified a total of 204 incidents associated with the use of infant support cushions in the CPSC epidemiological databases from January 1, 2010, through December 31, 2022. These included 79 fatal incidents and 125 non-fatal reports. The dispositions of the 125 non-fatal reports consisted of 22 emergency department-treated injuries, 3 hospital admissions, 1 victim leaving before being seen, 1 victim seen by a medical professional, 46 reports where no injury occurred, and 52 reports with either an unknown or unspecified disposition.

Given the anecdotal nature of CPSRMS, the data are not necessarily representative of incidents that have occurred throughout the nation, nor are they a complete count of every incident that has happened around the U.S. during the given timeframe. Instead, the reported incidents addressed in this memorandum represent a minimum for the number of incidents or fatalities that have occurred during the given timeframes.

In addition, because data collection is ongoing. CPSC may receive additional reports for the period covered in this memorandum in the future. As an incident is investigated and new information becomes available, or as other associated reports are received, the initial information is either corroborated or contradicted. If new information contradicts initial information, it may cause the currently reported incident numbers to change.

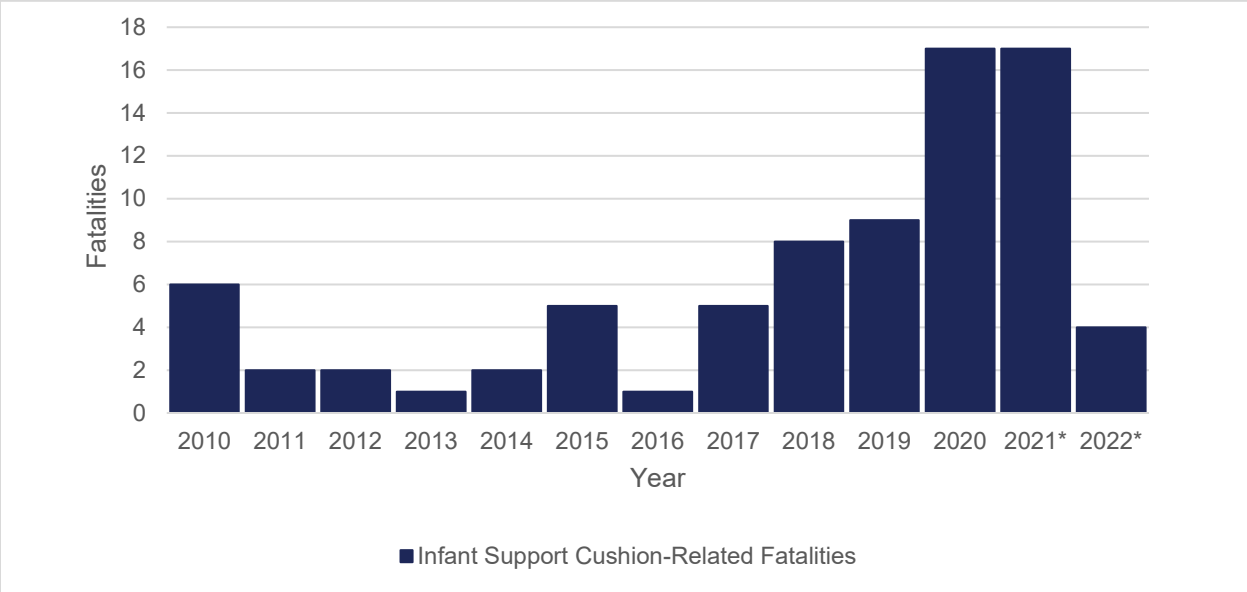
II. Results

Fatal Reports

CPSC staff is aware of 79 reported fatalities involving infant support cushions among children ages 12 months and younger. These deaths occurred between January 1, 2010, and December 31, 2022. Given the anecdotal nature and the ongoing reporting of the CPSRMS data, inferences based on year-over-year increases/decreases are discouraged.

[5] For CPSRMS incidents, staff relied on all available information, including product make/model, descriptions/pictures from in-depth investigations when available, to determine if an incident was in-scope. For NEISS incidents, staff mostly relied on the injury narrative for any description of the product to determine whether the report was in-scope.

Figure 1: Infant Support Cushion-Related Fatalities Reported by Year for Children 12 Months of Age or Younger: January 1, 2010–December 31, 2022.



Source: CPSRMS and NEISS databases.
Asterisks (*) indicate that reporting is ongoing for CPSRMS; the years 2021–2022 are considered incomplete.

Among the fatalities with known gender, males accounted for 38 fatalities (48 percent of the total) and females also accounted for 38 fatalities (48 percent of the total). Three fatalities involved an unknown gender (4 percent of the total). Infant support cushion-related fatalities in the 0-3 months age range accounted for 81 percent of all fatalities with a known age. Table 2 summarizes the number of reported infant support cushion-related fatalities for victims 12 months and younger by age in months and by gender.

Table 2: Infant Support Cushion-Related Fatalities for Victims Ages 12 Months and Younger by Age in Months and Gender: January 1, 2010–December 31, 2022

Age (In Months)	Total (% of Total)	Male (% of Total)	Female (% of Total)	Unknown (% of Total)
Total	79 (100%)	38 (48%)	38 (48%)	3 (4%)
1	26 (33%)	12 (15%)	14 (18%)	0
2	19 (24%)	10 (13%)	9 (11%)	0
3	18 (23%)	8 (10%)	10 (13%)	0
4	7 (9%)	4 (5%)	3 (4%)	0
5	3 (4%)	1 (1%)	0	2 (3%)
6	1 (1%)	0	1 (1%)	0
7	2 (3%)	1 (1%)	1 (1%)	0
8	0	0	0	0
9	0	0	0	0
10	1 (1%)	1 (1%)	0	0
11	1 (1%)	1 (1%)	0	0
12	0	0	0	0

Unknown	1 (1%)	0	0	1 (1%)

Source: CPSRMS and NEISS databases.
Percentages may not add to 100 due to rounding.
Reporting is ongoing for CPSRMS; the years 2021–2022 are considered incomplete.

Of the reported fatalities, 49 had an official cause of death as ruled by a Medical Examiner (ME) of asphyxia/probable asphyxia (62% of the total), 13 were determined to be sudden unexpected infant death (SUID) events (17% of the total), 12 had an undetermined cause of death (15% of the total), and the medical examiner's report was unavailable for 5 fatalities (6% of the total).

The scenario-specific information that indicated the placement of the decedents can be described as follows:

- 34 decedents were placed on infant support cushions in an adult-sized bed.
- 13 decedents were placed on an infant support cushion in a bassinet or bassinet portion of a play yard.
- 11 decedents were placed on an infant support cushion in a crib.
- 8 decedents were placed on an infant support cushion inside a play yard.
- 3 decedents were placed on an infant support cushion on top of a couch or futon.
- 4 decedents were placed on an infant support cushion on either a mat or on the floor.
- 1 decedent was placed on an infant support cushion inside a toddler bed.
- 1 decedent was placed on an infant support cushion in an air mattress.

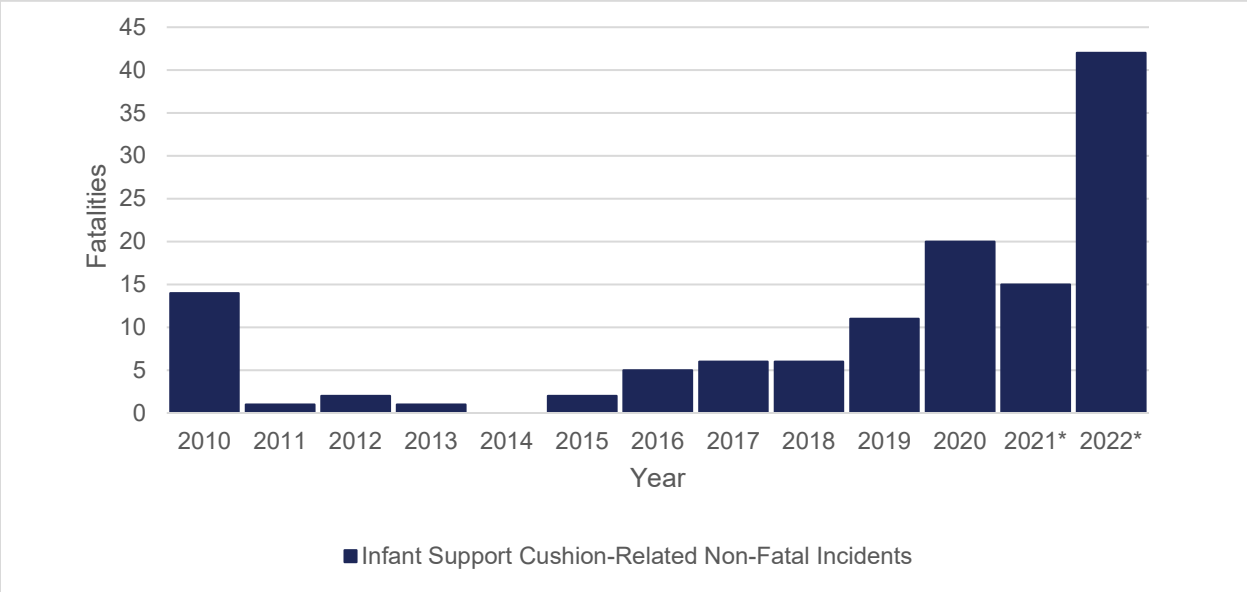
There were 4 fatalities for which the placement was either undetermined or unknown.

Nonfatal Reports

CPSC staff identified 125 reported nonfatal infant support cushion-related reports for children ages 12 months and younger that occurred between January 1, 2010, and December 31, 2022.[6] Given the anecdotal nature and the ongoing reporting of the CPSRMS data, inferences based on year-over-year increases/decreases are discouraged.

[6] Nonfatal incident reports submitted to CPSC come from reports entered into CPSC's CPSRMS database no later than 1/3/2023 and include completed NEISS investigations. All of the investigation reports based on NEISS injuries that occurred from 2010-2022 appear in the reported nonfatal incidents.

Figure 2: Infant Support Cushion-Related Non-fatal Reports by Year for Children 12 Months of Age or Younger: January 1, 2010–December 31, 2022.



Source: CPSRMS and NEISS databases.
Asterisks (*) indicate that reporting is ongoing for CPSRMS; the years 2021–2022 are considered incomplete.

Table 3 summarizes the number of reported non-fatal infant support cushion-related reports for victims 12 months and younger by month and gender. The reports in the non-fatal dataset are anecdotal and the reporting should be considered incomplete. Thus, the number of incidents identified should be considered a minimum.

Table 3: Infant Support Cushion-Related Non-fatal Reports for Victims Ages 12 Months and Younger by Month and Gender: January 1, 2010–December 31, 2022

Age Group (In Months)	Total (% of Total)	Male (% of Total)	Female (% of Total)	Unknown (% of Total)
Total	125 (100%)	27 (22%)	32 (26%)	66 (53%)
1	23 (18%)	10 (8%)	13 (10%)	0
2	12 (10%)	4 (3%)	6 (5%)	2 (2%)
3	5 (4%)	1 (1%)	3 (2%)	1 (1%)
4	8 (6%)	5 (4%)	3 (2%)	0
5	2 (2%)	1 (1%)	1 (1%)	0
6	3 (2%)	2 (2%)	1 (1%)	0
7	2 (2%)	0	2 (2%)	0
8	1 (1%)	0	1 (1%)	0
9	1 (1%)	0	1 (1%)	0
10	0	0	0	0
11	0	0	0	0
12	0	0	0	0
Unknown	68 (54%)	4 (3%)	1 (1%)	63 (50%)

Source: CPSRMS and NEISS databases.
Percentages may not add to 100 due to rounding.

Reporting is ongoing for CPSRMS; the years 2021–2022 are considered incomplete.

Table 4 provides a descriptive breakdown of the disposition of the infant support cushion-related non-fatal reports for Victims Ages 12 months and younger:

Table 4: Infant Support Cushion-Related Nonfatal Reports by Severity for Victims Ages 12 Months and Younger: January 1, 2010–December 31, 2022

Severity	Total Reports (% of Total)
Total Non-Fatal Reports	**125 (100%)**
Hospital Admissions	3 (2%)
Emergency Department Treated	22 (18%)
Left without being seen	1 (1%)
Seen by a Medical Professional	1 (1%)
Unspecified/Unknown	52 (42%)
No Injury	46 (37%)

Source: CPSRMS and NEISS databases.
Percentages may not add to 100 due to rounding.
Reporting is ongoing for CPSRMS; the years 2021–2022 are considered incomplete.

For the 46 reports that stated no injury occurred or provided no information about any injury, many of the descriptions indicated the potential for serious injury or even death.

Due to the self-reporting nature of the CPSRMS database, the descriptiveness and quality of incident narratives varied. Staff attempted to categorize the narratives to further analyze the reports. CPSC received 29 reports (23% of the total) of a victim being placed on various surfaces while on top of an infant support cushion and falling off, 27 reports involved a victim experiencing a scenario involving threatened asphyxia (22% of the total), and 17 reports that referenced a victim receiving various types of rashes from the product (14% of the total). Reports of limb entrapment, mold, choking, near strangulation, and vomiting all had one report each (1% of the total for each report). CPSC received 47 complaints (38% of the total) from consumers regarding infant support cushions in which no incident was clearly indicated. Table 5 illustrates the breakdown of non-fatal infant support cushion-related incidents by hazard pattern.

Table 5: Infant Support Cushion-Related Non-Fatal Reports by Hazard Pattern for Victims Ages 12 months and Younger: January 1, 2010–December 31, 2022

Event	Number of Non-Fatal Reports (% of Total
	Children (0 to 12 Months)
Fall	29 (23%)
Threatened Asphyxia	27 (22%)
Rash	17 (14%)
Limb Entrapment	1 (1%)
Mold	1 (1%)
Choking	1 (1%)
Near Strangulation	1 (1%)
Vomiting	1 (1%)
Consumer Complaints	47 (38%)
Total Non-Fatal Reports	**125 (100%)**

Source: CPSRMS and NEISS databases.
Percentages may not add to 100 due to rounding.
Reporting is ongoing for CPSRMS; the years 2021–2022 are considered incomplete.

TAB B: Health Science Staff's Assessment on Infant Pillow-Related Deaths, Injuries, and Potential Injuries

United States
Consumer Product Safety Commission

Memorandum

TO: Stefanie Marques, Infant Support Cushions Rulemaking Project Manager,
Directorate for Health Sciences

DATE: November 8, 2023

THROUGH: Mary Kelleher, Associate Executive Director
Directorate for Health Sciences

FROM: Ashley Johnson, Ph.D., Physiologist
Division of Pharmacology and Physiology Assessment,
Directorate for Health Sciences

SUBJECT: Health Science Staff's Assessment on Infant Support Cushion-Related Deaths, Injuries, and Potential Injuries

I. Introduction

In this memorandum, staff from the CPSC Directorate for Health Sciences (HS) provides an assessment and analysis on infant support cushion-related deaths, injuries, and potential injuries, including: a review of fatal and nonfatal incidents, the mechanisms and severity of injury associated with incidents, the hazard patterns associated with the use of infant support cushions, and a discussion of the most current medical literature pertaining to the pathophysiology of positional asphyxia.

II. Discussion

Directorate for Epidemiology (EPHA) staff conducted a search of CPSC databases[1] between January 1, 2010, and December 31, 2022, to identify incidents related to infant support cushions as defined in the draft proposed rule. This includes infant positioners, nursing products with dual use for lounging, infant loungers, and infant props or cushions marketed, designed, or intended to support an infant while reclining or lying in a supine, prone, or recumbent position. This does not include products intended to provide an infant sleep accommodation as defined by 16 C.F.R. part 1236 or products that exclusively support supervised nursing and feeding such as nursing products. Tab A contains information pertaining to data extraction criteria, scope of the data search, and tables/figures of reported fatal and nonfatal incidents (Smith, 2023). CPSC staff identified a total of 204 incidents associated with the use of infant support cushions. The data

[1] Data from NEISS are based on a nationally representative probability sample of approximately 100 hospitals in the United States and its territories. The NEISS reports capture one part of the treatment process (the emergency department visit), and typically do not show information on treatment after the initial visit.

CPSRMS is the epidemiological database that houses all anecdotal reports of incidents received by CPSC, "external cause"-based death certificates purchased by CPSC, all in-depth investigations of these anecdotal reports, as well as investigations of select NEISS injuries. Examples of documents in CPSRMS include the following: hotline reports, Internet reports, news reports, medical examiner's reports, death certificates, retailer/manufacturer reports, and documents sent by state/local authorities.

included 79 reported fatal incidents and 125 reported nonfatal incidents, including 22 emergency department-treated injuries, 3 hospital admissions, 1 visit to a medical provider, 1 victim that visited an ER and left without being seen, 46 reports where no injury occurred, and 52 reports with either an unknown or unspecified disposition.

Nonfatal incidents/reports

HS staff reviewed all 125 reported nonfatal incidents/reports associated with infant support cushions to identify the hazard patterns, including 22 emergency department-treated injuries, 3 hospital admissions, 1 visit to a medical provider, and 1 victim that visited an emergency department and left without being seen. The remaining 98 nonfatal incidents/reports either involved no injuries or the injuries and the level of care were not documented. The 125 nonfatal incidents/reports are further characterized in the epidemiology memorandum (Tab A, Smith, 2023). Products involved in nonfatal incidents/reports included loungers, large stuffed animal-shaped infant pillows, sleep positioners, wedges, tummy time pillows, and anti-flat head pillows. Where known, the average age of the infant was 2.7 months and at least 53 incidents/reports involved an infant under 6 months of age, a vulnerable age (see discussion below). Thirty-two (32) incidents/reports (26%) involved female victims, 27 incidents/reports (22%) involved male victims, and in 66 incidents/reports (53%) the gender was not known. Reports of nonfatal incidents/reports describe falls after being placed on infant support cushions (29 incidents, 23%); scenarios of threatened asphyxia after being placed on infant support cushions (27 incidents, 22%); various types of rashes received from infant support cushions (17 incidents, 14%); one report each (1%) of mold, choking, near strangulation, limb entrapment, and vomiting as a result of an infant pillow; and 47 consumer complaints (38%) about infant support cushions where no incident was clearly indicated.

Based on a review of nonfatal incident/report data, HS staff identified falls and threatened asphyxia as the two major nonfatal hazard patterns associated with infant support cushions.

1) *Falls*. Most reports did not specify the cause or manner of the fall, but infants and infant support cushions were placed on elevated surfaces in most fall incidents. These elevated surfaces included adult beds, bathroom and kitchen counters, chairs, tables (including kitchen tables, coffee tables, and side tables), and couches. In some incidents, infants were injured when they fell from the infant pillow onto the surface on which the pillow was placed. Injuries such as concussions, scalp injuries including hematomas and contusions, injuries to the face such as abrasions and lacerations, fractures, including skull fractures, and brain injuries can all result from falls.

2) *Threatened asphyxia*. The narratives describe scenarios of threatened asphyxia where victims were rescued after being found hanging partially off the infant pillow, completely off the infant pillow with mouth and nose obstructed, or with the infant's head wedged between the side cushions (in the case of sleep positioners). Infants were also found after sliding down into a vulnerable position on the infant pillow or after rolling to prone or unstable side positioning. Some narratives describe soft bedding, such as blankets and stuffed animals, that can be contributory causes to threatened asphyxia events.

Although most nonfatal incidents/reports did not report an injury, HS staff recognizes that infants placed on infant support cushions could potentially suffer injuries due to falls from elevated surfaces or injuries or death due to positional asphyxia/suffocation (see Discussion below).

Fatal Incidents

HS staff reviewed all 79 reported fatal incidents to identify the hazard patterns and the causes of death associated with infant support cushions. HS considered all available source documents from Injury or Potential Injury Incident (IPII) reports or from In-Depth Investigations (IDI), where available, including death scene investigations, police department incident reports, medical examiner (ME) reports, narratives from caregivers and witnesses, and death certificates. The official cause of death in all the fatal incidents was reported as asphyxia/probable asphyxia (49 incidents, 62%), sudden unexpected infant death (SUID) events (13 incidents, 17%), undetermined (12 incidents, 15%), or the official cause of death was not available at the time of writing this memorandum (5 incidents, 6%).

Determining an exact cause of death is difficult and sometimes not possible with the available information because of the nature of unwitnessed infant deaths. Autopsy findings in cases of asphyxia are commonly minimal and nonspecific. Other causes of death (natural and unnatural) must be excluded. Thus, in the absence of decisive findings, the pathological diagnosis of a medical examiner can include the medical history of the victim and the circumstances of the death, including the death scene investigation, in addition to a physical examination and/or autopsy (Polson and Gee, 1973; Spitz, 2006). Sudden unexpected infant death (SUID) is a term used to describe any sudden and unexpected death, whether explained or unexplained, occurring during the first 12 months of life. After case determination, the ME may rule that an unexpected infant death was caused by a specific natural cause, such as a preexisting condition, or accidental cause, such as positional asphyxia.

Positional asphyxia is a type of asphyxia associated with abnormal body position, where the position of the subject compromises adequate breathing (Chmieliauskas et al., 2018; Gordon and Shapiro, 1982; Gordon, 1975). Death is caused by body position that prevents adequate gas exchange or causes direct obstruction of the airways (e.g., smothering by an object) and by the failure or inability to move to another position. Unexpected infant deaths that cannot be explained and for which the cause cannot be determined are referred to as either sudden unexplained infant death (SUID), sudden infant death syndrome (SIDS), or undetermined/unknown. Because of the lack of diagnostic features/markers at autopsy, SIDS remains a diagnosis by exclusion and SUID is an umbrella term that may capture many different types of infant deaths. Considering the changes in definitions and guidelines, it is not surprising to find differences in the cause of death reporting by medical examiners (MEs) and coroners, a well-documented observance (Task Force on Infant Positioning and SIDS, 1996). Because there is no standardized method for the classification of asphyxia deaths among MEs/coroners, the terms “asphyxia” and “positional” can also be used differently by ME and Coroners.

Based on a review of incident data, HS staff identified positional asphyxia/suffocation as a fatal risk factor associated with infant support cushions. HS staff identified four major types of positional hazards associated with the use of infant support cushions (see below).[2] The victims ranged in age from 7 days old to 11 months old, with an average age of 2.5 months. Infants under 12 months old are at risk for positional asphyxia and sudden infant death syndrome (SIDS), with peak risk occurring when an infant is 2-6 months old. The victim was 6 months or younger in 74 fatal incidents (94%) and 3 months or younger in 64 fatal incidents (81%), a particularly vulnerable age bracket.

[2] In a subset of cases (14 cases, 18%), no hazard pattern was established due to unclear or unavailable reporting.

Infant support cushions involved in fatal incidents included loungers (63 incidents, 80%), large stuffed animal- shaped infant pillows (4 incidents, 5%), sleep positioners (10 incidents, 13%), a wedge (1 incident, 1%) and a small infant pillow (1 incident, 1%). In most incidents, the victim was placed on the infant pillow for extended, unsupervised sleep. This included both daytime naps and nighttime sleep. According to the narratives, infant support cushions were placed in infant sleep settings that included bassinets and bassinet portions of play yards (13 incidents, 16%), cribs (11 incidents, 14%), and play yards and non-full-sized cribs (8 incidents, 10%). Incident narratives also describe infant support cushions placed in non-infant sleep settings, including adult beds (34 incidents, 43%), couches or futons (3 incidents, 4%), an air mattress (1 incident, 1%), and a toddler bed (1 incident, 1%). The infant pillow was placed on the floor in 4 incidents (5%) and the placement was not known in 4 incidents (5%). Some incidents involved victims that were sharing the sleep setting with caregivers and/or siblings, a situation where the possibility of overlay or suffocation due to extraneous adult soft bedding can be a significant risk. Finally, the narratives describe scenarios of infants being placed to sleep on one or more items of soft, extraneous, bedding which poses an additional risk factor that may have contributed to the suffocation of the infant in some incidents.

Hazard patterns

1) *Use as an in-bed sleeper/bassinet to facilitate bedsharing.* HS staff identified 27 fatal incidents (34%) where the victims were sharing the sleep setting (an adult bed, a couch, or an air mattress) with caregivers and/or siblings. With or without the presence of an infant pillow, bedsharing with an infant exposes the infant to a potentially fatal asphyxia hazard by overlay or suffocation due to extraneous adult soft bedding (Fleming et.al., 2015; Nakamura, et.al., 1999; Tappin 2005). However, HS staff notes that many narratives specifically describe scenarios where the infant pillow was being used as an in-bed sleeper/bassinet to facilitate bed sharing (IDIs 211201HCC1442, 200917CCC3888, 200825HCC1839, as examples). As described above, because of the lack of pathological markers of asphyxia deaths at autopsy, determining an exact cause of death is difficult and sometimes not possible. Overlay deaths are frequently ruled as SUID associated with co-sleeping and unsafe sleeping conditions, or as SUID/Undetermined but noting that positional asphyxia due to overlay could not be ruled out. In fact, because of the complexity of overlay scenarios, infants were found in various positions including both prone (IDI 210831HCC1877, 210702HCC3238, 210916HCC1110, 210409CAA2585) and supine (IDI 220516HCC1623, 201026HCC1077, 200109CFE0001, 200917CCC2884) on the infant support cushions, partially off the infant pillow (IDI 211215HCC1519),entirely off the infant pillow (IDI 210428HCC3929, 200825HCC3806, 200917CCC3890, 200917CCC3888), and in some incidents, the found position of the infant was not described. In two incidents, the victims were found wedged. In IDI 201201HCC2106, the victim was found wedged between a wall and the mattress of an adult bed, and in IDI 210916HCC1096, the victim was found wedged between the side of an adult bed and a play yard. In incidents where the infant is wedged, depending on the circumstances of entrapment or wedging, the inversion of the upper body (in whole or part) interferes with normal respiration and circulation by compressing or flexing the torso to make breathing less effective; increases intrathoracic pressure and compression of the vena cava and carotid sinus (which changes blood distribution and reduces cardiac performance); and/or restricts the posture of the neck (hyperflexion or hyperextension) which can impede respiratory movements and lead to airway obstruction (Byard et al., 1994; Fleming et al., 1993; Gioia et al., 2020). Sustained pressure on the neck by the weight of the

mattress can lead to asphyxia by strangulation (Alston et al., 2021; Matshes et al., 2017).

2) *Neck Hyperextension*. HS staff identified 2 fatal incidents (3%) where the victim's neck was hyperextended. In one incident, the victim was found to have moved further up the infant pillow, with the victim's head off the pillow and now on a comforter and the victim's body remaining on the pillow (IDI 201016HCC1043). In the second incident, the victim partially rolled off the infant pillow and was found hyperextended, with his head over the back of the pillow (IDI 211215HCC1519). Neck hyperextension can result if an infant's unsupported head is tilted backwards over the top of the product. Sustained neck hyperextension restricts the posture of the neck and, where the head is below level of the infant's heart, impedes respiratory movements and can lead to oxygen desaturation and death (Byard et al., 1994; Fleming et al., 1993; Gioia et al., 2020).

3) *Rolling off product into hazardous setting.* Excluding the bedsharing incidents in which infants were found to have rolled or been otherwise moved as a result of overlay from the infant pillow, HS staff identified 14 fatal incidents (18%) where an infant rolled from the infant pillow into a hazardous setting. In 3 incidents, victims rolled from infant support cushions that had been placed on adult beds and became wedged. In one incident (IDI 10712HCC3276), the victim was found wedged between an adult bed and the wall. In a second incident, (IDI 200527HCC3540), the victim was found wedged between the footboard and mattress of the bed. In the third incident, (IDI 201103CCC2070), the victim's head was entrapped in a prone position between the edge of the bed and the wall in a 3-inch gap. When infant support cushions are placed in infant sleep settings, victims have been found entrapped between an infant pillow and the side of a crib with soft bedding contributing to entrapment (IDI 100810HWE2299), entrapped between infant support cushions and the side walls of bassinets (ID 110822CCC1939 and 200917CCC2883), and entrapped between infant support cushions and the side wall of a play yard (IDI 140827CCC3866). In other incidents, the victims rolled from infant support cushions and were found prone on other soft bedding in sleep settings (200825HCC2807 and 220926HCC1616, as examples). In 2 incidents, the victims slid down off the infant support cushions and remained supine but asphyxiated with their noses and mouths against adult pillows (IDI 200917CCC3891, 20926HCC1621). Clutter and extra bedding were visible in scene photographs from most of the incidents or described in the IDI narratives. If an infant is placed on an infant pillow and rolls off onto a surface where extraneous bedding or other soft items are located, this can lead to increased risk of suffocation through occlusion of the mouth and nose by the soft items. Occlusion of the nose and mouth by a pillow or other bedding can lead to suffocation.

4) *Remaining on product with nose and mouth occluded.* Excluding the bedsharing incidents where the infant was found to have remained on the infant pillow, HS staff identified at least 23 fatal incidents (29%) where the victim was found still on the infant pillow, with their nose and mouth occluded. According to the narratives, infants were typically placed supine or on their right or left side, an unstable infant position. The victims were found prone on the infant support cushions with their noses and mouths occluded by the infant pillow itself or by the infant pillow and/or other soft bedding present in the sleep setting (such as blankets) (IDI 101027CAA2082, 140903CBB1914, 200924CAA2899, 160310HFE0002, as examples. Infants can unexpectedly roll into a prone position on the infant pillow and be unable to reverse

action and extract themselves from a hazardous situation because either the soft infant pillow prevents it, or the infant was physically incapable of rolling back. If the nose and mouth are occluded in any scenario either against the soft infant pillow itself or other soft bedding in the sleep setting, it may lead to asphyxia. An infant can suffocate/asphyxiate against any object that partially or fully obstructs the nose and mouth and prevents breathing (Wanna-Nakamura, 2010). Obstruction of the airway can lead to unconsciousness in 30-180 seconds, and death as a result of asphyxia can occur in as little as 3 minutes.

Pathophysiology of Positional Asphyxia and Injury Mechanism Analysis

Infants differ greatly in their developmental skills in their first year of life. Unlike healthy adults, the limited physical and developmental capabilities of infants render them susceptible to asphyxiation in certain sleep settings. The American Academy of Pediatrics (AAP) recommends that infants be placed to sleep in a supine position and that soft bedding be avoided in the sleep setting (Moon et al., 2022). While all infants younger than 12 months of age are considered at risk of positional asphyxia, infants 2-6 months of age, premature infants, and infants who are born as a set of multiples are particularly vulnerable and are at the highest risk primarily due to physical inability and an immature physiological system that regulates breathing and arousal in the first few months of life. Physiological abnormalities and delays in the development of vital systems can further hamper an infant's ability to react to a hazardous sleep setting, such as arousing when air supply to the lungs is compromised. This age group is at risk for suffocation and sudden infant death syndrome (SIDS), which is thought to occur when an infant with an underlying biological vulnerability, who is at a critical development age, is exposed to an external trigger, such as an unsafe sleep setting (Dwyer et al., 1995; Byard et al., 1994; Fleming et al., 1993; Hauck et al., 2003; Ponsonby et al., 1993; Smialek et al., 1977).

Once an infant's airflow is compromised, decreased levels of oxygen in the blood can further impair the ability of the infant to respond to the situation. If an infant cannot respond, a feedback loop of decreased heart and respiration rate develops that can eventually lead to cessation of breathing and may become fatal if uninterrupted. Once an infant becomes hypoxic (a state of low levels of oxygen in body tissues) due to smothering, the prognosis depends primarily on the extent of oxygen deprivation, the duration of unconsciousness, and the speed of resuscitation. Rapid reversal of the infant's hypoxic state is essential to prevent or limit the development of pulmonary and cerebral edema, and the rapidity of this reversal ultimately predicts the patient's clinical prognosis (Dzikienė et al, 2021; Jongewaard et al, 1992; Medalia et al., 1991; van Handel et al., 2007). Thus, victims who are oxygen deprived for short durations or quickly receive cardiopulmonary resuscitation to reestablish air flow have the most favorable clinical outcomes. Because these types of wedging incidents and asphyxiations due to soft bedding often happen while an infant has been left alone to sleep on infant support cushions, while not under immediate supervision of a caregiver, the likelihood of the caregiver becoming aware of the event and rescuing the child is often low.

III. Conclusions

HS staff reviewed data on infant support cushion-related deaths, injuries, and potential injuries, including fatal and nonfatal incidents, the mechanism and severity of injury associated with the incidents, the hazard patterns associated with the use of infant support cushions, and the most current medical literature pertaining to the pathophysiology of positional asphyxia. HS staff identified positional asphyxia/suffocation as a health hazard associated with infant support cushions. A primary contributing factor to infant fatality appears to be when infant support

cushions are used for extended, unsupervised rest or sleep on an adult bed or in an infant sleep setting such as a crib, bassinet, or play yard. Other contributing factors staff noted from the narratives included an infant's prematurity, being a twin or other multiple, small size for age of infant, recent respiratory illnesses, the presence of extraneous soft bedding (which can create additional suffocation hazards that are contributory), cluttered sleep settings, bedsharing (risk of overlay), and infant positioning other than supine. Infants should be placed to sleep in a supine position on a firm, flat, level surface without soft bedding in the sleep setting according to the AAP. While all infants under 12 months of age are at high risk from positional asphyxia, infants two to six months of age are at particular risk because they may be developmentally capable of moving around in the sleep environment and moving into a vulnerable situation that can put them at risk of suffocation but not yet have the physical capability to extricate themselves from a hazardous situation.

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TAB C: Staff Recommended Performance Requirements for the Notice of Proposed Rulemaking for Infant Support Cushions

United States
Consumer Product Safety Commission

Memorandum

TO: Stefanie Marques, Ph.D., Supervisory Scientist
Division of Pharmacology and Physiology Assessment,
Directorate for Health Sciences

DATE: November 8, 2023

THROUGH: Andrew G. Stadnik, P.E., Associate Executive Director
Directorate for Laboratory Sciences

Michael Nelson, Director,
Division of Mechanical Engineering,
Directorate for Laboratory Sciences

FROM: Mark Eilbert, Mechanical Engineer
Division of Mechanical Engineering,
Directorate for Laboratory Sciences

SUBJECT: Staff Recommended Performance Requirements for the Notice of Proposed Rulemaking for Infant Support Cushions

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I. Introduction

The U.S. Consumer Product Safety Commission (CPSC) directed staff to prepare a Notice of Proposed Rulemaking (NPR) for infant support cushions, which are defined in the draft proposed rule, under section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA).

The ASTM F15.21 Infant Loungers Subcommittee (ASTM Loungers Subcommittee) has been developing a voluntary standard for infant loungers[1]. The ASTM Subcommittee, with input from CPSC staff, has drafted firmness requirements for the occupant support surface (OSS), the top of the sidewall, and the intersection of sidewall and OSS, and other requirements in order to reduce the likelihood that an infant could suffocate from the product conforming to the face, staff proposes firmness and dimensional requirements to address suffocation within the product and asphyxia hazards identified in the Directorate for Health Sciences, Division of Pharmacology and Physiology Assessment memorandum (Tab B) and based partially on the ASTM subcommittee draft standard. This memorandum describes the process CPSC staff used in developing general and performance requirements for infant support cushions, including the use of infant loungers and head pillows in sample product testing.

[1] Draft Standard for Infant Loungers v2 2023, The most recent update was April 16, 2023.

II. Background

Figure 1 shows the types of support cushions used for testing and analyses for this NPR.

Infant Loungers

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Flat-Head Preventing Pillows

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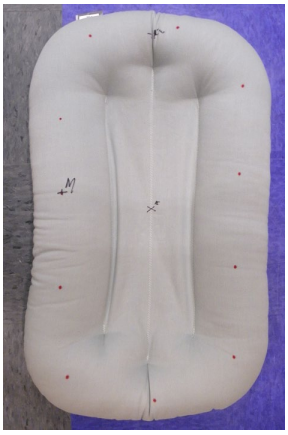

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Figure 1 Test Samples

At least one manufacturer of infant loungers claims to have tested to the firmness test method in British Standard BS 4578 (1970) Test for Hardness of and for Air Flow Through Infant Pillows.[2] The British standard requires that a pillow shall not deflect more than 25% of the thickness at rest when tested with a probe under a 10 N (2.2 lb) force. Due to this 25% proportionality requirement, the requirement allows thicker pillows more absolute deflection than thinner pillows.

Boise State University (BSU), under contract with CPSC[3], published a report describing a performance requirement and test method for the firmness of infant support products, including flat-head-preventing pillows and loungers. The test requires that a 3-in (7.6 cm) diameter hemispherical probe ("3-in probe") must require a force greater than 10 N (2.2 lb) to deflect into the product 1.0 in (2.5 cm). The BSU report describes the probe's size and shape as based on infant head dimensions and the applied 10 N force as approximately the weight of an infant's head. Figure 2 shows the BSU 3-in. head probe. BSU did not specify a length for the probe.

In development work, BSU assessed the firmness tests in BS 4578 and in AS/NZS 8811.1[4]. BSU rejected the BS 4578 test method because the flat face of the probe did not represent the suffocation risk of a more realistic three-dimensional probe. Staff, moreover, are aware of fatal incidents due to facial occlusion. Staff therefore assess that the BS 4578 is not adequate to address the facial occlusion hazard for infant support cushions.

BSU established that crib mattresses exhibited a safe level of firmness because they complied with mattress testing in AS/NZS 8811.1. In BSU's testing, those mattresses also deflected less than 1.0 in (2.5 cm) with the 3-in head probe test. Thus, BSU established a 1.0 in (2.5 cm) deflection as a safe limit for infant lounger and head pillows. Tests on lounger and head pillow products (Figure 2) indicate that some of the test locations on these products complied, but that none fully complied. The BSU recommendation is that "[t]he force required for this 1-in (2.5 cm) displacement should be >10 N (2.2 lb) to pass the firmness test." The BSU testing was conducted with a vertical test fixture applied to generally horizontal product surfaces. Nevertheless, the test method can be adapted to other test orientations.

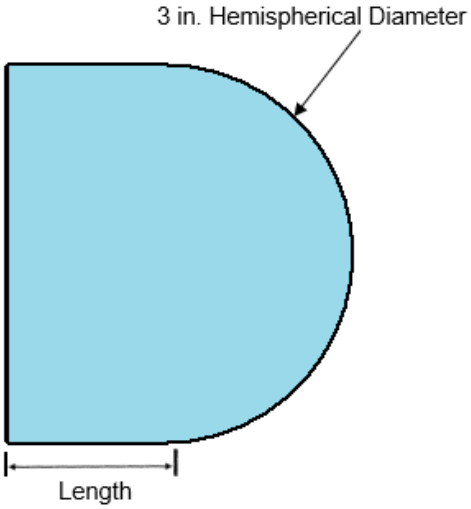

Figure 2. 3-in. Head probe

[2] The requirements associated with the BS 4578 test method are in BS 1877-8 (1974) Domestic Bedding.
[3] Mannen, E. M., Davis, W., Goldrod, S., Lujan, T., Siddicky, S. F., Whitaker, B., & Carroll, J. (2022). *Pillows Product Characterization and Testing*. Prepared for the U.S. Consumer Product Safety Commission under contract no. 61320620D0002, task order no. 61320621F1015. Available: https://www.cpsc.gov/content/Pillows-Product-Characterization-and-Testing.
[4] AS/NZS 8811.1:2013 Methods of testing infant products Method 1: Sleep surfaces—Test for firmness

III. Discussion

For the NPR, CPSC staff recommend using the firmness requirements and test developed by BSU and incorporating language, amended by staff, that ASTM F15.21 Infant Loungers Performance Task Group ("ASTM TG") drafted for firmness and dimensional requirements and test methods for infant loungers and infant support cushions. These requirements and test methods address the contributions to the suffocation hazards described in the incident review by staff that are attributable to the involved infant lounger and cushion products. CPSC staff discussed firmness and dimensional requirements with the ASTM TG in meetings from August 2022 to January 2023. ASTM drafted requirements to reduce the likelihood that the products could obstruct an infant's face and cause suffocation. The consensus was to require a minimum firmness for the occupant support surface, the top of sidewalls, and the intersection of sidewall and occupant support surfaces, as well as sidewall height, sidewall angle, and maximum incline angle requirements. An ASTM standard has not yet been balloted for infant loungers. Below, staff discuss requirements and test methods for firmness, sidewall height and angle, and maximum incline angle and provide recommendations for the draft proposed rule.

A. Discussions of Staff Proposals for Requirements and Test Methods

i. Firmness

CPSC staff fabricated test fixtures and conducted testing on a sampling of infant cushion products (Figure 1) to evaluate the BSU test method. Staff included adjustable fixturing such that the probe can be orientated perpendicular to the product surface, including the occupant support surface (OSS), the top of sidewalls, and the intersection of OSS and sidewalls. Staff evaluated the BSU test method (Figure 3) in which a 3-in. head probe is lowered vertically down such that a 0 to 10 N force is applied to the test surface of an infant cushion, such that the force can be measured at the point that the deflection equals 1.0 in. If the measured force is 10 N or less at the 1.0 in. deflection, the test location fails the test. If a 1.0 in. deflection won't be reached due to the firmness of the product, the probe can be advanced further in a similar manner until the force exceeds 10 N and the deflection is less than or equal to 1.0 in., in which case the test location passes the test. Specific firmness tests for the occupant support surface (OSS), the top of sidewalls, and the intersection of OSS and sidewalls will be discussed, including orientations of the 3-in head probe for each test surface.

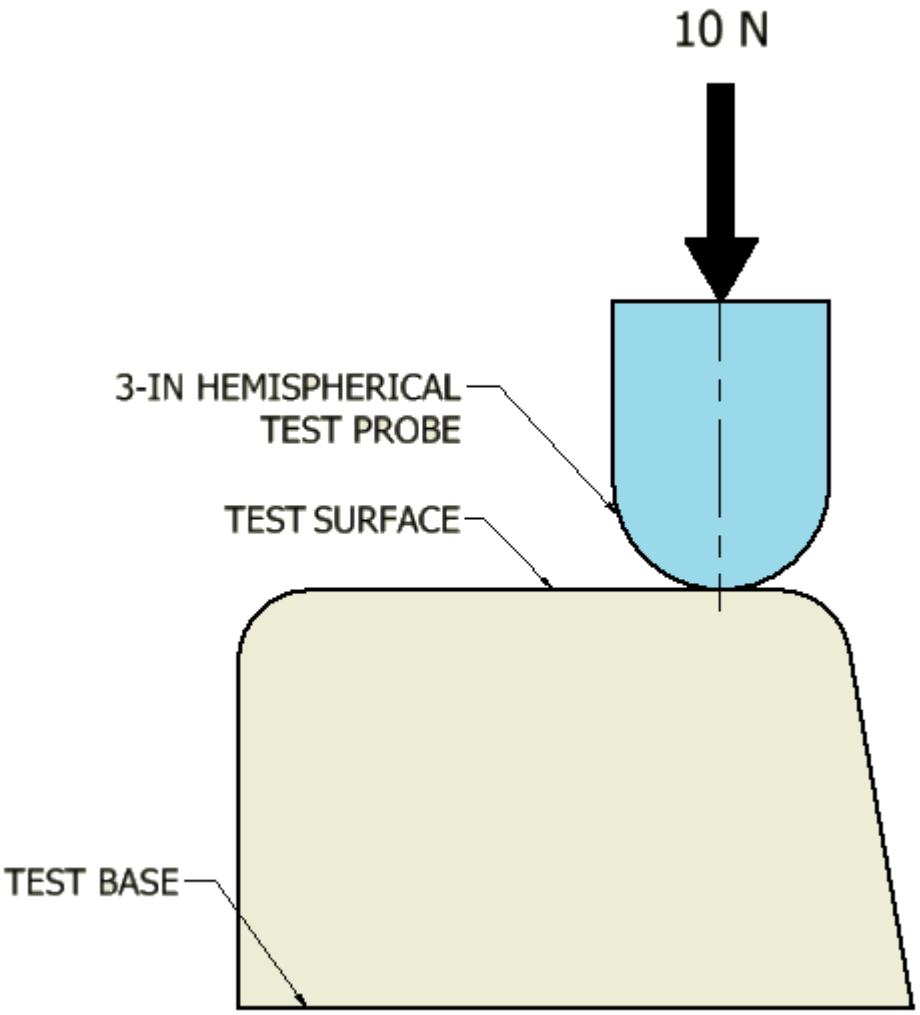

Figure 3 BSU Test Configuration for Firmness Tests

Figure 4 depicts the results of two exemplary tests that show passing and failing the recommended firmness test. Testing begins at a nominally zero deflection and force. Testing continues until either the 1.0 in. deflection is reached before the force exceeds 10 N (red failure), or the 10 N force is exceeded before the 1.0 in. deflection is reached (bright green pass).

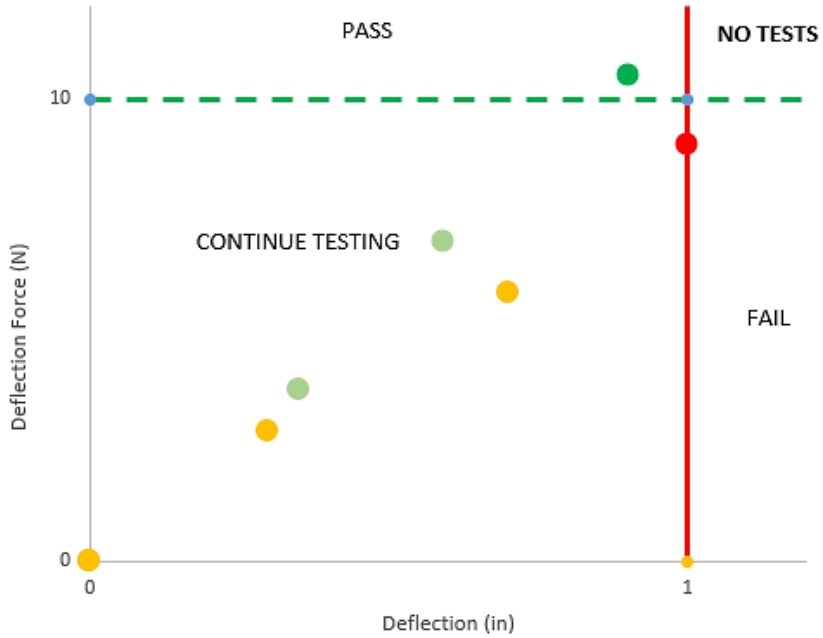

Figure 4. General Firmness Test, Force versus Deflection

The ASTM firmness requirements and test methods are influenced by the BSU recommended firmness test. In the ASTM sidewall and the intersection of sidewall and OSS firmness tests, the displacement shall not be equal to or greater than 1.0 in when a 10 N force is applied with a 3-in (7.62 cm) hemispherical probe. Tests are conducted at 6 in-intervals around the product. An important difference in the two test methods is that the ASTM requirement has a deflection limit and a test method that applies a fixed force, while the BSU requirement has a force limit and a test method that applies a fixed deflection. A lead screw advances the probe in the BSU test, and the force measurement is taken after at 1 minute time delay. The time delay is included in the BSU test method to allow the material to "relax" to a stable reading. How ASTM applies the force is not stated, however, the deflection is measured when the force is applied, so the force should be applied quickly. Staff assesses that the time delay required by the BSU method increases the repeatability of the test measurements, and that not specifying the method with which force is applied or including a time delay in the ASTM test method can cause issues with repeatability of test results. Staff recommends the BSU test method because it accounts for the downward decay of test forces, and the lead screw enables precise control of deflection.

Staff recommends the BSU firmness test, with modifications that add certain procedural steps to improve the infant cushion firmness test method. In the BSU test method, the force is allowed to stabilize for approximately 1 minute prior to measuring the final force at the 1.0 in. deflection. Through infant lounger testing, staff determined that a 30-s. stabilization period is sufficient to bring changes in the force measurement, which is still slightly decreasing after 30 s., to within an accuracy of 0.05 N (0.01 lb) at the deflection of 1.00 in. (2.54 cm), deflection measured to an accuracy of 0.03 in. (0.08 cm). Staff assesses that these force and deflection accuracies are reasonable goals given the nature of measuring force and distance with a soft product such as the infant cushion. In other procedural steps, staff recommends that the firmness test method

include a rate of approach for the probe of 1 in. per 10 s. and a waiting period between successive tests of 5 minutes if adjacent locations are within 3 in., including successive trials at the same location. The total duration of a test would combine the total time of the rate of approach (10 s.) and the stability period (30 s.), resulting in 40 s. The purpose for the approach rate and stabilization and waiting periods is to improve repeatability and reproducibility. Staff recommends these and additional testing procedures be applied to firmness tests for the occupant support surface (OSS), the top of sidewalls, and the intersection of the OSS and sidewall of infant cushion products.

Staff recommends that these testing procedures be included in the firmness test method:

Test sample conditioning.

- Precondition the product to a standard indoor temperature. Staff recommends the product should be conditioned for 48 hours at 23 °C +/- 2 °C (73.4 °F +/- 3.6 °F) and a relative humidity of 50 % +/- 5 %[5] and those conditions be maintained throughout testing. The time duration is reasonable for the typically thick infant cushion products to acclimate prior to firmness testing.

- Perform tests with products as received and after laundering and drying according to the manufacturer's instructions. Washing and drying can change the properties of products, including the firmness at specific locations following the removal and installation of a fitted cover.

Test locations on product.

- Perform tests in all intended or feasible product configurations and orientations. An example of a product orientation that is intended is a top occupant support surface identified by the manufacturer. A feasible orientation can be the opposite side from the intended when the two sides can be considered to have equal firmness. Product configurations include those that present distinct firmness such as by folding or by layering of component pieces.

- Allow some discretion in selecting testing locations. Experienced test personnel can assess which location(s) may present lower firmness measurements based on judgements on factors such as product design or changes from laundering.

Test repeatability and reproducibility.

- Specify the rigidity of the test fixture when secured to a base support to reduce movement that could affect the force or deflection measurement. Staff recommends that a force of 10 N (2.2 lb), the required force in the firmness tests, when applied to the test probe should not cause a measured deflection of greater than 0.01 in. (0.03 cm). This equipment requirement will limit the measurement error due to flexing of the test fixturing to a reasonable 1 % of full scale, that is 0.01 in divided by the 1.00 in. (2.54 cm) test method deflection.

[5] Pre-conditioning specified in AS NZS 8811.1 (2013) *Methods of testing infant products Method 1 Sleep surfaces Test for firmness*.

- Specify that the product should be secured to prevent movement that could affect test results. Firmness tests will compress the test surface and measurement of the deflection of that surface should not be affected by shifting or rotation of the product.

- Use a method to advance and hold precise deflection prior to force measurements. Staff recommends that the test probe be advanced by a lead screw or similar devices or fixturing that can adjust and hold position along a single direction.

- Base the zero reference on the product to begin the deflection measurement on a small initial force rather than by visual inspection. Staff recommends that the deflection be zero at an initial force of 0.1 N, which agrees with the BSU method.

- Specify a maximum rate of travel for the probe into the product. As discussed, staff recommends a rate of 0.1 in per second.

- Specify a time delay prior to the force measurement at each location to allow the material changes to stabilize. As discussed, staff recommends a 30 s. delay.

Testing Burden.

- Allow fewer test locations in areas in which the thickness is 1.0 in. or less. Staff assesses by inspection that deflection testing to a requirement of 1.0 in. is inconsequential at locations with product thicknesses of 1.0 inch or less. Staff recommends that only one firmness test location should be required if the test surface has a homogeneous 1.0 in. thickness or less.

ii. Testing Orientations

The ASTM Subcommittee's definition for occupant support surface (OSS) is "the area that holds up and bears the infant or any portion of the infant." The OSS for infant loungers provides both support for the infant's body and head. Some infant support cushions provide head support, while the infant's body rests on some surface outside the product. The OSS is represented as a reference in four ASTM draft test methods. ASTM derived a firmness test method from the firmness method for mattresses in the AS/NZS 8811.1 standard, in which the deflection from the weight of an 8-in (20.3 cm) diameter probe is used to gauge deflection. The ASTM method places the 8-in probe on the OSS and allows it to "level," which assumes the OSS is a horizontal reference. Similarly, in measuring side height, a 6 in by 6 in (15.2 cm by 15.2 cm) aluminum plate is placed on the OSS as reference for a vertical height measurement, which again assumes a horizontal OSS. In the angle measurement between sidewall and OSS and in the angle specified for the firmness test for the intersection of sidewall and OSS, the OSS is assumed to be a flat plane, but not horizontal. In all four of these test methods, the OSS is assumed to be a flat plane and used as a reference.

On inspection of infant lounger/pillow samples (shown in Figure 1), staff considers the OSS of samples 220, 230, and 410 to be approximately horizontal and planar when laid down on a similar surface (e.g., tabletop). In the remaining samples, the OSS is formed into a curved form, such as with button-like stitching (samples 240, 250, 260, 270, 280, 310), or the OSS is a thin, flexible fabric that is stretched between sidewalls (sample 400). The OSS's of the CPSC

samples are, in general, neither planar nor horizontal. Thus, the four test methods described do not completely address these designs.

To simplify and clarify the determination of the OSS orientation for the test methods for loungers and infant support cushions, staff proposes to conduct the recommended OSS firmness and sidewall firmness tests and measurements of loungers/support cushions vertically if the OSS surface is on average equal or less than 5 degrees from horizontal and to conduct tests and measurements perpendicular to the OSS surface if than greater than 5 degrees. The purpose for this 5-degree allowance at test locations is to avoid unnecessary equipment adjustments and variations in test orientations that can affect test repeatability and reproducibility among test laboratories. Staff assesses that the difference between the deflection and force measurements conducted perpendicular to a 5-degree surface and vertical to that surface, as recommended, is less than 0.5 percent[6], which is not a deviation expected to affect results.

iii. Occupant Support Surface (OSS) Firmness

The firmness of the OSS is most critical at each location where an infant's face may make contact. A test for firmness should be designed to apply to all those locations. In the ASTM requirement for OSS firmness, the feeler arm outside the edge of an 8-in (20.3 cm) diameter "firmometer" probe must not contact the OSS. The 8-in diameter size of the "firmometer" was not intended to represent the form of any part of a child's body. ASTM specifies three test locations in terms of the major axis of the product. Among the infant loungers and support cushion samples tested by CPSC, staff finds that the ASTM firmometer is larger than the area of most OSS's and, for the circular-shaped sample loungers (240, 250, 260, 270, 280), contact with the "feeler arm" is outside the OSS. For those samples, the ASTM OSS firmness test does not give results for the OSS, which is the surface firmness that section of the standard seeks to test. For example, in Figure 5 the feeler gauge on the 8-in probe contacts the sidewall of sample 240, and not the OSS. Additionally, staff assessed through testing that certain OSS features, such as deep dimples created by stitch patterns, that could create suffocation hazards are masked by the size of the 8-in wide probe. The 3-in head probe, however, has a size and shape that more closely approximates an infant's head/face and can reach areas of an OSS the firmometer cannot. Firmness measurements with that probe would also be consistent with those in both the sidewall and the intersection of the sidewall and OSS firmness test methods. Staff recommends that the 3-in head probe firmness requirement and test method be used to measure firmness of the OSS. Figure 6 shows the recommended test: a 10 N load applied to a 3-in. head probe directed at the OSS. In addition, staff recommends modifications to the test locations. To address all areas of the OSS, the number of tests performed should be commensurate with the size of the OSS and, because firmness variations do not align with prescribed test locations, testing should include at least one location most likely to fail. Staff inspected one sample that had an OSS thickness of less than 1 in and concluded that compliance to a 1.0-in (2.54 cm) firmness requirement could be satisfied with a reduced testing requirement. Staff recommends that products with an OSS with all areas less than a 1-in thickness may be tested at a single representative location.

[6]Cosine (5 degree) = 0.996, such that the force and deflection in a vertical direction on a 5-degree surface is mathematically 0.4 % less than that of a perpendicular test to the same surface.

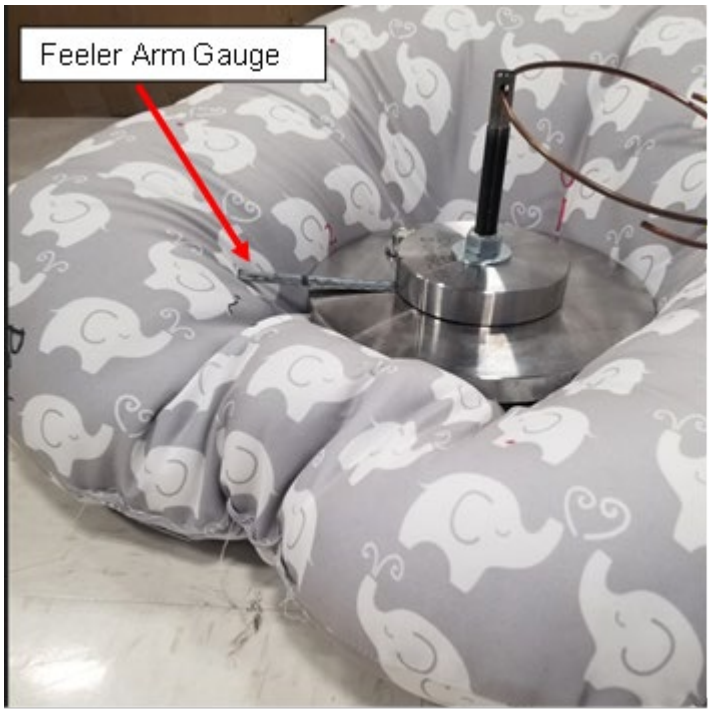

Figure 5. ASTM OSS Test with 8-in Diameter Probe, Sample 240

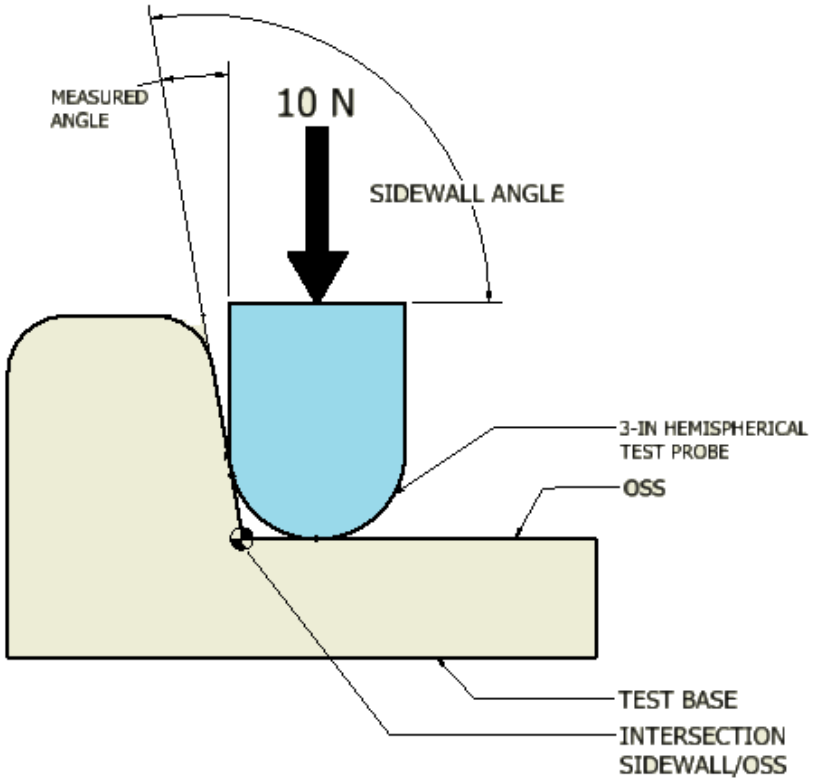

Figure 6. Test Fixture Configuration for Occupant Support Surface Firmness and Sidewall Angle Measurement

iv. Sidewall Firmness

An infant's head or face may rest on the sidewall of the product. Because the sidewall is distinct from the OSS, a separate sidewall firmness test is necessary to address its dimensions and extents. The ASTM sidewall firmness test requires that the deflection shall not be equal to or greater than 1.0 in when a 10 N force is applied with a 3-in (7.62 cm) hemispherical probe. directed downwards on top of the sidewall, with testing conducted in 6-in increments around the product. Consistent with the General Firmness Test Method, staff recommends a sidewall firmness requirement in which the force required for a 1.0-in (2.54 cm) displacement should be greater than 10 N (2.2 lb). To accommodate smaller head pillows and larger lounger products, staff recommends a minimum of four sidewall firmness tests should be conducted, starting at a test location of maximum sidewall height, and at intervals not to exceed 6 in (15.2 cm). In addition, staff recommends that the test locations include at least one location most likely to fail.

v. Intersection of Sidewall and Occupant Support Surface Firmness

This firmness test is intended to address hazards of suffocation in infant cushion products due to the presence of a sidewall adjacent to an OSS. In the transition from OSS to sidewall, where parts join, sharply transition, or overlay other parts and that can form internal or concave surfaces, the face of the infant can contact multiple surfaces simultaneously. The draft ASTM requirement for deflection at the intersection where a sidewall and OSS meet requires that the deflection must not be equal to or greater than 1.0 in (2.54 cm) when a 10 N (2.2 lb) force is applied through a 3-in (7.62 cm) diameter hemispheric probe directed at an angle to that intersection that bisects the angle between the OSS and the sidewall. Figure 7. Tests are conducted every 6 in (15.2 cm) along the edge where the OSS and the sidewall intersect. For CPSC samples, that intersection for the two rectangular loungers (samples 400, 410) and for the flat head preventing pillows (samples 220, 230) is between a sidewall and OSS that transition with distinctive angle changes. For the remaining loungers (samples 240, 250, 260, 270, 280, 310), that intersection is a curved transition between a thicker outside perimeter and the recess of an occupant support. To reduce the hazard of suffocation between sidewalls and the OSS, staff recommends, consistent with all recommended firmness tests, that the force required for a 1.0-inch displacement should be greater than 10 N (2.2 lb). To accommodate smaller head cushions and larger lounger products, staff recommends a minimum of four sidewall firmness tests should be conducted, starting at a test location of maximum sidewall height, and at intervals not to exceed 6 in (15.2 cm). In addition, staff recommends that the test locations include at least one location most likely to fail.

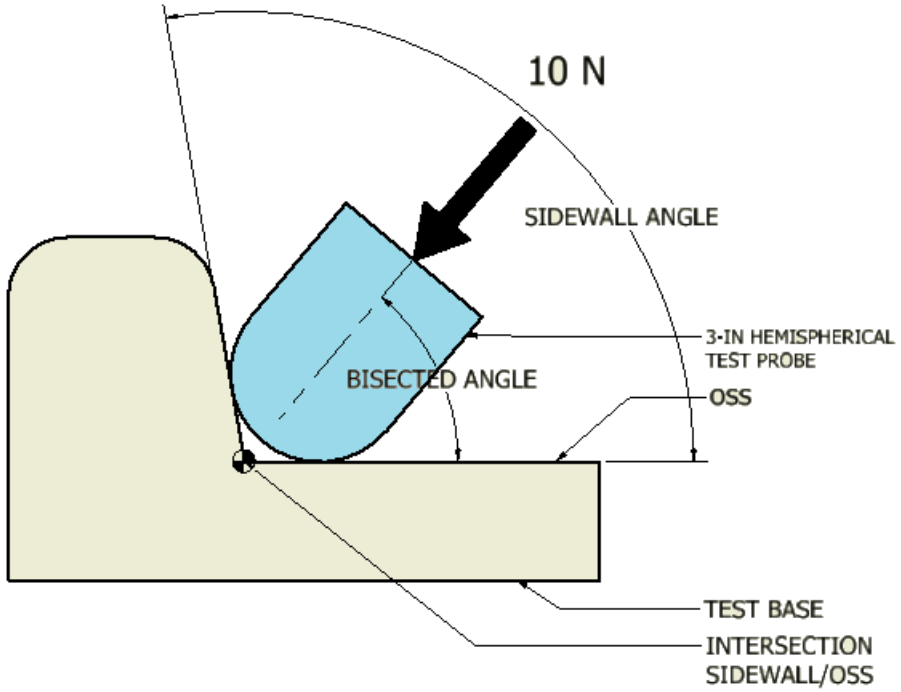

Figure 7. Test Configuration for Intersection of Sidewall and Occupant Support Surface Firmness

The locations ASTM determined for several tests and measurements reference the edge or intersection of the OSS and sidewall. ASTM locates the measurement for sidewall height "next to the sidewall," and the sidewall angle measurement and a firmness test at the "intersection of the sidewall and the occupant support surface." On inspection of CPSC samples, staff finds that the transition from an inner infant support surface to an outer raised surface (e.g., sidewall) has various defining features. The rectangular loungers (400, 410) have continuously sewn perimeters at the intersection between the much thinner OSS and the raised sidewall. Flathead preventing pillows (220, 230), have a center depression to provide head support and have a distinct intersection of sidewall and OSS. In the remaining CPSC samples (240, 250, 260, 270, 280, 310), which are circular in basic shape, the OSS is a depression bordered by a series of button-like stitches. The "buttons" clearly mark the OSS border, but the fabric between the buttons is continuous with no true intersection of OSS and sidewall. Locating the intersection or transition from sidewall to OSS will be a challenge in some products. Figure 8 shows the firmness probe aligned approximately to the intersection (dashed red lines) between the raised side (i.e., sidewall) and the OSS in sample 250. Because this transition varies among products, staff does not have a recommendation for a method to determine the exact intersection of the sidewall to OSS. For some CPSC samples, the OSS intersection was obviously at a stitching, but for others it was an inexact, virtual intersection. However, because staff also recommends firmness requirements for sidewalls and occupant support surfaces, which are adjacent to this firmness test for the intersection of sidewall and occupant support surfaces (OSS), the three firmness tests (sidewall, intersection, and OSS) will adequately cover the firmness of the product in representative locations, including products with variable transitions between the sidewall and OSS. Staff therefore recommends that "intersection" adequately describes the transition

between the sidewall and OSS and the exact test locations should be left to the judgement of the testing laboratory

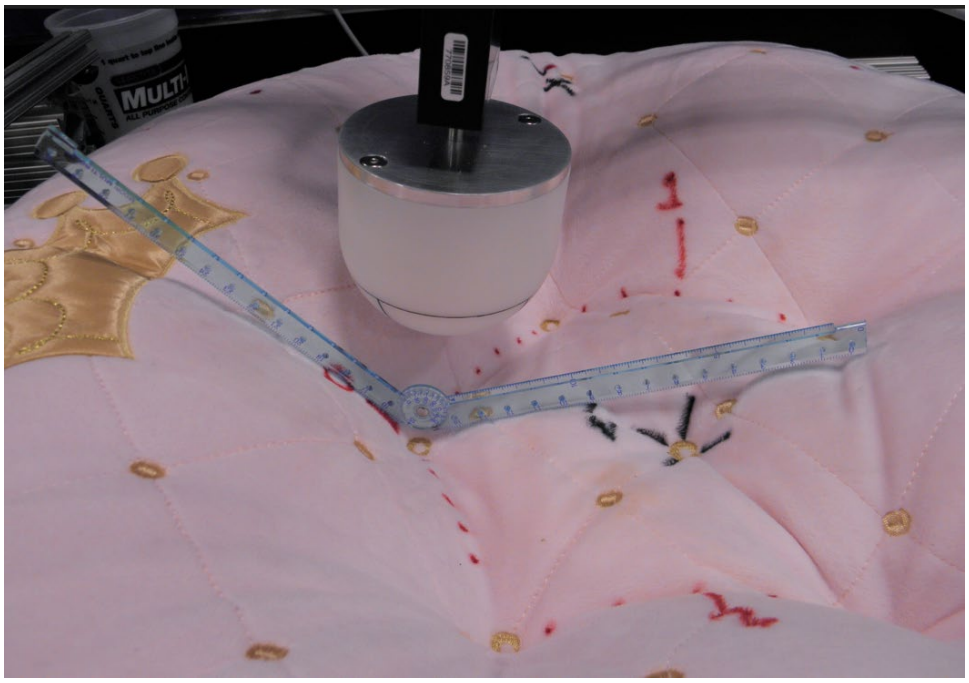

Figure 8 Firmness Probe at Intersection of Sidewall and OSS, Sample 250

vi. Maximum Incline Angle

Positional asphyxia and hazardous positioning of an infant's head and neck that can be caused by inclined sleep, are discussed in the Directorate for Health Sciences, Division of Pharmacology and Physiology Assessment memorandum. The Infant Sleep Products Rule (ISP Rule) has a requirement, Maximum Seat Back/Sleep Surface Angle, for infants up to 5 months of age, that provides for infant sleep products, "The angle of the seat back/sleep surface intended for sleep along the occupant's head to toe axis relative to the horizontal shall not exceed 10 degrees tested in accordance with 7.11.2". The referenced test method requires:

- If applicable, place the product in the manufacturer's recommended highest seat back/sleep surface angle position intended for sleep.
- Place the hinged weight gauge-infant[7] in the product and position the gauge with the hinge centered over the seat bight line and the upper plate of the gauge on the seat back/sleep surface. Place a digital protractor on the upper torso/head area lengthwise.

The draft ASTM performance requirements includes a similar section entitled "Maximum Seat back Angle", which requires that the angle of the seat back along the head-to-toe axis relative to the horizontal shall not exceed 10 degrees when tested with the infant hinged weight gauge. The

[7] A two-part, hinged, metal gauge to represent the approximate form and weight of an infant when lying prostate or supine. This gauge is used in several ASTM infant safety standards.

product is placed into the highest of the manufacturer's recommended seat back angle position that is intended for lounging. The infant hinged weight gauge is positioned with the hinge aligned over the seat bight line[8] and with the upper torso/head plate of the gauge on the seat back. The angle is measured with a digital protractor resting on the upper gauge area. The draft ASTM "Maximum Seat back Angle" is intended for lounging while the ISP "Maximum Seat Back/Sleep Surface Angle" is intended for sleep. As discussed in the Directorate for Engineering Sciences, Division of Human Factors memorandum, based on the scope pertaining to infant sleep, as defined in the draft proposed rule, staff recommends that loungers and infant support cushions should have a maximum incline angle that shall not exceed 10 degrees. However, staff recommends modifications to the requirement and test method for a maximum incline angle test to address more potential infant positions relative to the infant cushion product and improve test consistency across all infant support cushion products (Refer to Figure 9):

- Unlike inclined sleep products, infant support cushions do not typically have a defined seat and back. Staff recommends that a maximum 10-degree seat back angle requirement should apply to the foreseeable use in infant support cushions of the sides or a sidewall to support the head for reclining. The maximum incline angle requirement should apply to all manufacturer's recommended use positions, and also to all other infant cushion surfaces that can feasibly support an infant's head (OSS-head), including the angle from the sidewall (if present) to the OSS or from the OSS-head to the floor when no elevated sidewall is present or from sidewall to floor when an elevated sidewall is present.

- A second modification is to use the newborn hinged weight gauge ("newborn gauge") instead of the infant hinged weight gauge. The newborn gauge is lighter than the infant counterpart and presents a worse-case scenario because the lighter newborn gauge would cause the pillow to deflect less, creating a more inclined seat back angle.

- The third modification is a reasoned change to the placement of the newborn gauge. Staff proposes that the torso/head portion of the newborn gauge be positioned so that it rests against the top surface of the product, with the top edge of the torso/head portion positioned according to the use position of the product, and the hinge of the gauge to be supported on an OSS or test base, as appropriate, even if this positioning causes the hinge of the gauge to not align with the bight line or the lower portion of the gauge to rest on surfaces other than the OSS. The top edge of the upper portion of the newborn gauge should be aligned to the product according to whether the use position is inside or outside the product. For lounger products with an OSS and sidewalls, the top edge should be aligned plumb to the outside of the product as shown in Figure 9. For use positions in which the newborn gauge will rest on the test surface, such as for head cushions, the newborn gauge should be adjusted to the greatest incline angle in which the top edge of the gauge maintains contact with the top surface of the product.

The number of test locations should include the manufacturer's recommend use position(s), and a suitable number of locations that represent the feasible uses of the infant support cushion for inclined support. For example, in Figure 8 the newborn hinged weight gauge can represent the feasible locations for an infant resting with an inclined support if the gauge were placed on all four sidewalls, whether or not the manufacturer intends those placements.

[8] Seat bight: The intersection between the seat or occupant support surface and seatback or sidewall.

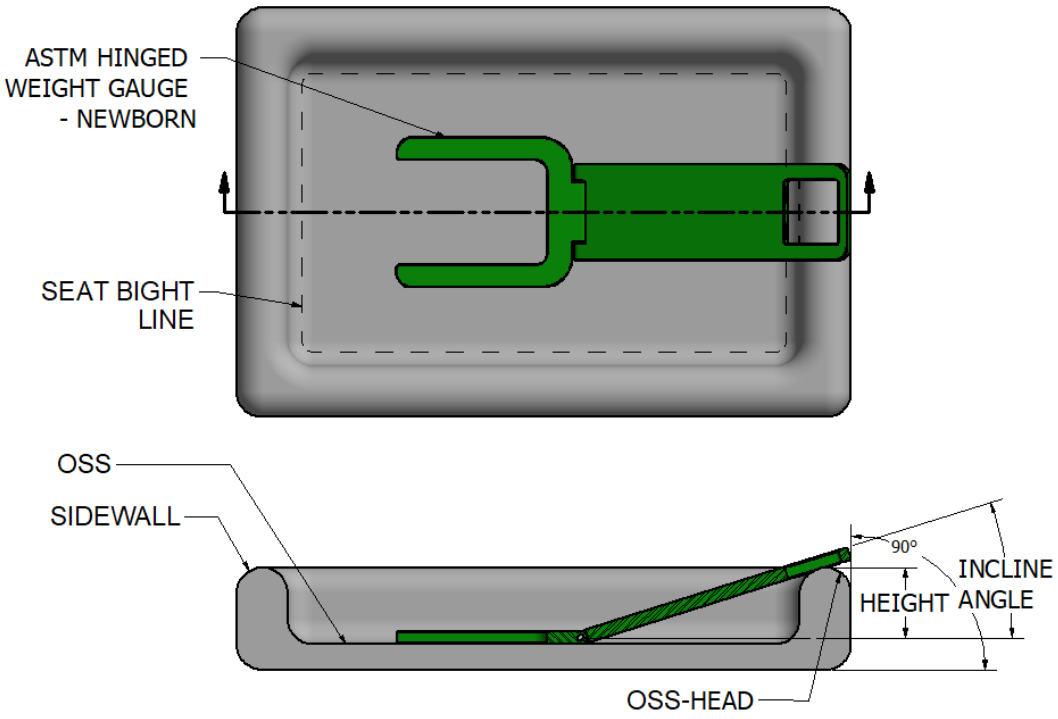

Figure 9 Test Fixture Configuration to Measure Incline Angle on an Infant Lounger-type Product

Based on staff's testing and analysis, these recommendations for positioning and using the newborn hinged weight gauge and the resulting maximum incline angle measurement better represent the positioning on the product for the youngest occupant. These recommended modifications of the maximum seat back angle requirement would also limit the heights of OSS-head surfaces for infant support cushion products, as discussed in Sidewall Height Measurement.

vii. Sidewall Height Measurement

The draft ASTM requirement states that the height of the sidewall must be less than 4 in (10.2 cm), however CPSC staff is concerned, as discussed in the Division of Human Factors, Directorate for Engineering Sciences memorandum, that caregivers may judge that a product with 4 in. high sidewalls can safely contain an infant without supervision and may be used on an adult bed or in a crib despite instructional or product warnings. Staff also has concerns with the position of the infant's head and neck on or against the sides of products. Hazardous neck positioning, as described in the Directorate for Health Sciences, Division of Pharmacology and Physiology Assessment memorandum, is due to an infant's head resting on the sidewall with the body positioned either inside or, in the case of head cushions, outside of the product. Accordingly, CPSC staff recommends that side height requirement that addresses hazardous neck positioning and inclined sleep resulting from an infant's head being on the raised sidewall or side of a product.

For lounger-type products, the sidewall height is taken from the OSS-body of the product. For head cushions, the sidewall height is taken from the test base. The maximum sidewall height will depend on the type of product and firmness of the sidewall. In testing of products without side walls such as head cushions, the maximum "sidewall" heights were measured to be up to 3 in. (7.6 cm)[9]. Based on geometry of the newborn hinged weight gauge, staff calculated that the height for very firm products should be limited to approximately 1.9 in (4.8 cm) [10].

Addressing the neck positioning hazards in this manner will also address the hazard that a side height of up to 4 inches may give caregivers the mistaken impression that the product can safely contain a child without supervision, because this will result in lower sidewall heights as explained above. Staff invite comments on an appropriate sidewall height to address the positional asphyxia hazard.

CPSC staff also considered an alternate test method for sidewall height. Further discussion of the alternate test method that was considered but is not recommended is in the Appendix.

viii. Sidewall Angle Measurement

In lounger and head cushion products, the transition from the OSS to the sidewall varies from a small change in elevation (for example, samples 220 and 280 in Figure 1) to the abrupt rise of a sidewall (samples 400.410). Staff recommends a firmness requirement for this area, as described in Intersection of Sidewall and Occupant Support Surface Firmness. However, an additional concern that is not addressed through a firmness requirement alone is the suffocation hazard that a sidewall poses if it overhangs the OSS and encompasses part of the infant's face. In a draft ASTM requirement, the angle between the sidewall and the occupant support surface (OSS) must be greater than 90 degrees. The ASTM draft standard measures the angle with a protractor, or similar tool, every 4 in (10 cm) along the inside perimeter of the product. Staff agrees that the ASTM's 90-degree requirement for sidewall angle will address a suffocation hazard. However, staff proposes to modify the test method, so that (1) consistency of measurement is less affected by the typically irregular surfaces of the products, (2) angles are measured while the OSS has force applied to it that represents the infant's head weight, and (3) the angular assessment is accomplished using the 90-degree angle probe, such that sidewalls that lean away from the infant that is resting on the OSS are safer than sidewalls that lean in and over the infant. Staff's recommended test method is depicted in Figure 10, in which the 90-degree angle requirement for the sidewall is assessed using a 90-degree probe, specifically the cylindrical side of the 3-in probe, applied with a 10 N (2.2 lb) force and placed with the probe side tangent to the intersection of sidewall and OSS. Contact with the probe side by the product sidewall will constitute an angle equal to or less than 90 degrees and no contact will signify an angle greater than 90 degrees.

[9] For infant head cushions, that have no sidewall, the height of the product is measured.

[10] The minimum passing sidewall height would occur when the sidewall has no deflection under the weight of the newborn gauge in the incline angle test: trigonometrical, it is 11-inch times sin (10 degrees) = 1.91 in., or the vertical rise of the 11 -in. upper segment length of the newborn gauge at a 10-degree incline angle. The maximum sidewall height depends on the sidewall construction. No sample passed both proposed maximum incline angle and sidewall firmness tests. However, samples 220 and 230 (head cushions) are instructive as they had maximum incline angles near 10 degrees (220: 10.6 degrees; 230: 11.2 degrees), and their sidewall heights were 2.72 in. (sample 220) and 2.66 in. (sample 230), measured from the top of the sidewall to the test base.

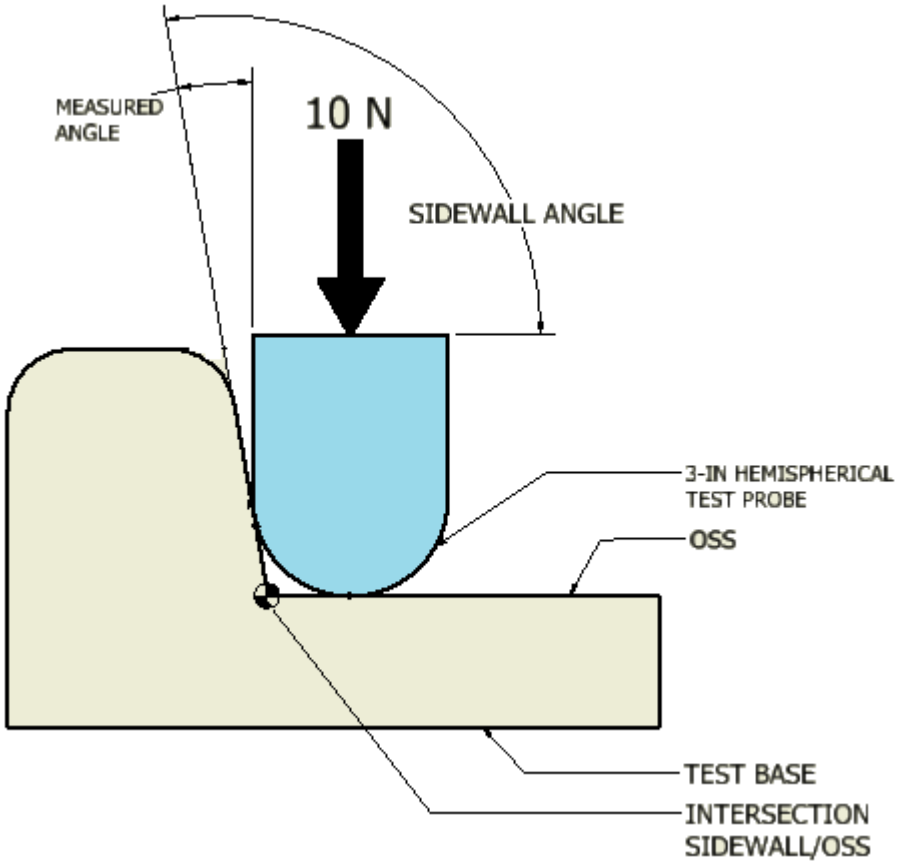

Figure 10 Test Fixture Configuration for Sidewall Angle Measurement

ix. Infant Restraints

The draft ASTM performance requirements include a section entitled “Restraint” that prohibits “a restraint system Staff agrees that loungers and support cushions should not include restraint systems for infants because staff is aware of incidents in which infants have become entrapped in the restraints of similar products.

x. Seam Strength

Infant support cushions, as discussed in the Directorate for Economic Analysis memorandum, may be in use for several years, with multiple infants. Support for the product is intended to be on the floor. The seams of the infant support cushions secure the filling material that, if released, can be swallowed by the infant. Staff is aware of incidents involving seams opening and incidents in which infants accessed, and in some cases choked on, filling materials. The federal regulation, 16 CFR part 1250 has requirements that seams withstand a tension force of 10 lb (45 N) for an age category for intended infants of 0-18 months old and 15 lb (67 N) for 18–36-month-old infants. Because infant support cushions are durable infant products, the required force for testing the strength of seams should be at least as great or greater than that for toy products. Staff recommends that infant support cushions seams be tested with a tension force of 15 lb (67

N) applied with ¾ in. diameter clamping fixtures, based on the 16 CFR part 1250 tension test force for 18-month-old infants and using the specified clamping fixture.

xi. Removal of Components

Components include elements that provide a function to the product, such as zipper pulls and buttons, or provide protection to the infant from hazards. Removal of components can expose the infant to sharp points or edges or to choking hazards, including from the component itself. The draft ASTM voluntary standard's general requirements include a section entitled "Protective Components" that requires protective components may not be removed when subject to a "Removal of Protective Components Test." Staff assesses that, in addition to protective components, components on infant support cushions can include other possibly detachable parts, such as zipper tabs and buttons. If detached these parts can expose the infant to hazards such as choking, sharp points, and sharp edges. Staff recommends that infant support cushions have requirements for removal of components that are graspable by an infant and that present hazards if removed.

xii. Bounded Openings

Any completely bounded opening that is above the OSS or the floor may be a potential head entrapment hazard. These openings can include those created when attaching accessories products. An opening may present an entrapment hazard if the space between any interior opposing surfaces allows an infant's head to enter, but those same or other involved surfaces do not allow the head to be withdrawn. Head entrapment requirements are common in infant products. ASTM F406-22 *Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards* requires that if a small head probe can enter an opening in an accessory, a large head probe must also enter through the opening. The small head probe leads into an opening, while the large head probe represents the worst-case entrapment potential in the opening. Staff recommends that infant support cushions have entrapment requirements for bounded openings.

B. CPSC Staff's Recommended Test Methods

Staff recommends the basic firmness requirement and test method developed by BSU, as modified by staff, the ASTM firmness test methods for occupant support surfaces, sidewalls, and intersection of OSS and sidewalls, and the sidewall height and angle and maximum incline angle requirements and test methods, as modified by staff, the ASTM infant restraint requirement, and other requirements. Staff's recommended general and performance requirements and test methods for infant support cushions appear in Tab F, Recommended Regulatory Text for the Draft Proposed Rule

IV. Testing

Staff tested sample infant support cushions to assist in development of the test methods. Below we discuss the test results that support staff's recommendations for the draft NPR.

A. Maximum Incline Angle and ASTM Sidewall Height Measurements

Table 2 contains staff's test results from testing to the draft ASTM sidewall height and CPSC maximum incline angle requirements for the CPSC samples. Maximum ASTM sidewall heights are required to be less than 4 in (10.2 cm). The CPSC maximum incline angle measurements are required to be less than 10 degrees. Passing tests are in green highlight. Results show that the draft ASTM Sidewall Height test method resulted in passing nine of ten samples. Two of ten samples (260, 270) passed the Maximum Incline Angle requirement. (An ASTM test method for maximum incline angles is more narrowly defined than the CPSC staff test method and applies to none of the CPSC samples). The CPSC limit to Maximum Sidewall Height results were not determined because none of the samples passed both the sidewall firmness and the maximum incline angle requirements, both of which affect sidewall height. These results indicate that the Maximum Incline Angle requirement, which is affected by the sidewall height and firmness is a more stringent requirement than the ASTM Sidewall Height requirement alone.

Table 2. Sample Maximum Incline Angle Measurements and ASTM-CPSC Sidewall Heights Comparisons

Sample	ASTM Max. Sidewall, Height (in)	CPSC, Limit to Max. Sidewall Height* (in)	CPSC Max. Incline Angle (degrees)	Comment
220	2.72	n/a	10.6	Gauge on top of side
230	2.66	n/a	11.2	Gauge on top of side
240	3.91	n/a	42.2	Hinge at bight line
250	3.23	n/a	28.2	Gauge at edge
260	1.66	n/a	1.6	Gauge at edge
270	1.86	n/a	4.6	Gauge at edge
280	3.39	n/a	22.8	Gauge at edge
310	3.93	n/a	42.5	Hinge at bight line
400	3.17	n/a	21.4	Gauge at edge
410	4.13	n/a	13.5	Gauge at edge

*The CPSC sidewall height limit pertains to samples that pass both the sidewall firmness and maximum incline angle requirements. No samples passed both requirements.

B. Sidewall Angle Measurements

Table 3 shows test results for the sidewall angles of the samples. Staff assessed sidewall angles by adding the measured angle from the vertical side of the cylindrical 3-in probe to the sidewall according to the staff recommended method, and as depicted in Figure 10. Staff's recommendation is that the sidewall angle be greater than 90 degrees to address the suffocation hazard of the envelopment of the infant's face into a sidewall overhang. Results show that two of ten samples failed to comply with the sidewall angle requirement. A failure means that an infant could suffocate because the face can become enveloped into the space between the sidewall and OSS, even if not forced into that area, as addressed in the Intersection of Sidewall and OSS firmness requirement.

Table 3. Sample Maximum Sidewall Angle Measurements

Sample	Sidewall Angle (degree)	Compliance	Angle Bisect	Comment
220	130	Pass	65	
230	140	Pass	70	
240	120	Pass	60	
250	120	Pass	60	
260	150	Pass	75	
270	130	Pass	65	
280	120	Pass	60	
310	130	Pass	65	
400	=/< 90	Fail	45	90° is failure
410	=/< 90	Fail	45	90° is failure

C. Firmness Test Results, Occupant Support Surface

Table 4 displays results of the OSS firmness test. Staff measured Occupant Support Surface firmness as the force to deflect the surface 1.0 in (2.54 cm) using the 3-in hemispherical probe oriented vertically, according to the staff recommended method, and as depicted in Figure 6. Staff recommends a force greater than 10 N (2.2 lb) to address the suffocation hazard due to soft surfaces. Results show that nine of the ten samples failed to comply with all the firmness requirements. Sample 410 passed the test because the thickness of the OSS was less than 1.00 in (2.54 cm). The failures mean that an infant could suffocate in those OSS surfaces.

Table 4. Sample Firmness Results Occupant Support Surface

Sample	Maximum Force (N)	Minimum Force (N)	Deflection Set to (in)	All Locations Compliance	Comment
		10.0	1.00		Requirement: > 10 N at 1.0 in deflection
220	6.92	6.92	1.00	Fail	
230	8.15	8.15	1.00	Fail	
240	5.11	3.65	1.00	Fail	
250	5.90	3.09	1.00	Fail	
260	5.32	3.63	1.00	Fail	
270	4.96	2.70	1.00	Fail	
280	6.47	4.02	1.00	Fail	
310	7.57	6.21	1.00	Fail	
400	4.00	3.34	1.00	Fail	
410	16.02	10.63	0.5	Pass	Force > 10 N at < 1.0 in deflection

D. Firmness Test Results, Sidewall

Table 5 displays the sidewall firmness test results. Staff measured sidewall firmness as the force to deflect the surface 1.0 in (2.54 cm) using the 3-in hemispherical probe oriented vertically, according to the staff recommended method. Staff recommends a force greater than 10 N (2.2 lb) to address the suffocation hazard due to soft surfaces. Results show that all ten samples failed to comply with all the firmness requirements. Two samples (310, 400), although they failed, were sufficiently firm at some test locations, as shown in Figure 11. The failures mean that an infant could suffocate in those sidewall surfaces.

Table 5. Sample Firmness Results - Sidewall

Sample	Maximum Force (N)	Minimum Force (N)	Deflection Set to (in)	All Locations Compliance	Comment
		10.0	1.00		Requirement: > 10 N at 1.0 in deflection
220	6.75	4.45	1.00	Fail	
230	6.15	4.75	1.00	Fail	
240	6.47	3.52	1.00	Fail	
250	6.27	4.20	1.00	Fail	
260	4.64	2.98	1.00	Fail	
270	4.27	2.79	1.00	Fail	
280	5.78	2.35	1.00	Fail	
310	11.6	4.91	1.00	Fail	Mixed result
400	13.7	4.71	1.00	Fail	Mixed result
410	5.49	2.72	1.00	Fail	

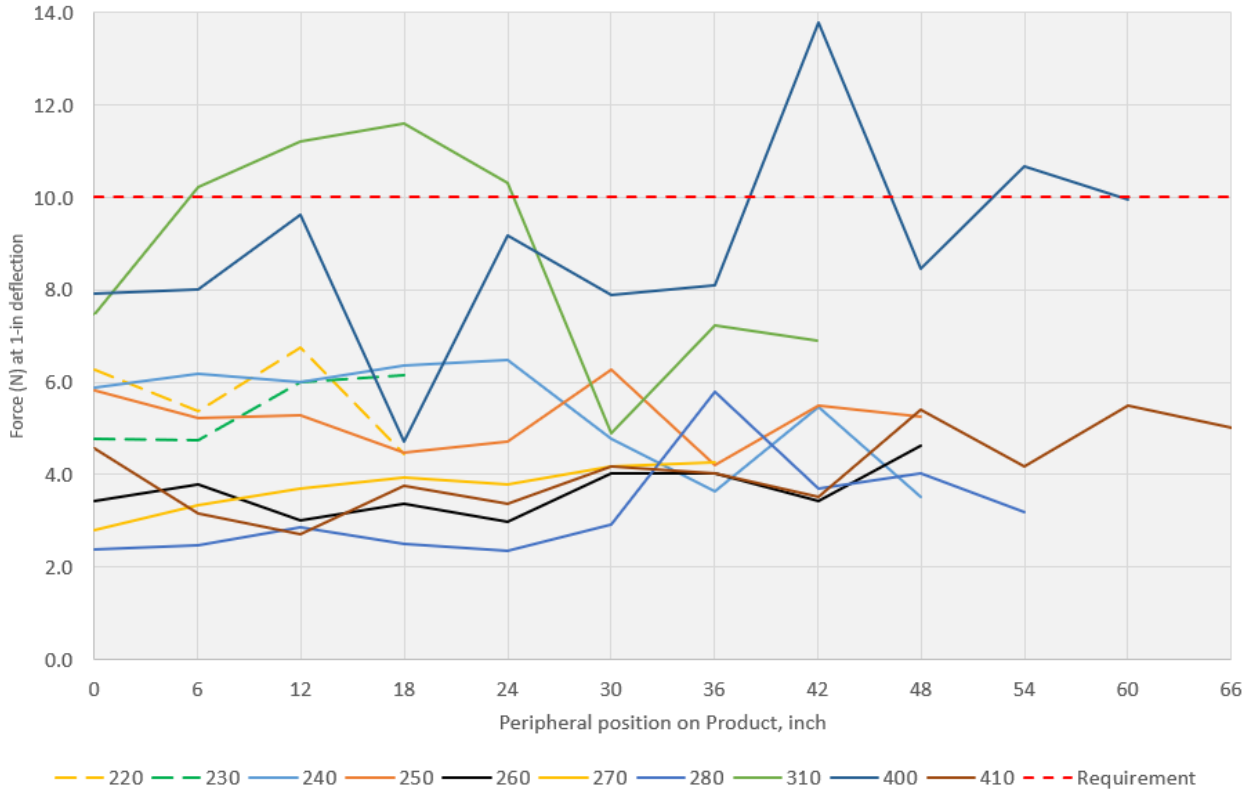

Figure 11 Sidewall Firmness Results

E. Firmness Test Results, Intersection of Sidewall and Occupant Support Surface (OSS)

Table 6 displays the intersection of sidewall and OSS firmness test results. Staff measured firmness at the intersection of sidewall and OSS as the force to deflect the surface 1.0 in (2.54 cm) using the 3-in hemispherical probe oriented at an angle, determined according to the staff recommended method, and as depicted in Figure 7. Staff recommends a force greater than 10.0 N (2.24 lb) to address the suffocation hazard due to soft surfaces. The probe orientation was set to the bisecting angle from horizontal, which was determine as one half the angle measured in the Maximum Sidewall Angle measurement, shown in Table 3. Results show that eight of the ten sample intersections failed to comply with all the firmness requirements. Samples 220 (10.6 N, 4.7 lb) and 230 (11.0 N, 4.9 lb) are head support cushions that complied with the firmness requirements. Three samples (240, 310, 400), although they failed, were sufficiently firm at some test locations, as shown in Figure 12. The failures mean that an infant could suffocate when the face is forced into the intersection of the sidewall and the OSS.

Table 6. Sample Firmness Results, Intersection of Sidewall and OSS

Sample	Maximum Force (N)	Minimum Force (N)	Deflection Set to (in)	All Locations Compliance	Comment
		10.0	1.00		Requirement: > 10 N at 1.0 in deflection
220	11.7	10.6	1.00	Pass	Head Cushion
230	13.9	11.0	1.00	Pass	Head cushion
240	10.76	4.01	1.00	Fail	Mixed result
250	9.90	5.79	1.00	Fail	
260	5.75	3.55	1.00	Fail	
270	5.02	4.29	1.00	Fail	
280	4.35	3.20	1.00	Fail	
310	17.49	5.66	1.00	Fail	Mixed result
400	14.82	4.62	1.00	Fail	Mixed result
410	3.00	1.35	1.00	Fail	

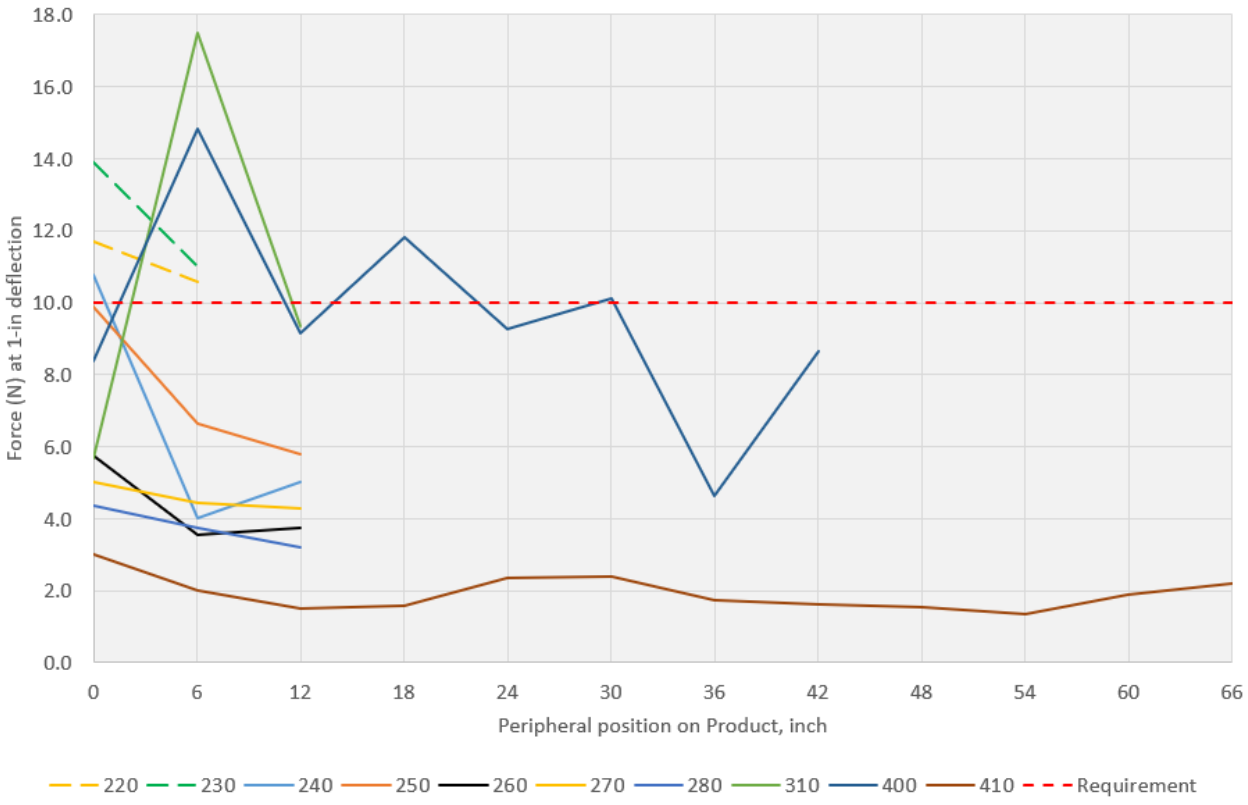

Figure 12 Intersection of Sidewall and OSS Firmness Results

V. Conclusion

LSM staff recommends for the draft NPR general and performance requirements for infant support cushions and infant loungers that are based on draft requirements developed by the ASTM F 15.21 Infant Loungers Performance Subcommittee and CPSC staff, and on the information and analysis in the published contract report by Boise State University that studied infant suffocation in infant loungers and support cushions. Staff concludes that the firmness and associated requirements and test methods, as set forth in the BSU report reduce the suffocation and other hazards associated with the use of loungers and infant support cushions. Staff recommends a set of firmness requirements for product surfaces that an infant may contact while on the product, and general requirements for the dimensions of that contact.

Appendix

Alternative Sidewall Height Method

To develop a safer sidewall requirement, while maintaining ASTM's 4-in height requirement, staff considered that the method to measure the side height could be improved to produce a more realistic height to which the infant is exposed. The BSU anthropometric 3-in hemispherical probe, which is already used for the draft ASTM firmness tests, could be used in measuring side height and replace the 0.25 in thick by 6 in by 6 in plate in the ASTM method. More importantly, the hemispherical probe can apply a relevant force through an anthropometric shape. Applying a force to the OSS would increase the measured sidewall height. Staff applied the 10 N (2.24 lb) force from the OSS firmness test method. Comparing the results of testing using the ASTM height testing method and testing using CPSC staff's height testing method shows that the CPSC staff method results in higher measured sidewall heights. This is because the additional deflection distance of the OSS by the 10 N force on the 3-in probe yields a higher total height measurement using the CPSC test method. Accordingly, for a certain sidewall on a product that has a height near the 4-in height limit, the height measured by the ASTM method can be less than 4 in and pass the requirement, as compared to the height measured by the more realistic CPSC staff method, which can be more than 4 in and fail the requirement. These products would therefore need to be redesigned with lower sidewalls to comply with the 4-in requirement, which would result in products with less perceived utility for unattended sleeping and therefore safer for infants.

In the alternate CPSC method, the side of the 3-in probe is vertical and tangent to the intersection of sidewall and OSS, and a 10 N (2.2 lb) force is applied. The measured height is taken from the base of the hemisphere to the top of the sidewall. Because the draft ASTM test method does not specify testing locations, staff chose a minimum of four sidewall height measurements that should be taken at intervals not to exceed 6 in (15.2 cm).

Test results for Maximum Incline Angles are included in this discussion to show the similar levels of compliance of the samples to the alternate CPSC sidewall height requirement. The height requirement can be another distance. The 4.0 in requirement is used to assess the ASTM and this alternate CPSC test methods. Staff seeks comments on whether and what appropriate sidewall height would sufficiently address the hazard of positional asphyxia for a potential alternative sidewall or OSS height requirement.

Requirement

The sidewall height shall not exceed 4.0 in (10 cm) when tested to Sidewall Height Measurement.

Sidewall Height Test Method

a. Orient the 3-in (7.62 cm) diameter hemispherical head probe (Figure A1) vertically and place the probe over the occupant support surface with the cylindrical surface of the probe tangent to the intersection of the sidewall and the OSS. Advance the probe onto the product and set the

deflection to 0.0 in when a force of 0.1 N (0.02 lb) force is reached. Apply a 10 N (2.2 lb) downward force.

b. After 30 s, measure the sidewall height as the vertical distance from bottom of the probe to the top of the adjacent side wall. Measure a minimum of four sidewall heights at intervals not to exceed 6 in (15.2 cm) along the intersection of the sidewall and the OSS.

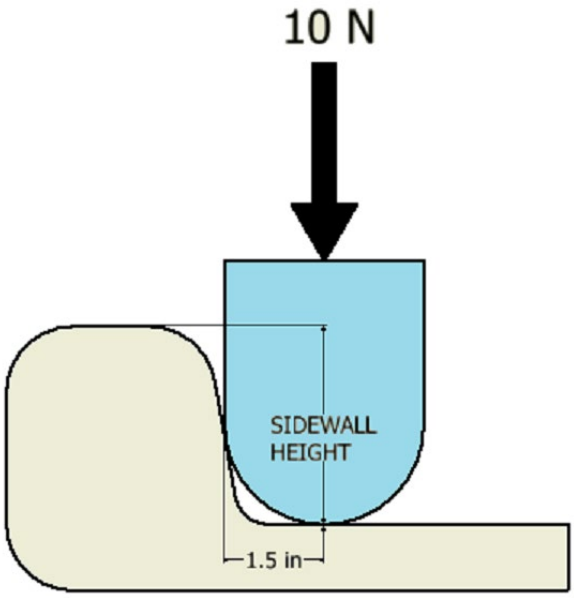

Figure A1 Alternate Sidewall Height Measurement

Test results of maximum sidewall heights and maximum incline angles for the CPSC samples are shown in Table A1. Maximum sidewall height measured by either the ASTM Sidewall Height method or this alternative CPSC sidewall height method is required to be less than 4 in (10.2 cm). Maximum incline angles measured by the recommended Maximum Incline Angle test method are required to be less than 10 degrees. Passing tests are in green highlight. Testing shows that the draft ASTM test method resulted in lower side height measurements and that seven of eight samples passed compared to the two samples that passed the CPSC staff's alternative test method. That is, most of the samples would not pass according to the CPSC test, but most would pass according to the ASTM test. The testing also shows that the maximum side height measurements that passed the CPSC requirement (samples 260 and 270) correspond to the same two samples that passed the CPSC staff's requirement for maximum incline angle. For the later reason, the Maximum Incline Angle test achieves similar results and therefor supersedes this alternative CPSC Sidewall Height test method.

Table A1 Sample Sidewall Height and Maximum Incline Angle Measurements

Sample	CPSC Method, Max. Height (in)	ASTM Method, Max. Height (in)	CPSC minus ASTM (in)	CPSC Max. Incline Angle (degrees)	Comment
410	4.46	4.13	0.33	13.5	Gauge at edge
310	4.90	3.93	0.97	42.5	Hinge at bight line
240	5.29	3.91	1.38	42.2	Hinge at bight line
280	4.93	3.39	1.54	22.8	Gauge at edge
250	4.64	3.23	1.41	28.2	Gauge at edge
400	4.65	3.17	1.48	21.4	Gauge at edge
270	3.43	1.86	1.57	4.6	Gauge at edge
260	3.24	1.66	1.58	1.6	Gauge at edge

TAB D: Human Factors Review of Incident Data and Recommended Requirements for Infant Support Cushions

United States
Consumer Product Safety Commission

Memorandum

TO: Stefanie Marques, Ph.D., Project Manager Infant Pillow NPR
Directorate for Health Sciences

DATE: November 8, 2023

THROUGH: Mark E. Kumagai, Associate Executive Director,
Directorate for Engineering Sciences

Rana Balci-Sinha, Ph.D., Director,
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SUBJECT: Human Factors Review of Incident Data and Recommended Requirements for Infant Support Cushions

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I. Introduction

In June 2022, ASTM International (ASTM) began the process of developing a voluntary standard for "Infant Loungers," which will contain requirements for various pillow-like infant products intended for infants during awake time, specifically not for sleep. Although ASTM has not yet published the voluntary standard, the draft voluntary standard includes performance requirements for these products, as well as product and packaging marking requirements, which include requirements for warnings that must appear on loungers covered by the standard. The draft voluntary standard also includes requirements for instructional literature to accompany products covered by the standard.

The Consumer Product Safety Commission (CPSC or Commission) staff is preparing for Commission consideration a draft proposed rule on infant support cushions under section 104 of the Consumer Product Safety Act of 2008 (CPSIA) that is based, in part, on the draft voluntary standard for infant loungers.

This memorandum, prepared by staff of CPSC's Directorate for Engineering Sciences, Division of Human Factors (ESHF), reviews the available incident data involving infant support cushions, including relevant use patterns, discusses human factors issues pertaining to the ASTM draft voluntary standard's draft performance, warning, and instructional requirements, and provides recommendations for the infant support cushions proposed rule.

II. Discussion

Infant loungers typically are identified as pillows or mat cushions intended to support an infant while sitting, lying, reclining, or resting. They are also lightweight and portable. While ASTM's draft standard indicates that loungers are intended for use with adult supervision and are not marketed for sleep, numerous "lounger" products available for online purchase specifically state, or show in marketing photographs, that infant loungers and pillows are for use by infants while sleeping. Due to the differences in the scope of the proposed ASTM standard and staff's recommended scope as described in the draft proposed rule, staff invites comments for in-scope and out-of-scope products. In particular, staff is aware that some infant products, such as bouncers, rockers, and swings, are designed with permanently attached infant support pillows. Staff encourages comments on whether these products should also be included in this rule, or just support cushions sold independent of these and other products.

Used infant support cushions are sometimes available from secondary marketplaces such as eBay. For example, at 2:30pm on June 16, 2023, CPSC staff performed a simple search in eBay using phrases "infant head positioner", "infant lounger", "baby lounger", "wedge pillow" infant", "sleep positioner" baby ", "sleep positioner" infant", "infant pillow", and "baby pillow" and filtered the results by selecting "used" as the condition of the product. Staff found that portion of used products ranged from zero percent for "infant head positioner" and "wedge pillow" to 45 percent for the phrase "infant lounger". This suggests that consumers perceive certain infant support cushions as having a future useful life beyond the initial infant user. In addition, consumers who anticipate having multiple children are likely to retain the infant support cushion for future children. Some manufacturers facilitate such reuse by selling replacement outer covers that further extend the useful life of infant support cushions.

In their 2022 Updated Recommendations for a Safe Infant Sleeping Environment, the American Academy of Pediatrics (AAP) states that it is not safe to place soft materials or objects, such as pillows (including semi-circular or other nursing pillows), quilts, comforters, or fur-like materials, even if covered by a sheet, under a sleeping infant (Moon et al., 2022).

Further, the AAP[1], along with the CPSC[2] and the FDA, warns against the use of positioning products. This is due to the lack of evidence showing these products to be effective against SIDS, suffocation, or gastroesophageal reflux and because of suffocation and entrapment risks. If positioning devices are used in the hospital as part of physical therapy, they should be removed from the infant sleep area well before discharge from the hospital (Moon et al., 2022).

A. Review of Incident Data

As staff of CPSC's Directorate for Epidemiology, Division of Hazard Analysis (EPHA), discusses in Tab A, staff identified a total of 204 incidents/reports associated with the use of infant support cushions in the CPSC epidemiological databases from January 1, 2010, through December 31, 2022. The data included 79 fatal incidents and 125 non-fatal reports. The dispositions of the 125 non-fatal reports are comprised of 22 emergency department-treated injuries, 3 hospital

[1] https://publications.aap.org/aapnews/article/31/11/27/23431/Infant-sleep-positioners-pose-suffocation-risk?_ga=2.136139320.863140124.1684349484-1986427679.1684349484 (Last accessed September 2023).

[2] Deaths prompt CPSC, FDA warning on infant sleep positioners https://www.cpsc.gov/Newsroom/News-Releases/2010/Deaths-prompt-CPSC-FDA-warning-on-infant-sleep-positioners Last accessed September 2023.

admissions, 1 victim leaving before being seen, 1 victim was seen by a medical professional, 46 reports where no injury occurred, and 52 reports with either an unknown or unspecified disposition.

Fatal incidents:

Of the reported 79 fatalities, 49 had an official cause of death of asphyxia/probable asphyxia (62% of the total), 13 fatalities were determined to be sudden unexplained infant death (SUID) events (17% of the total), 12 fatalities had either an undetermined or unknown cause of death (15% of the total), and for 5 of the fatalities, the medical examiner report was unavailable (6% of the total). Infants in the 0-3 months age range accounted for 80 percent of all pillow-related fatalities.

Following is scenario-specific information indicating the placement of the decedents:

- 34 decedents were placed on infant pillows in an adult-sized bed;
- 25 decedents were placed on an infant pillow in a crib/bassinet;
- 8 decedents were placed on an infant pillow inside a play yard;
- 3 decedents were placed on an infant pillow on top of a couch/futon;
- 4 decedents were placed on an infant pillow on either a mat or on the floor; and
- 1 decedent was placed on an infant pillow inside a toddler bed.

Decedent placement in 4 fatalities was either undetermined or unknown.

Among the 79 fatalities, staff was able to discern that the subject products were used for sleep in at least 74 incidents. Of the 79 fatalities, 71 were placed on top of a couch or on adult bed, inside a crib/bassinet, play yard or toddler bed. Staff observed bedsharing with caregivers or siblings in at least 27 fatal incidents. As discussed in the Division of Pharmacology and Physiology, Directorate for Health Sciences (HSPP) memorandum (Tab B), HSPP staff identified positional asphyxia/suffocation as a fatal risk factor associated with infant support cushions. Staff notes that many narratives specifically describe scenarios where the infant pillow was being used as an in-bed sleeper/bassinet to facilitate bed sharing.

In 63 of the fatalities, staff categorized the product as a lounger; in five incidents, staff categorized the product as a pillow; in 10 incidents, staff categorized the product as a sleep positioner, and in one incident, the product was a wedge. Given the foreseeability of these products being used for sleep, staff recommends that performance, warning, and labeling requirements be applied to all products within the scope of the proposed rule.

Nonfatal incidents:

Among nonfatal incidents, CPSC received 29 reports (23% of the total) of a victim being placed on elevated and soft surfaces including adult beds (9), couches (6), cribs (2), an ottoman (1), and a chair (1), as well as elevated and hard surfaces such as countertops and tables (5) while on top of an infant pillow and falling off, 27 reports of a victim experiencing threatened asphyxia (22% of the total), and 17 reports of a victim receiving a rash from the product (14% of the total). Reports of limb entrapment, mold, choking, near strangulation, and vomiting all had one report

each (1% of the total for each report). CPSC received 47 additional complaints (38% of the total) from consumers regarding infant pillows, however, no incident was clearly indicated.

B. ASTM Standard Development and Staff Recommendations for the Proposed Rule

In January 2022, ASTM formed an Infant Loungers subcommittee. This subcommittee is in the process of developing a voluntary standard for "infant loungers." However, as of the writing of this memo, a draft voluntary standard for these products has not yet been balloted or published.

Side Height and Surface Angle Performance Requirements

The ASTM draft voluntary standard currently allows infant loungers to have a maximum side height, relative to the occupant support surface, of under 4 inches. Staff is concerned that a side wall with a height of up to 4 inches may give caregivers the impression that the product can safely contain a child without supervision, regardless of what the product warnings might say. The presence of a distinct, raised perimeter surrounding the occupant support surface, as observed in various products on the market, provides a visual cue to consumers that the infant is safely contained in the product. Infant loungers currently marketed for sale often display images of infants sleeping or resting in such products, and thus convey the appearance of effective containment for purposes of sleep. Despite the fact that most of these infant loungers would fail the requirements in the Safety Standard for Infant Sleep Products (the ISP Rule), 16 C.F.R. part 1236, staff assesses that infant loungers are likely to continue to be used by caregivers for sleeping and napping. For this reason, staff recommends an alternative performance requirement for the angle of the seat back/occupant support surface along the occupant's head to toe axis, relative to the horizontal, not to exceed 10 degrees; this is the same requirement that appears in the ISP rule.

In addition, because the infant support cushions are designed to support all or part of an infant's body, it is likely the user's head will be placed on any side of the product. In this position, with a side height greater than 4 inches an infant could potentially be at a compromised angle that would interfere with breathing. Therefore, staff recommends that the same angle restriction be required from side/sidewall to the occupant support surface as well as from floor to the side/sidewall and from floor to the occupant support surface. Staff invites comments on an appropriate sidewall height to address potential positional asphyxia hazards. As discussed in the Laboratory Sciences Mechanical Engineering memorandum (Tab C), CPSC staff recommends additional requirements such as firmness of the occupant support surface and sidewalls and a sidewall angle measurement to improve the safety of infant support cushions.

Warning and Instructional Requirements

Safety and warnings literature consistently identify a classic hierarchy of approaches that should be followed to control product-associated hazards. Warning about hazards is viewed universally as less effective at eliminating or reducing exposure to hazards than either designing the hazard out of a product or guarding the consumer from the hazard; therefore, the use of warnings is lower in the hazard-control hierarchy than the other two approaches (Laughery & Wogalter, 2011; Vredenburgh & Zackowitz, 2005; Wogalter, 2006; Wogalter & Laughery, 2005). Warnings are less effective than the alternatives because they rely on educating consumers about the

hazard, and then persuading consumers to alter their behavior in some way to avoid the hazard. To be effective, warnings also depend on consumers behaving consistently, regardless of situational or contextual factors that influence precautionary behavior, such as fatigue, stress, or social influences. Thus, one should view warnings as a measure that supplements, rather than replaces, redesign or guarding efforts, unless these higher-level, hazard-control efforts are not feasible.

The current draft of the ASTM voluntary standard for Infant Loungers includes marking and labeling requirements, which include requirements for warnings that must appear on infant lounger products covered by the standard. Figure 1 shows the draft standard's proposed warning statements that must appear on all infant loungers, formatted to be consistent with the design, or format, requirements that also are specified in the draft standard.

Figure 1 Draft Infant Lounger Warning Label

The draft voluntary standard also includes requirements for instructional literature to accompany products covered by the standard. These requirements state that the instructional literature that accompanies infant loungers must include the warnings on the product, as well as the following additional warnings:

- Read all instructions before using this product.
- Keep instructions for future use.
- Do not use this product if it is damaged or broken.

The instructions also must indicate the manufacturer's recommended maximum weight, height, age, developmental level, or combination thereof, of the infant. If the product is not intended for use by a child for a specific reason, the instructions must state this limitation.

On-Product Warning Requirements

CPSC staff worked with the ASTM Infant Loungers subcommittee to develop the on-product marking requirements in the draft standard and support the use of the warning content and format requirements for products within the scope of the draft voluntary standard. However, manufacturers of infant support cushions, as defined for the NPR, should not expect to be exempted from this draft proposed rule simply by using a warning label that indicates the product is not for sleep. As noted above, a warning label is the last means of changing a consumer's behavior. If the warning contradicts consumers' experiences, consumers tend to rely on their own knowledge and disregard the warning.

CPSC does not support the use of infant loungers, or other products within the scope of the draft proposed rule, for sleep.[3] Thus, staff recommends the same warning to be present for all infant support cushions.

ESHF staff also recommends that the proposed rule include:

- a requirement for the warning to be conspicuous, and a definition of "conspicuous" that clarifies the required placement of the warning on the product, in terms of when the warning must be visible to the consumer; and

- warning permanence requirements and test methods that are consistent with other ASTM juvenile products standards.

The following subsections describe staff's rationale for the proposed warning requirements.

Warning Content

The primary U.S. voluntary consensus standard for product safety signs and labels, ANSI Z535.4, *Product Safety Signs and Labels*, and other literature and guidelines on warnings (*e.g.*, Robinson, 2009; Wogalter, 2006; Wogalter, Laughery, & Mayhorn, 2012), consistently recommend that on-product warnings include content that addresses the following three elements:[4]

- a description of the hazard;
- information about the consequences of exposure to the hazard; and
- instructions regarding appropriate hazard-avoidance behaviors.

As mentioned in staff's review of the incident data, the primary hazards associated with the use of infant loungers are asphyxia, or suffocation, and to a lesser extent, falls. Virtually all fatal incidents involved asphyxia or possible asphyxia, as well as consumers placing infants in or on the product for sleep.

Staff's proposed warning content pertaining to the hazard and its consequences directly addresses these issues. Specifically:

[3] Baby Safety Tips | CPSC.gov
[4] All three elements may not be necessary in some cases, such as if certain information is open and obvious or can be readily inferred by consumers; however, people often overestimate the obviousness of such information to consumers.

- The warning begins with the statement, "USING THIS PRODUCT FOR INFANT SLEEP OR NAPS CAN KILL." This statement immediately communicates to consumers the potential deadly consequences of using infant support cushions within the scope of the rule for sleep, which is the primary use pattern that has resulted in fatalities with these products. Beginning the warning with an explicit, succinct, and strongly worded description of the usage pattern that often leads to death, printed in all-uppercase lettering, is necessary. The references not only to "sleep" but also to "naps" prevent consumers from concluding that the hazard only applies to cases where the product is used for overnight sleep.
- The warning further explains the hazard and potential consequences with the statement, "Babies can turn over or roll out without warning and CAN SUFFOCATE in only a few minutes." Staff concludes this statement is needed to clarify how infants are dying ("CAN SUFFOCATE") and to communicate not only the mechanism by which infants are suffocating, but the unpredictability and speed with which such incidents can occur. Information about the imminence of the suffocation hazard is often lacking in the warnings on existing products and may not be obvious to consumers. The features of staff's proposed warning should provide consumers with a better understanding of the speed with which suffocation can occur when infants are left unattended in these products and are likely to increase consumers' motivation to comply with the warning message.[5]
- The warning includes a statement that alerts consumers that "Babies have been injured from FALLS." Falls are the most common incidents resulting in injury, and staff concludes that warning statements pertaining to this hazard are necessary. Nevertheless, this hazard is less severe and common than the suffocation hazard; thus, staff has positioned the associated warning messages near the bottom of the warning. A description of the additional fall-related warning content appears below.

CPSC staff and members of the ASTM Infant Loungers subcommittee discussed the key actions that consumers should take, or avoid, to prevent suffocation when using an infant lounger. Based on the available incident data, key actions include not using the product for sleep, not leaving the infant unattended in the product, using the product only on the floor and not in sleep products, and keeping soft bedding out of the product. Staff's proposed warning content addresses these and other issues relevant to infant support cushions within the scope of the rule:

- The warning emphasizes the importance of using infant support cushions within the scope of the rule only with infants who are awake. Warnings for products that are not intended for sleep often tell consumers not to use the product for sleep, and the initial statement of staff's proposed warning ("USING THIS PRODUCT FOR INFANT SLEEP OR NAPS CAN KILL") already strongly indicates that consumers should not use the product this way. However, given that this is the primary suffocation avoidance behavior that consumers can take, explicitly addressing this behavior after the hazard description is important. Staff has written this statement in a more positive, or affirmative, form—that is, "Use only with an AWAKE baby"—to further reinforce the message that the infant should be *awake* during use and to remove all doubt about whether consumers could make exceptions for napping, as opposed to overnight sleep. Recognizing that consumers are likely to be presented with scenarios where the infant falls asleep during use, a follow-up sentence reinforces the safe-sleep message that consumers should move the infant to a firm, flat sleep surface if the infant falls asleep after feeding. This

[5] For example, the imminence of a hazard tends to increase the perceived threat associated with that hazard (Gass & Seiter, 1999), which is more likely to lead to compliance with the warning.

language is generally consistent with language developed by the ASTM Ad Hoc Language task group[6]

- The warning includes statements that explicitly address leaving the infant unattended in the product. Specifically, the warning tells consumers to stay near and watch the baby during use of the product. As staff noted in its review of the incident data, reported fatalities with infant loungers often involved consumers using the product to prop up the infant within a sleep product, and common sleep products involved in these incidents include cribs, portable playpens or play yards, and bassinets. Thus, the warning includes a statement warning against using infant support cushions in sleep products in general, with cribs and bassinets called out as specific examples. Beds were another common sleep-related product in which infant support cushions were used. Nearly all fatalities involved infant sleep and involved the infant lounger or pillow being used for lounging or sleeping.
- The warning includes a clear and concise statement telling consumers to use the product only on the floor with the baby face-up on its back and to not use on soft surfaces or in sleep products like cribs and bassinets. Staff notes that in 75 of the 79 fatalities where the location of the incident product was known, all were placed in or on another product such as adult bed (34), crib (11), play yard (11), bassinet (9), or other (couch, futon, toddler bed, portable crib) and only four were placed on the floor.
- The warning includes keeping blankets and other soft bedding and other soft items out of the product. At least 58 fatalities involved the lounger or pillow being used on sleep surfaces with bedding, blankets, and other support cushions, which may have contributed to the suffocation hazard.
- Nonfatal injuries from falls most frequently involved placing the infant in the product atop an elevated surface. Thus, the primary hazard-avoidance statement related to falls instructs consumers not to use on beds, sofas, or other raised surfaces. Beds and sofas, or couches, are identified explicitly because they are the most common elevated surfaces involved in these types of falls. The final warning pertaining to falls ends by telling consumers never to carry or move the product while the baby is in the product.

Warning Format

When assessing the adequacy of a warning, one must consider not only the content of a warning, but also its design or "form" (Laughery & Wogalter, 2006; Madden, 1999; Madden, 2006). The current draft of the ASTM Infant Loungers voluntary standard includes warning format requirements that are consistent with the recommendations of the ASTM Ad Hoc Language Task Group. Since 2016, ASTM juvenile products standards have begun adopting warning format requirements that are consistent with the recommendations of this task group, which ASTM formed to develop standardized language across ASTM juvenile products standards, and which has developed recommendations for a consistent warning format to be applied to these products. One of the authors of this memorandum is a member of the Ad Hoc TG and serves as the CPSC staff representative on the ANSI Z535 Committee on Safety Signs and Colors, which publishes the Z535 series of voluntary standards, including ANSI Z535.4, *Product Safety Signs and*

[6] The ASTM Ad Hoc Language Task Group was formed to develop standardized language across ASTM juvenile products standards. This task group is discussed more in the next, *Warning Format*, subsection. The latest version of the Ad Hoc-approved recommended language is published in the "Committee Documents" section of the Committee F15 ASTM website.

Labels.[7] ESHF staff collaborated with the other members of the ASTM Ad Hoc Language Task Group to develop recommendations for warning format that are based primarily on the requirements of ANSI Z535.4, *Product Safety Signs and Labels*, while also accounting for the wide range and unique nature of durable nursery products, the concerns raised by industry representatives, and ESHF staff recommendations associated with durable nursery product rulemaking projects over the past several years. These recommendations include requirements for:

- content that is "easy to read and understand," not contradicted elsewhere on the product, and in English, at a minimum;
- conformance to the following sections of ANSI Z535.4 – 2011, *Product Safety Signs and Labels*:
  - ANSI Z535.4, sections 6.1–6.4, which include requirements related to safety alert symbol use, signal word selection, and warning panel format, arrangement, and shape;
  - ANSI Z535.4, sections 7.2–7.6.3, which include color requirements for each panel; and
  - ANSI Z535.4, section 8.1, which addresses letter style;
- minimum text size and text alignment; and
- the use of bullets, lists, outline, and paragraph form for hazard-avoidance statements.

The Ad Hoc TG recommendations also include recommended text for general labeling issues, such as labeling permanency, and content related to manufacturer contact information and date of manufacture. As staff pointed out earlier, the latest version of the Ad Hoc-approved recommended language is published in the "Committee Documents" section of the Committee F15 ASTM website.[6]

Warning Placement

The draft ASTM Infant Loungers voluntary standard would require the warning label for in-scope products to be "conspicuous." Numerous ASTM juvenile products standards specify the placement of product warnings by including a requirement for warnings to be "conspicuous," which is defined in terms of when the warning must be visible to the consumer.

ANSI Z535.4 provides general guidance on the placement of warnings by stating that warnings must be placed so they are "readily visible to the intended viewer" and will "alert the viewer to the hazard in time to take appropriate action" (section 9.1).[8] This guidance is consistent with the guidance typically offered in human factors and warnings literature. The warning content for infant loungers is directed not to *any* consumer, but to the consumer who would be interacting

[7] ESHF staff consistently uses this standard—the primary U.S. voluntary consensus standard for the design, application, use, and placement of on-product warning labels—when developing or assessing the adequacy of warning labels. Literature on the design and evaluation of on-product warnings frequently cites ANSI Z535.4 as the minimum set of requirements that products containing such labels that are sold in the United States should meet (*e.g.*, Vredenburgh & Zackowitz, 2005; Wogalter & Laughery, 2005). Hellier and Edworthy (2006) and Peckham (2006) report that this conclusion has been reaffirmed by the U.S. courts, who have accepted the ANSI Z535 series of standards in general, and the ANSI Z535.4 standard in particular, as the benchmark against which warning labels are evaluated for adequacy, because these standards are seen as the state of the art (also see Laughery & Wogalter, 2006).[7] Furthermore, the scope of ANSI Z535.4 is broad enough to encompass nearly all products, including children's products and toys (see Kalsher & Wogalter, 2008; Rice, 2012).

[8] However, warnings must not be presented so far ahead that the consumer might forget the message when exposed to the hazard.

with and placing the infant in the product. Thus, ESHF staff recommends the following definition of "conspicuous":

> "visible, when the product is in each manufacturer's recommended use position, to a person while placing an infant into or onto the product."

CPSC staff recommended that the ASTM Infant Loungers subcommittee adopt this definition for their pending voluntary standard, and the most recent version of the draft voluntary standard includes a similar definition. The ASTM Infant Loungers Scope and Definitions task group is considering revisions to the draft voluntary standard to bring its definition more in line with staff's recommendation.

Warning Permanence

The draft voluntary standard would require warning labels for infant loungers to be "permanent." The draft standard includes warning label permanence requirements in the *General Requirements* section and specifies that warning labels must be permanent when tested in accordance with specific test methods that appear in the *Test Methods* section. ESHF staff supports these requirements and test methods, which are consistent with the general approach taken across ASTM juvenile products standards. ESHF staff recommends that the draft proposed rule for infant support cushions include all these permanency-related requirements and test methods.

In addition, staff believes that it is important to include an additional warning-permanency requirement that would address so-called "free-hanging" labels; that is, labels that attach to the product at only one end of the label. Warning labels that are attached in this way are more likely to be torn or ripped off, or otherwise altered by the consumer, which would eliminate the potential safety benefit of the warning for future users of the product. Given their importance, the required warnings must be as permanent as possible and discourage easy removal. Thus, staff recommends that the draft proposed rule include the following additional requirement:

> x.x.x Warning labels that are attached to the fabric of the product with seams shall remain in contact with the fabric around the entire perimeter of the label, when the product is in all manufacturer-recommended use positions, when tested in accordance with x.x.

A similar requirement appears in the ASTM voluntary standard for infant bedding (F1917 – 20e1), as well as in the CPSC final rule for sling carriers (16 C.F.R. part 1228) to address identical concerns that commenters raised during the NPR public comment period for that proposed rule.

Instructional Literature Requirements

The draft ASTM Infant Loungers voluntary standard includes requirements for instructional literature to accompany infant loungers. These requirements are based on the ASTM Ad Hoc Language Task Group recommended requirements for instructional literature and for the formatting of warnings in instructional literature, and ESHF staff worked with the ASTM Ad Hoc

Language Task Group to develop these requirements. The requirements generally specify that the accompanying instructions shall

- be easy to read and understand and be in the English language, at a minimum;
- include information regarding specific tasks associated with the product such as assembly, maintenance, cleaning, and use, where applicable;
- address the same warning and safety-related statements that must appear on the product, with similar formatting requirements, but without the need to be in color; and
- not include any instructions that contradict or create confusion about the meaning of the required information, or otherwise mislead the consumer.

The ASTM Infant Loungers subcommittee included the following additional warnings and related statements that must be addressed in the instructional literature that accompanies these products:

- statements about reading all instructions before using the product and keeping the instructions for future use
- a warning to not use the product if it is damaged or broken
- information about the manufacturer's recommended maximum weight, height, age, developmental level, or combination thereof, of the infant intended to be supported by the product, and if the product is not intended for specific children (*e.g.*, related to a specific disability) a description of this limitation

The draft Instructional Literature section also refers the reader to ANSI Z535.6, *Product Safety Information in Product Manuals, Instructions, and Other Collateral Materials*, for additional guidance on the design of warnings for instructional literature.

C. Use Patterns

Although, CPSC staff and ASTM Subcommittee members have developed requirements for warnings and instructional literature for infant loungers to comply with the most current guidance for wording, design, and format, ESHF staff concludes that infant support cushions/loungers will likely be used for infant sleep despite warnings against such use. Consistent with this, 55 of the 79 fatalities occurred when the lounger was being used in a sleep environment, such as a bed, crib, bassinet, play yard, or toddler bed. In the Caregiver Perceptions and Reactions to Safety Messaging user research study (Fors Marsh Group, 2019), the majority of participants reported adding a comfort item to sleep products for their infant. This ranged from adding a plush mattress to laying down a pillow or blanket to make the sleep experience better for their infant. Grandparents reported adding blankets to their infant's sleep environment more than parents.

Infant loungers are marketed and promoted as comfortable, pillow-like products that snuggle and comfort infants. Manufacturers' use terms such as "baby nest," "soft pillow," "portable bassinet," "womb-like," and "safe, secure" to describe loungers. These products are shown in marketing and advertisements being used with sleeping infants on couches, beds, cribs, bassinets, and play yards. Consumers associate pillows with sleep and therefore, infant loungers that are promoted for resting or lounging, or are either promoted as or have the appearance of pillows, will likely be used for napping and sleeping. Although staff has recommended various performance requirements such as firmness and side height to reduce the likelihood that infant support cushions will be used for sleeping and will be less hazardous when used on the floor,

using the products in environments such as in cribs and bassinets or on a sofa, or on adult beds will create a positional asphyxia/suffocation risk.

III. Conclusions

ASTM is developing a voluntary standard for “Infant Loungers,” which will contain requirements for a very limited set of pillow-like infant products intended for infants to use during awake time, and specifically not for sleep. The draft voluntary standard includes warnings and instructional literature using current, internationally recognized guidance for wording, design, and formatting. Although there may be some existing “infant loungers” that will meet the requirements of the proposed voluntary standard, most infant support cushions/loungers currently available to consumers are marketed and promoted for use by infants while sleeping. Due to the overall design of infant support cushions/loungers, consumer familiarity with pillow products, and the abundance of marketing and promotional materials showing infants sleeping in these products, ESHF staff contends that changing the warnings and instructional literature without also making any physical changes to the product will not dissuade many consumers from using the product for sleep. Products meeting performance requirements will have a firmness similar to a crib mattress, have low sidewalls under 2 inches thick that do not give the impression of containing a child and provide an inclined angle not exceeding 10 degrees, and have warnings against using in a sleep product. Staff assesses that products meeting the proposed requirements may inform and discourage some consumers from using an infant support cushion in a sleep setting, however, many caregivers will continue to use these products for sleep and in sleep environments because they perceive that a support cushion provides a more comfortable sleep environment for a baby. The use of an infant support cushion in a sleep environment will present a suffocation hazard and staff continues to recommend against this practice.

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TAB E: Initial Regulatory Flexibility Analysis for the Draft Proposed Rule to Establish a Mandatory Safety Standard for Infant Support Cushions

United States
Consumer Product Safety Commission

Memorandum

TO: Stefanie Marques, Ph.D., Infant Support Cushions Rulemaking Project Manager,
Directorate for Health Sciences

DATE: November 8, 2023

THROUGH: Alex Moscoso, Associate Executive Director and
José Tejeda, Division Director,
Directorate for Economic Analysis

FROM: Susan Proper, Economist
Directorate for Economic Analysis

SUBJECT: Initial Regulatory Flexibility Analysis for the Draft Proposed Rule to Establish a Mandatory Safety Standard for Infant Support Cushions

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I. Introduction

CPSC staff has developed a draft Notice of Proposed Rulemaking (NPR) to establish a mandatory safety standard for infant support cushions, as defined in the draft proposed rule.

Section 603 of the Regulatory Flexibility Act (RFA, 5 U.S.C. §603) requires the Commission to prepare an Initial Regulatory Flexibility Analysis (IRFA) for a proposed rule, describing the impact of the proposed rule on small entities, and identifying efforts by the Commission to reduce those impacts. This memorandum presents the main findings of the IRFA for the infant support cushions' draft proposed rule.

As specified in the RFA, the IRFA must contain:

> (1) a description of the reasons why action by the agency is being considered;
> (2) a succinct statement of the objectives of, and legal basis for, the proposed rule;
> (3) a description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply;
> (4) a description of the projected reporting, recordkeeping and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record;
> (5) an identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap or conflict with the proposed rule.

In summary, staff assesses that this draft proposed rule would have a significant impact on a substantial number of small entities because no existing mandatory or voluntary performance standards exist for infant support cushions, so the requirements are new for all entities. In addition, several thousand small entities are in this market segment, including many very small hand-crafter businesses and small importers.

II. Reason for Agency Action

CPSC staff identified a total of 204 incidents associated with the use of infant support cushions in CPSC's injury and incident databases[1] from January 1, 2010, through December 31, 2022 (see Tab A). The incidents include 79 fatal injuries and 125 non-fatal incidents, including 22 emergency department treated injuries and 3 hospital admissions. The most common cause of death was asphyxia or probable asphyxia, while the most common cause of non-fatal injuries was a fall, followed by threatened asphyxia. In 2020 alone, the most recent year for which complete data is available, there were 17 fatalities involving infant support cushions, so the existing ban is not addressing the hazards of non-banned infant pillows.

The current ban on "infant pillows" in 16 C.F.R. §1500.18(a)(16) only applies to "infant pillows" that are loosely filled with a granular material, as well as other characteristics. This ban was published in 1992. Most infant support cushions on the market today are filled with some type of foam or fibrous batting, rather than a "granular material," and are therefore not banned.

Despite the significant number of child deaths and injuries discussed above, currently no mandatory safety standard exists for non-banned infant pillows that addresses the hazards of these products being used for infant sleep or propping, sometimes on elevated surfaces, including adult beds, or inside an infant sleep product. Also, no voluntary standard addresses infant support cushions; however, ASTM is developing a voluntary standard for "infant loungers" that has not yet been balloted. The scope of that voluntary standard does not include most types of infant support cushions; for instance, it does not cover sleep positioners, play mats, wedge pillows, or other pillow products marketed for sleep.

Free-standing products marketed or intended to provide sleeping accommodations for infants up to five months of age are in the scope of the mandatory "Safety Standard for Infant Sleep Products" (16 C.F.R. part 1236). However, staff identified incidents associated with infant support cushion products that are not marketed for sleep but have a foreseeable use for sleep and are not covered by another CPSC standard. Staff also identified incidents associated with support cushions that are marketed for sleep, but do not contain an infant (and are thus not "sleeping accommodations"), such as wedge pillows and sleep positioners. Some incidents associated with support cushion products involve children older than 5 months. This rule would establish mandatory safety standards for all infant support cushions intended, marketed or designed for children up to 12 months old that are not covered by another mandatory CPSC standard for durable infant or toddler products as specified in 16 C.F.R. 1130.2(a), except for nursing pillows marketed only for nursing.[2] The scope of this draft proposed rule includes products that support any part of an infant for lounging, rest, or sleep, such as head positioner pillows.

Consequently, because section 104 of the CPSIA requires the Commission to regulate durable infant or toddler products, and because infant support cushions are associated with known hazards that are not addressed by an existing mandatory or voluntary standard, CPSC staff proposes that the Commission publish this draft proposed rule to establish specific performance

[1] Two main databases were used: NEISS and CPSRMS. NEISS (National Electronic Injury Surveillance System) is a collection of consumer product-related injury and incident data from a statistical sample of emergency department at U.S. hospitals; NEISS produces nationwide estimates of product-related injuries. CPSRMS (Consumer Product Safety Risk Management System) is a database of consumer product incident reports.

[2] Nursing pillows are covered by another CPSC draft proposed rule. That draft proposed rule defines nursing pillows as "any product intended, marketed, or designed to position and support an infant close to a caregiver's body while breastfeeding or bottle feeding. These products rest upon, wrap around, or are worn by a caregiver in a seated or reclined position."

standards to address these hazards; and to require a specific warning label, a customer registration card, and instructions; as well as third-party testing to demonstrate compliance.

III. Objectives and Legal Basis of the Proposed Rule

A. Objectives of the Draft Proposed Rule

The objective of the draft proposed rule is to establish a mandatory safety standard for infant support cushions that addresses known hazards from infant support cushions.

B. Legal Basis of the Draft Proposed Rule

Section 104(b)(1) of the CPSIA requires the Commission to assess the effectiveness of voluntary standards for durable infant or toddler products, if such standards exist, and to adopt mandatory standards for these products. 15 U.S.C. § 2056a(b)(1). No voluntary standard currently exists for infant support cushions, so staff has drafted a proposed rule to address the hazard presented by these products.

The CPSIA also authorizes the Commission to require manufacturers of durable nursery products to provide consumers with a postage-paid consumer registration form with each such product, and to permanently place the manufacturer name and contact information, model name and number, and the date of manufacture on each durable infant or toddler product. 15 U.S.C. § 2056a(d). This draft proposed rule would add infant support cushions to the list of products for which registration cards are required.

The CPSIA also sets forth the requirements for third-party testing of children's products, and for the accreditation of such testing laboratories. 15 U.S.C. § 2063. This draft proposed rule would add infant support cushions to the list of durable infant products specified in 16 C.F.R. part 1112 "Requirements Pertaining to Third Party Conformity Assessment Bodies."

C. Compliance with Proposed Rule

The draft proposed rule establishes new performance and labeling requirements. Suppliers would need to conduct third-party testing to demonstrate compliance, provide the specified warning label and instructions, and provide a product registration card.

These are new requirements for these products for all suppliers, large and small. Infant support cushions are currently not required to be third-party tested to any CPSC standard, unless textile content, lead or phthalates content, or small parts requirements apply to a particular item. Most pillows are made of textile materials that are exempt from those testing requirements for lead or phthalates for the textile portion, as specified in 16 CFR §1500.1, although any metal or plastic fasteners may require testing for lead or phthalates content. In any case, the third-party testing requirements in this NPR will be new for all suppliers.

The labelling and instructions requirements are also new for these products. Some pillows currently on the market have warning labels, but not the specific labels or instructions required by this rule. Suppliers would also be required to provide a product registration card, which some companies may already provide.

The labeling and instructions requirements constitute a burden under the Paperwork Reduction Act. CPSC staff will submit an Information Collection Request to the Office of Management and

Budget of the Executive Office of the President (OMB) for approval and obtain an OMB control number for this information collection. Certificates of compliance, called children's product certificates, are already required for all children's products under OMB Control Number 3041-0159. Product Registration cards are exempt from PRA burden analysis under section 104(d)(1) of the CPSIA.

IV. Entities to Which This Rule Would Apply

A. The Product

The draft proposed rule would apply to infant support cushions as described in the draft proposed rule.

Products within the scope of the rule would include, but would not be limited to:

- Head positioner pillows
- Flat baby loungers
- Crib pillows
- Wedge pillows for infants
- Infant sleep positioners, unless regulated by the FDA as medical devices[3]
- Stuffed toys marketed for use as an infant support cushion
- Infant "tummy time" or "lounging" pillows, whether flat or inclined
- Multi-purpose pillows marketed for both nursing and lounging
- Anti-rollover pillows with or without straps that fasten the pillow to the infant
- Infant "self-feeding" pillows that hold a bottle in front of the face of a reclining or lying infant[4]
- Pads and mats
- Accessory pillows and other padded accessories, often marketed for use with an infant car seat, stroller or bouncer, but not sold with that product and therefore, not included in the mandatory safety testing for those products.

Some of these products are marketed for use inside a crib or other sleep product. Given that newborns normally sleep 16 to 17 hours a day,[5] marketing a support cushion product as "not for sleep" is unlikely to prevent caregivers from foreseeably using the support product during infant sleep. The exception would be products that have a clear purpose for entertaining an awake infant, such as an activity mat with attached toys. However, marketing a product for "tummy time" or "lounging" is unlikely to influence caregiver behavior if the product is a pillow or similar support product (which are typically associated with sleep) and can foreseeably be used for sleep or placed in an infant's sleep environment. CPSC staff considers these types of products to be within scope of this rule.

B. Products Out of Scope

[3] The FDA discourages the use of infant sleep positioners and has never approved a pillow product for preventing sudden infant death syndrome (SIDS). See https://www.fda.gov/consumers/consumer-updates/do-not-use-infant-sleep-positioners-due-risk-suffocation

[4] These products are banned in the UK due to suffocation and pneumonia hazards. https://www.gov.uk/product-safety-alerts-reports-recalls/product-safety-alert-baby-self-feeding-pillows-slash-prop-feeders-psa3

[5] https://www.healthychildren.org/English/ages-stages/baby/sleep/Pages/default.aspx

The following products are out of scope:

- Pillows not marketed or intended for use by infants, including adult bed pillows
- Nursing pillows that are marketed only for feeding and are not marketed, intended, or foreseeably used for lounging, if they meet the requirements of the Commission's proposed nursing pillow rule 88 FR 65865 (Sept. 26, 2023) if that rule is finalized
- Crib and play yard mattresses; that are in scope of the play yard and crib mattress standard in 16 C.F.R. part 1241
- Purely decorative nursery pillows, such as those personalized with the baby's name and birthdate, if they are not intended, designed, or marketed for infant use.
- Stuffed toys (unless they meet the definition of an infant support cushion in this proposed rule)
- Padded seat liners that are sold with a rocker, stroller, car seat, infant carrier, swing, highchair or bouncer that are specifically designed to fit that product
- Sleeping accommodations, which are regulated under the Commission's infant sleep product rule at 16 CFR part 1236

C. The Market

Staff cannot precisely determine the annual sales volume of new infant support cushions, given the variety of products within the scope of this rule and the large number of suppliers.

Some parents may already own a product that was purchased for an older child, particularly in the case of loungers and sleeping pads that may also be used by toddlers and are marketed for the toddler age range as well as for children under 12 months old. Also, these products are marketed for different uses, for example a head positioner pillow versus a padded sleep mat, so parents may buy more than one product within the scope of this draft proposed rule for their infant or may receive more than one of these items as a gift. However, not every infant support cushion currently in use represents a newly manufactured product. There is a considerable market in used infant support cushions on prominent second-hand online sites. In June 2023, staff found listings on Mercari for used changing pads, large stuffed toys marketed for infant sleep, crib wedge pillows, baby neck pillows, baby sleep positioners, baby loungers, baby sleep mats, baby "pillow chairs", infant "self-feeding" pillows, baby/toddler bean bag chairs, and crib pillows.

Most types of new infant support cushions are sold online, including from general online retailers, online sites for "big box" stores, online baby products sites, and online marketplaces for hand-crafted items. A few types of infant support cushions, however, are also available from brick-and-mortar baby specialty stores and general retail stores, particularly crib pillows and baby loungers. Prices for new infant support cushions range from under $15 for a simple head positioner pillow or crib pillow to more than $250 for a lounger with a removable cover or a large stuffed toy marketed for sleep, with the average price at roughly $30. Infant support cushions are supplied by several thousand manufacturers and importers, including hundreds of handcrafters and direct foreign shippers.[6] Staff observes that infant support cushions are widely available used from secondary marketplaces such as Ebay and Mercari, particularly the larger items that may also be marketed for the toddler age range and the more expensive items.

[6] Based on staff analysis of products in scope of this NPR for sale online by major general retail chain stores, department stores, specialty baby stores, a prominent handcrafter site, and the websites of individual companies in the U.S. and other countries.

D. Small Entities to Which the Proposed Rule Would Apply

This draft proposed rule would apply to entities that supply infant support cushions to the U.S. market. These include manufacturers and importers, as well as foreign direct shippers. More than 2,000 suppliers are in this market, the majority of which are small.

The Small Business Administration (SBA) sets size standards for what constitutes a U.S. small business for the purpose of various federal government programs.[7] SBA size standards are based on the number of employees or the annual revenue of the firm, and there is a specific size standard for each 6-digit North American Industry Classification Series (NAICS) category.[8] The U.S. Census Bureau conducts an annual survey of small businesses in the United States, and counts how many large and small businesses are in each NAICS category.[9] The SBA size standard for what constitutes a "small" business is typically 500 to 750 employees for manufacturers and 100 to 150 employees for wholesalers, depending on the industry category. Importers are a type of wholesaler. Manufacturers and importers of infant support cushions could be in a wide variety of such categories, depending on their primary line of business, which often is not support cushions but rather some more general category of children's products or other consumer goods.

Based on staff's assessment of prominent online and brick-and-mortar retail sources for infant support cushions in the Spring of 2023, there appear to be more than 2,000 suppliers of infant support cushions to the U.S. market, including many small U.S. crafters, small importers, small manufacturers, and direct foreign shippers.

E. Entities to Which the Draft Proposed Rule Would Not Apply

The draft proposed rule would not have any direct impacts on retailers of any size, except for retailers that have "store brand" infant support cushions and are therefore also manufacturers of infant support cushions. Products manufactured before the effective date of the final rule could still be sold by retailers of any size. There could be an indirect impact on retailers in the longer term, including small retailers, if certain products are removed from the market altogether, so retailers lose the revenue from those future sales.

The draft proposed rule would not have any direct impacts on the many small businesses that make cases or covers for other companies' infant support cushion products. However, there could be an indirect impact on those firms if they make cases or covers for a specific product, and that product is redesigned or removed from the market by the manufacturer.

V. Compliance, Reporting, Paperwork, and Recordkeeping Requirements of the Draft Proposed Rule

[7] The size standards are in listed in the Code of Federal Regulations. See 13 CFR part 121.
[8] The North American Industry Classification System (NAICS) is the standard used by Federal statistical agencies in classifying business establishments for the purpose of collecting, analyzing, and publishing statistical data related to the U.S. business economy. For more information, see https://www.census.gov/naics/. Some programs use 6-digit NAICS codes, which provide more specific information than programs that use more general 3 or 4-digit NAICS codes.
[9] https://www.census.gov/programs-surveys/susb/data/tables.html

Suppliers would be required to comply with the performance requirements of the draft proposed rule, and to provide a warning label, a consumer registration card, and user instructions; as well as conducting third-party testing to demonstrate compliance. This section discusses the reporting and paperwork requirements. The compliance costs are analyzed in detail in section VII.

Manufacturers and importers must demonstrate that they meet the performance requirements of the rule by testing products to the rule and certifying that the products meet the requirements of the rule in a children's product certificate. Also, as specified in 16 C.F.R. part 1109, manufacturers or importers who are not the original manufacturer, such as importers, may rely on testing or a certificate of conformity provided by another firm, as long as the firms meet the requirements in part 1109. Manufacturers and importers must also provide product registration cards. Recordkeeping and compliance documentation do not require specialized expertise. CPSC's public website provides instructions and examples for how to develop the children's product certificate and product registration cards.[10]

While some products currently have labels, all products would have to meet the specific labeling requirements and instructions specified in the draft proposed rule, which provides the text and graphics for the required labels and instructions. Therefore, specialized graphics design expertise would not be required to develop the warnings and instructions. The ongoing cost of the new labels and instruction manuals is estimated at less than $1 per item for materials. The initial cost for labor of developing the labels and instruction manuals is included in the cost of redesigning models to comply with this draft proposed rule, which is discussed in more detail in section VII of this memo. As noted earlier, the labeling and instructions requirements constitute a burden under the Paperwork Reduction Act. CPSC staff will submit an Information Collection Request to OMB for approval and obtain an OMB control number for this information collection.

CPSC's Office of the Small Business Ombudsman provides additional online resources for small businesses to assist with the recordkeeping requirements.[11]

VI. Federal and State Rules that May Overlap with this Draft Proposed Rule

CPSC staff has not identified any other Federal rules that duplicate, overlap, or conflict with the proposed rule. As noted earlier, CPSC has an existing ban on certain types of infant pillows that have granular filling. Because those products are banned, there should not be any on the market that are in the scope of this draft proposed rule. Multiple states have bans on certain flame retardants in children's products, including pillows, but this draft proposed rule does not set requirements on the use of flame retardants, so there is no overlap or conflict. CPSC has an NPR for nursing pillows in development that covers pillows that are marketed and designed for nursing and bottle-feeding. To the extent these nursing pillow products are also marketed and designed for lounging or resting, they must comply with both the CPSC's draft nursing pillow rule and this draft proposed rule. Some infant support cushions may be in scope of the Commission's ISP rule and/or the Safe Sleep for Babies Act's ban on inclined sleepers for infants if they provide sleeping accommodations.

[10] See for example: https://www.cpsc.gov/Testing-Certification/Childrens-Product-Certificate-CPC; and https://www.cpsc.gov/Business--Manufacturing/Business-Education/Durable-Infant-or-Toddler-Products/FAQs-Durable-Infant-or-Toddler-Product-Consumer-Registration

[11] See: https://www.cpsc.gov/Business--Manufacturing/Small-Business-Resources

VII. Potential Impact on Small Entities

This draft proposed rule would likely have a significant impact on a substantial number of small entities, based on the estimated costs of modifying the product to achieve compliance, and the ongoing cost of testing to demonstrate compliance. Staff considers one percent of annual revenue to be a "significant" economic impact on a company, consistent with regulatory impact analyses by other federal government agencies. Nearly all the U.S. suppliers of infant support cushions are small entities, and there are more than 2,000 of them.

A. Cost of Modifying Product

Most infant support cushion products on the market would require redesign to meet the requirements in the NPR, and no products on the market currently have all the specific labels, customer registration forms, and warnings required by the draft proposed rule. A few products on the market may already meet the performance requirements in the draft proposed rule, such as a thin, very firm pillow or nap pad with no straps. However, all products would require third-party testing to demonstrate compliance. Testing costs are covered in part B of this section.

The effort required for a one-time redesign is estimated by CPSC subject matter experts to be 200 hours of professional staff time per model, including in-house testing of the prototypes and development of labels, customer registration forms, and instruction materials.[12] Using current (December 2022) Bureau of Labor Statistics (BLS) Employer Costs of Employee Compensation,[13] the estimated cost per model is $12,530, at a current cost for professional labor of $62.65 per hour, rounded for the purpose of analysis to $12,500 per model. Materials costs for prototyping are estimated to be minimal, likely under $1,000, given that pillows are typically made of fabric and stuffing materials. The total cost of redesign is approximately $13,500 per model ($12,500 for labor and $1,000 for materials). The cost per company would depend on how many different models each company manufactures.

For small crafters and other non-employee businesses, the cost of labor reflects the economic "opportunity cost" – while such a small business might not hire an engineer for redesign at $62.65 an hour, they would still need to spend approximately 200 hours redesigning their product, which is 200 hours they would not have for other activities to support their business. Some engineering expertise would likely be required for the redesign, to ensure that in particular the firmness requirement and other requirements are met, using a force gauge and other equipment as specified in the NPR regulatory text. For small crafters, their "opportunity cost" (the value of their time spent on redesign that cannot be spent on other activities) might be worth less than $62.65 an hour to them. Online prices of handcrafted items vary widely, but the lower end of the handcrafter market does demonstrate that some crafters value their own time at less than $62.65 an hour. For example, if a hand-crafted item is priced under $50, and the item appears to require more than one hour to construct and ship, it is likely that crafter valued their own time at less than $50 an hour. Small crafters may also be able to reduce their redesign costs by observing and learning from how larger companies generally achieve compliance with this rule, such as through certain fabrics, threads, or types of stuffing.

[12] Staff estimate of labor effort reflects that it may require multiple prototypes and design iterations to develop a product that is compliant with the requirements in this NPR. The firmness requirement particularly may require several attempts to meet the requirement.

[13] https://www.bls.gov/news.release/archives/ecec_03172023.pdf. These costs reflect the employers' cost for salaries, wages, and benefits for civilian workers.

Many U.S. manufacturers have outsourced production to foreign countries but design their products in North America. Therefore, this estimate reflects U.S. labor and materials costs for prototype designs. While importers would not directly pay for the cost of redesign by foreign suppliers, the cost of redesign would almost certainly be reflected in the wholesale price.

As noted earlier, staff considers one percent of annual revenue to be a "significant" economic impact on a company, consistent with regulatory flexibility analyses conducted by other federal government agencies. The estimated $13,500 cost to redesign would be one percent of revenue for a firm with $1.35 million in revenue. The cost is likely to be significant for a substantial number of small U.S. firms that have less than $1.35 million in revenue, including small manufacturers and small importers. Small home crafters are a subset of small manufacturers; they would likely be significantly impacted by this rule.

With an estimated 2,000 models that need to be redesigned, at $13,500 per model, the total cost for the industry as a whole is estimated at up to $27 million for redesign in the first year after the rule is published, assuming that all suppliers decide to remain in the market. The cost could be less, depending upon the cost for individual firms. It is possible many small volume home crafters will exit the market rather than redesign, and that some of the foreign suppliers to small importers would also exit the market rather than redesign, at least temporarily. If firms choose to exit the market, the impact of lost sales could be significant for those firms. However, because the performance requirements could be met by replacing the stuffing with a firmer type and changing the shape of the product's sides, which does not necessarily require specialized engineering expertise or tools, it is possible that many of the small volume crafters and other small manufacturers would bear the expense of redesign and stay in the market. For small crafters, their "opportunity cost" (the value of their time spent on redesign that cannot be spent on other activities) might be worth less than $62.65 an hour to them, in which case their cost of redesign could be less than $13,500. Some engineering expertise would likely be required for the redesign, to ensure that in particular the firmness requirement and other requirements are met, using a force gauge and other equipment as specified in the NPR regulatory text. Small crafters may also be able to reduce their engineering costs by observing and learning from how larger companies generally achieve compliance with this rule, such as through certain fabrics, threads, or types of stuffing. However, that approach will require them to wait until the larger companies introduce compliant products onto the market, and they must also not violate any patented or trademarked designs by larger companies.

Firms may be able to reduce the impact of design costs by raising the retail or wholesale price of infant support cushions to cover the cost of redesign, in which case the impact might not be significant, even for small suppliers. The retail price increase to cover redesign costs could be relatively minor, even for relatively small volume suppliers. For example, a firm supplying 5,000 infant support cushions per year could cover the entire cost of redesign by raising the price by $2.70. ($13,500 for redesign, with the cost divided by the 5,000 units, equals a cost of $2.70 per unit.) Small manufacturers and small importers with several employees might have this level of sales volume, although most small crafters and single person importer businesses would not. However, small crafters and single person importers could cover at least some of their redesign costs by raising price by a few dollars per unit. Given that all suppliers would be redesigning products to comply with this draft proposed rule, small businesses may not necessarily be less competitive if nearly all firms, regardless of size, raise prices to cover costs. Small crafters may also be able to collaboratively share solutions to achieve compliance with other small crafters, thus reducing the engineering costs for redesign by any one firm.

B. Third-Party Testing Costs

Manufacturers of infant support cushions would be required to comply with the standards of this draft proposed rule, and to demonstrate this compliance through third-party testing. As specified in 16 C.F.R. part 1109, entities that are not manufacturers of children's products, such as importers, may rely on the testing or certification provided by another firm, as long as they follow the requirements in part 1109. Staff assumes that foreign manufacturers would pass on at least some of the cost of testing for compliance to small U.S. importers.

Third-party testing will be a new cost for all suppliers, because infant support cushions are not currently required to be third-party tested unless required by another CPSC regulation, such as small parts, toys, lead, or phthalates.[14] Estimated third party testing costs for infant support cushions is estimated at $500 to $1,000 per model, based on current prices for testing other children's durable nursery products. The cost of testing would depend on where the testing takes place, and whether manufacturers' associations or groups add infant support cushions to their certification programs to receive volume discounts for third-party testing. The annual cost of samples for testing is estimated at around $100. Costs of testing per model will be similar for all sizes of suppliers, although larger firms are more likely to qualify for testing lab volume discounts.

The cost of testing alone could be significant for some small hand crafters. A cost of $600, the low end of the testing cost estimate including cost of samples for testing, would represent one percent of annual revenue for a company generating $60,000 in annual revenue. At an estimated average price of $30 per pillow, this would represent sales of 2,000 units. Many hand crafters show historical sales of less than 100 units. However, a company selling as few as 200 units could cover the cost of annual testing by raising the price $3, or 10 percent of the average price, which could reduce the impact of the draft proposed rule on that small business.

Small importers are less likely to find that testing costs (as reflected in increased wholesale costs from foreign suppliers) are a significant burden. For example, baby head sleep positioner pillows are currently available on Alibaba[15] for about $1 to $3, with lower prices for larger volume orders. If testing costs added ten percent to the wholesale cost, that would be less than 50 cents per unit, and importers could raise the retail price to cover compliance costs with minimal, if any impact, on consumer demand. However, small importers may not be able to find a compliant supplier, depending on the decisions foreign manufacturers make about whether to redesign and test to the CPSC standard.

C. Summary of Impacts

Redesign costs would be a potentially significant cost for a substantial number of small firms for the first year that the draft proposed rule is effective. One-time redesign costs, including costs of designing warning labels and instruction manuals, are estimated at $13,500 per model. The cost for crafters and other very small businesses may be more of an "opportunity cost" if they undertake some of the redesign themselves. Small crafters' cost may also be less if the cost of

[14] Several manufacturers make vague references to third-party testing in their marketing; such references are likely in relation to testing for textile content, lead content of fasteners, or small parts.
[15] Alibaba is a prominent Chinese site for wholesale consumer products.

their own labor is below the BLS average for professional staff (i.e., small business owners take less wages and are instead compensated by equity in their business) or if their engineering costs can be shared with other small crafters. Ongoing annual testing costs are estimated at $600 to $1,100 per model, including the cost of the samples for testing. Small companies may be able to reduce the impact of the rule by raising retail prices by 10 percent or less to cover all or a portion of redesign and testing costs.

Staff assesses the impact to be significant for a substantial number of small firms with low volume sales. Many small volume hand crafters may stop selling infant support cushions. Small volume hand crafters may not have the sales volume to cover the expense of redesign and testing and still generate a profit, even if they raise prices, while small volume importers may not be able to find a compliant supplier. There may be reduced demand for redesigned products.

Remarketing options are limited, as most infant support cushion products are clearly intended for sleep or foreseeably used for sleep. A few possible exceptions are stuffed toys, activity mats with toys, and changing pads, which could be credibly remarketed as not for sleep.

Consumers may not experience a significant loss of consumer utility as small volume sellers exit the market, as there are many different products available from different suppliers, including a large number of online sellers. However, if the redesigned products are less appealing to consumers, there may be a loss in sale volumes of specific products as a result of this draft proposed rule. Small businesses may decide to exit the market if there is not sufficient demand for redesigned product.

The performance requirements in this draft proposed rule require that products meet certain firmness criteria and incline requirements. While any product within the scope of this draft proposed rule could be redesigned to meet its performance requirements, some suppliers may decide to exit the market rather because they anticipate that consumers would not want the redesigned products. For example, a “wedge” pillow could be redesigned to be compliant with this rule, but its incline would need to decrease significantly from its current angle. An infant sleep positioner could be redesigned to be compliant, but it would need to meet the firmness requirements in the draft proposed rule. In terms of small businesses, the impact of removing a product from the market instead of redesigning it could be significant as a result of a potentially large volume of lost sales.

Product redesign may not increase the ongoing cost of producing the product, given that the materials and production methods are likely to remain roughly similar. If companies decide to pass the ongoing cost of testing onto consumers, the price increase could be relatively modest, perhaps under $3 at retail, or 10 percent of the price of a $30 item.

VII. Efforts to Minimize Impact, Alternatives Considered

The RFA specifies that the IRFA must contain a

> description of any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes, and which minimize any significant economic impact of the proposed rule on small entities. Consistent with the stated objectives of applicable statutes, the analysis shall discuss significant alternatives such as-
> (1) the establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities;

(2) the clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities;
(3) the use of performance rather than design standards; and
(4) an exemption from coverage of the rule, or any part thereof, for such small entities.

CPSC staff did not consider either exempting small entities from this draft proposed rule or parts of it or establishing differing requirements for small entities because neither of these options would be consistent with the applicable statutes on durable infant or toddler products. 15 U.S.C. § 2063(d)(4)(C). Staff has also developed simplified compliance and reporting requirements for all entities that render additional simplification for small entities unfeasible. For example, a children's product certificate can be one page, and there are detailed guidelines and examples on the Commission's [16] website. Finally, the standard in this NPR is already a performance standard rather than a design standard.

CPSC staff considered several alternatives to this draft proposed rule, which are discussed in more detail below, including:

- Not establishing a safety standard for infant support cushions
- Delaying the draft proposed rule until a voluntary standard is published
- A shorter effective date

Not establishing a safety standard for infant support cushions

Not establishing a safety standard for infant support cushions would result in no regulatory impact on small businesses, but it would also lead to a continuation of the injury and death patterns from the known hazards associated with infant support cushions. Deaths and injuries from the use of infant support cushions[17] would continue to occur, likely at similar rates as those observed by CPSC during the period from January 1, 2010, through December 31, 2022. In 2020, the most recent year for which complete data is available, there were 17 fatalities involving infant support cushions. (see Tab A)

Not implementing the rule would reduce the regulatory burden on small firms, but at high societal cost in terms of deaths and injuries. The rule may provide a temporary competitive advantage to small firms whose products already meet the requirements in this rule.

Delaying the Draft Proposed Rule until a Voluntary Standard is published

ASTM has not yet balloted or published a voluntary standard for infant support cushions. ASTM is developing a voluntary standard for infant loungers, which would include a much narrower scope of products than would this draft proposed rule.

Staff does not know, given the predominance of very small companies in this product sector, whether there would be sufficient interest in developing a voluntary standard that covers all types of infant support cushions within the scope of this draft proposed rule. Therefore, delaying the draft proposed rule until a voluntary standard is developed could cause an indefinite delay. Such a delay would reduce the impact on small businesses but would also allow the hazard to

[16] https://www.cpsc.gov/Testing-Certification/Childrens-Product-Certificate-CPC
[17] Even though there is a ban on infant pillows, this ban in 16 CFR 1500 does not apply to most infant pillows on the market today. Based on hazard data, the existing ban does not address the hazard of people using infant pillows to prop up sleeping infants on elevated surfaces, and/or inside other sleep products. The existing infant pillow ban in 16 CFR 1500 was published in 1992.

continue for an unspecified time. In addition, any eventual voluntary standard may not be as stringent as this draft proposed rule and may not adequately address deaths and injuries.

A different effective date

Staff recommends an effective date of 180 days. In the past, 180 days has generally been sufficient time for suppliers to come into compliance with durable infant or toddler product rules. Additionally, six months from the change in a voluntary standard is the period that JPMA uses for its certification program, so compliant manufacturers are used to this time frame to comply with a modified standard. Testing laboratories should have no difficulty preparing to test to the proposed new mandatory standards within a 180-day period, given that no new complex testing instruments, devices, or procedures are required to test infant support cushions for compliance to this draft proposed rule.

The majority of businesses supplying infant support cushions are small, and that currently there are no existing performance standard or labeling requirements for infant support cushions. A shorter effective date could provide safety benefits more quickly, but it would likely increase the burden on small businesses to quickly redesign and test their products. It could also result in temporary shortages of infant support cushions, because testing labs may need to apply for accreditation, and potentially approximately 2,000 businesses would need to have their products tested for compliance. A longer effective date would reduce the burden on small businesses to redesign their products quickly, and schedule third party testing, but would delay the safety benefits of the rule. Considering the burden on small businesses, the testing lab requirements, and the safety benefits of this rule, staff is recommending 180 days.

IX. Impact on Testing Labs

In accordance with section 14 of the CPSA, all children's products that are subject to a children's product safety rule must be tested by a third-party conformity assessment body that has been accredited by CPSC. These third-party conformity assessment bodies test products for compliance with applicable children's product safety rules. Testing laboratories that want to conduct this testing must meet the Notice of Requirements (NOR) for third-party conformity testing (CPSC has codified NORs in 16 C.F.R. part 1112). This section assesses the impact a proposed amendment would have on small laboratories.

Staff concludes that there should be no significant adverse impact on testing laboratories as a result of this rule. No new complex testing instruments, devices, or procedures are required to test infant support cushions for compliance to this draft proposed rule. The testing devices include a probe, a distance measurement device, a force gauge, a hinged weight gauge, and a frame to hold the product and testing devices in place. Testing laboratories are not required to provide these testing services; only those laboratories that make the business decision that there is sufficient demand for such services would need to procure the testing devices and apply for accreditation.

For the reasons described above, revising the NOR to add infant support cushions to the list of products subject to part 1112 would not have a significant adverse impact on small laboratories. Most laboratories are not small U.S. businesses. Companies in the lab testing industry include companies with hundreds of locations, including labs in Asia and Europe, and thousands of employees. Therefore, the Commission could certify that the NOR for the infant pillow mandatory standard will not have a significant impact on a substantial number of small laboratories.

X. Conclusion

The NPR would likely have a significant impact on a substantial number of small entities. Using the SBA size standards, nearly all the manufacturers and importers of infant support cushions are small businesses. Most products currently on the market would need to be redesigned, and all products would need new labelling and instructions. The cost of redesign and testing would likely be significant for most small businesses currently in the market. It is possible that many small volume hand crafters and small importers would exit the market[18] because of the relatively large cost of compliance as compared to their annual revenue. Remarketing to be out of scope of the draft proposed rule is not feasible for most in-scope products, with the possible exceptions of some stuffed toys, activity mats with toys, and changing pads, all of which have a credible purpose other than infant sleep.

Consumers may not experience a significant loss of utility due to the exit of small businesses from the market, as the standard adopted in the draft proposed rule is not expected to raise prices of infant support cushions by more than 10 percent ($3 on a $30 item), and currently there is a large variety of infant pillow products available in the market. All of the product types identified as within the scope of the draft proposed rule could meet the requirements of this draft proposed rule with redesign and labeling. However, it is also possible that many small suppliers would choose to remove their products from the market rather than redesign them, which will mean that consumers can no longer purchase those products.

[18] Note that "exit the market" does not necessarily mean going out of business. Small businesses that sell a variety of products may stay in business, but stop selling infant support cushions, either temporarily or permanently.

TAB F: Recommended Regulatory Text for the Draft Proposed Rule

TO: The Infant Support Cushions Rulemaking Project File **DATE:** November 8, 2023

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

FROM: The Infant Support Cushions Rulemaking Team

SUBJECT: Recommended Regulatory Text for the Draft Proposed Rule

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Part XXXX-Safety Standard for Infant Support Cushions

§ XXXX.1 Scope, Purpose, Application, and Exemptions

(a) *Scope and Purpose*. This consumer product safety standard prescribes requirements to reduce the risk of death and injury from hazards associated with *infant support cushions*, as defined in XXXX.2. This includes but is not limited to *infant positioners*, nursing products with a dual use for lounging, *infant loungers*, and infant props or cushions used to support an infant. All *infant support cushions* must be tested according to the requirements of XXXX.5 and comply with all requirements of this part.

(b) *Application*. All infant support cushions that are manufactured after [effective date], are subject to the requirements of this part XXXX.

(c) *Exemptions*. Products subject to another standard listed in 16 CFR 1130.2(a) *are* exempt from this part XXXX. Nursing pillows that also meet the definition of *infant lounger*, however, are not exempt from this part XXXX.

§ XXXX.2 Definitions

Conspicuous — visible, when the product is in each manufacturer's recommended use position, to a person while placing an infant into or onto the product.

Infant lounger – an infant product with a raised perimeter, a recess, or other area that provides a place for an infant to recline or to be in a supine, prone, or recumbent position.

Infant positioner - a product intended to help keep an infant in a particular position while supine or prone.

Infant support cushion – an infant product that is filled with or comprised of resilient material such as foam, fibrous batting, or granular material, or with a gel, liquid, or gas, and which is marketed, designed, or intended to support an infant's weight or any portion

of an infant while reclining or in a supine, prone, or recumbent position.

Occupant support surface (OSS) – the area that holds up and bears the infant or any portion of the infant.

Seat bight line — the intersection of the seat back surface with the seat bottom surface.

§ XXXX.3 General Requirements

(a) *Hazardous Sharp Edges or Points*—There shall be no hazardous sharp points or edges as defined in 16 CFR 1500.48 and 16 CFR 1500.49 before or after the product has been tested.
(b) *Small Parts*—There shall be no small parts as defined in 16 CFR 1501 before testing or presented as a result of testing.
(c) *Lead in Paints*—All paint and surface coatings on the product shall comply with the requirements of 16 CFR 1303.
(d) *Toys*—Toy accessories attached to, removable from, or sold with an infant pillow, as well as their means of attachment, shall comply with the applicable requirements of Consumer Safety Specification for Toy Safety 16 CFR part 1250.
(e) *Side Height*—The maximum side height for the product, measured from the OSS-body or test base, as appropriate, to the top of the sidewall, shall not exceed the maximum of the side heights determined in § XXXX.5(d)(8).
(f) Removal of Components. When tested in accordance with § XXXX.5(g), any removal of components that are accessible to an infant while in the product or from any position around the product shall not present a small part, sharp point, or sharp edge as required in § XXXX.3(a) and § XXXX.3(b)
(g) *Permanency of Labeling and Warnings*
(1) Warning labels, whether paper or non-paper, shall be permanent when tested in accordance with XXXX.5(b)(1)-(3)
(2) Warning statements applied directly onto the surface of the product by hot stamping, heat transfer, printing, wood burning, etc. shall be permanent when tested in accordance with XXX.5(b)(4)i-iii.
(3) Non-paper labels shall not liberate small parts when tested in accordance with XXXX.5(b)(5).
(4) Warning labels that are attached to the fabric of the product with seams shall remain in contact with the fabric around the entire perimeter of the label, when the product is in all manufacturer-recommended use positions, when tested in accordance with XXXX.5(b)(3).
(h) If the infant support cushion can be converted into another product for which a consumer product safety standard exists, the product also shall comply with the applicable requirements of that standard.

§ XXXX.4 Performance Requirements

(a) *Restraint*— The product shall not include a restraint system.
(b) *Seam Strength* – When tested in accordance with § XXXX.5(j), fabric/mesh seams and points of attachment shall not fail such that a small part, sharp point, or sharp edge is

presented, as required in § XXXX.3(a) and § XXXX.3(b).

(c) *Bounded Openings*— When tested to XXXX.5(c), all completely bounded openings that exist at the front, sides, or back of the occupant lounging area, or that are created when an accessory is attached to the product, shall not allow complete passage of the small head probe unless it allows the complete passage of the large head probe.

(d) *Maximum Incline Angle*—The maximum incline angle shall not exceed 10 degrees when tested in accordance with XXXX.5(d).

(e) *Firmness*

(1) *Occupant support surface firmness*-When the 3-in diameter (Figure 1) hemispherical head probe is applied according to the test method for occupant support surface firmness XXXX.5(f), the force required for a 1-inch displacement shall be greater than 10N.

(2) *Sidewall firmness*- When the 3-in diameter hemispherical head probe is applied according to test method sidewall firmness XXXX.5(g), the force required for a 1-inch displacement shall be greater than 10N.

(3) *Firmness at intersection of sidewall and occupant support surface*-When the 3-in diameter hemispherical head probe is applied according to test method for Firmness at intersection of sidewall and occupant support surface XXXX.5(h), the force required for a 1-inch displacement shall be greater than 10N.

(f) *Side Wall Angle*-Sidewall angle shall be greater than 90 degrees when determined according to the Sidewall Angle Determination XXXX.5(i).

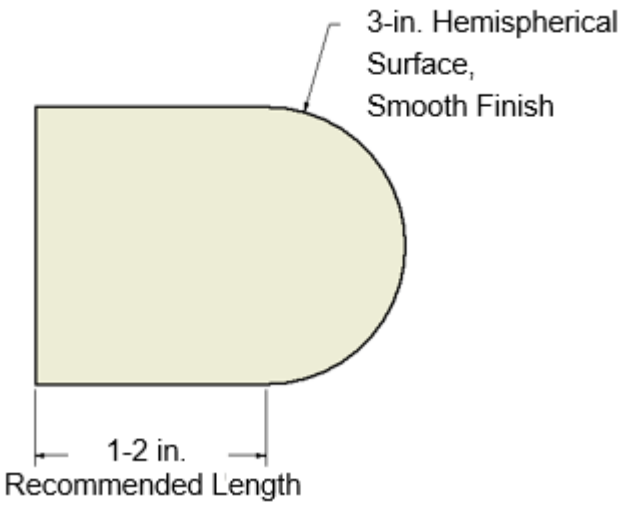

Figure 1. 3-in Head Probe

§ XXXX.5 Test Methods

(a) Test Conditions.

(1) Condition the product for 48 hours at 23 °C +/- 2 °C (73.4 °F +/- 3.6 °F) and a relative humidity of 50 % +/- 5 %.

(b) Permanence of Labels and Warnings:

(1) A paper label (excluding labels attached by a seam) shall be considered

permanent if, during an attempt to remove it without the aid of tools or solvents, it cannot be removed, it tears into pieces upon removal or such action damages the surface to which it is attached.

(2) A non-paper label (excluding labels attached by a seam) shall be considered permanent if, during an attempt to remove it without the aid of tools or solvents, it cannot be removed or such action damages the surface to which it is attached.

(3) A warning label attached by a seam shall be considered permanent if it does not detach when subjected to a 15-lbf (67-N) pull force applied in any direction using a 3⁄4-in. diameter clamp surface.

(4) Adhesion test for warnings applied directly onto the surface of the product.

i. Apply the tape test defined in Test Method B, Cross-Cut Tape Test of ASTM Test Methods D3359, eliminating parallel cuts.

ii. Perform this test once in each different location where warnings are applied.

iii. The warning statements will be considered permanent if the printing in the area tested is still legible and attached after being subjected to this test.

(5) A non-paper label, during an attempt to remove it without the aid of tools or solvents, shall not be removed or shall not fit entirely within the small parts cylinder defined in 16 CFR 1501 if it can be removed.

(c) *Head Entrapment Test*— For all applicable openings, rotate the small head probe (Figure 2) to the orientation most likely to fail and gradually apply an outward force from the occupant lounging area of 25 lb (111 N). Apply the force to the probe in the direction most likely to fail within a period of 5 s and maintain it for an additional 10 s. If the small head probe can pass entirely through the opening in any orientation, determine if the large head probe (Figure 3) can be freely inserted through the opening.

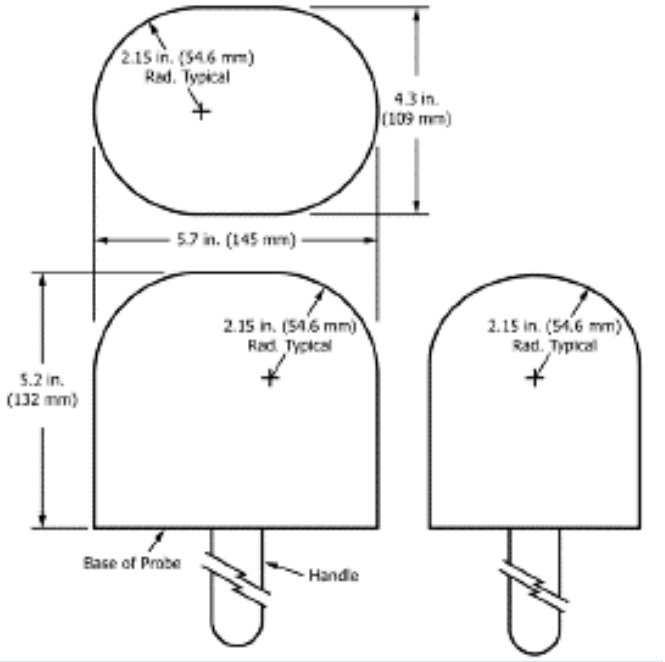

Figure 2. Small Head Probe

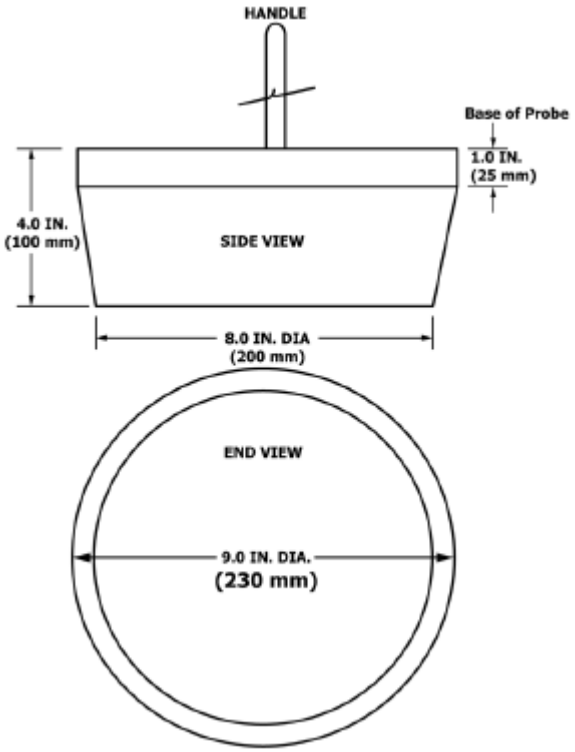

Figure 3. Large Head Probe

(d) *Maximum Incline Test*:

(1) Equipment:

i. Digital Protractor with accuracy +/- 1 degree
ii. Hinged Weight Gauge–Newborn, Figures 10 and 11.
iii. A test base that is horizontal, flat, firm, and smooth.

(2) If applicable, place the product in the manufacturer's recommended highest seat back angle position intended for lounging.

(3) If applicable, place the hinged weight gauge–newborn in the product and position the gauge with the hinge centered over the seat bight line and the upper plate of the gauge on the seat back. Place a digital protractor on the upper torso/head area lengthwise and measure the incline angle.

(4) Place the head/torso portion of the newborn hinged weight gauge on the product according to the manufacturer's recommended use position with the seat portion of the gauge, depending on the product design, allowed to lay freely on the product or on the test base (Figure 4).

(5) Move and rotate the newborn hinged weight gauge the minimum amount necessary such that the head/torso portion rests on an OSS that could foreseeably support an infant's head and place the head/torso portion of the gauge according to all situations that apply:

a. In tests on products with an OSS for the infant's body, align the top edge of the head/torso portion of the gauge to coincide with a plumb line to the outermost edge of the OSS-head.
b. In all tests, place the seat portion of the gauge on the test base, adjust the newborn gauge to the greatest incline angle in which the top edge of the gauge maintains contact with the top surface of the product.

(6) If a product's seating bight area prevents reasonable positioning of the head/torso portion to the outermost edge, then position the seat portion of the newborn hinged

weight gauge as far forward as possible towards the outermost edge and allow the head/torso portion of the gauge to rest on the product.

(7) Place a digital protractor lengthwise on the head/torso portion of the gauge and measure the incline angle.

(8) Remove the newborn gauge and determine the side height at the incline angle location, measured from the OSS-body or test base, as appropriate, to the top of the OSS-head.

(9) Measure the incline angle at the manufacturer's recommended use location(s), at feasible locations such as perpendicular to the recommended use location(s), and at least one location likely to fail in which the newborn gauge seat is supported on the test surface.

(10) Determine the maximum incline angle from the incline angle measurements.

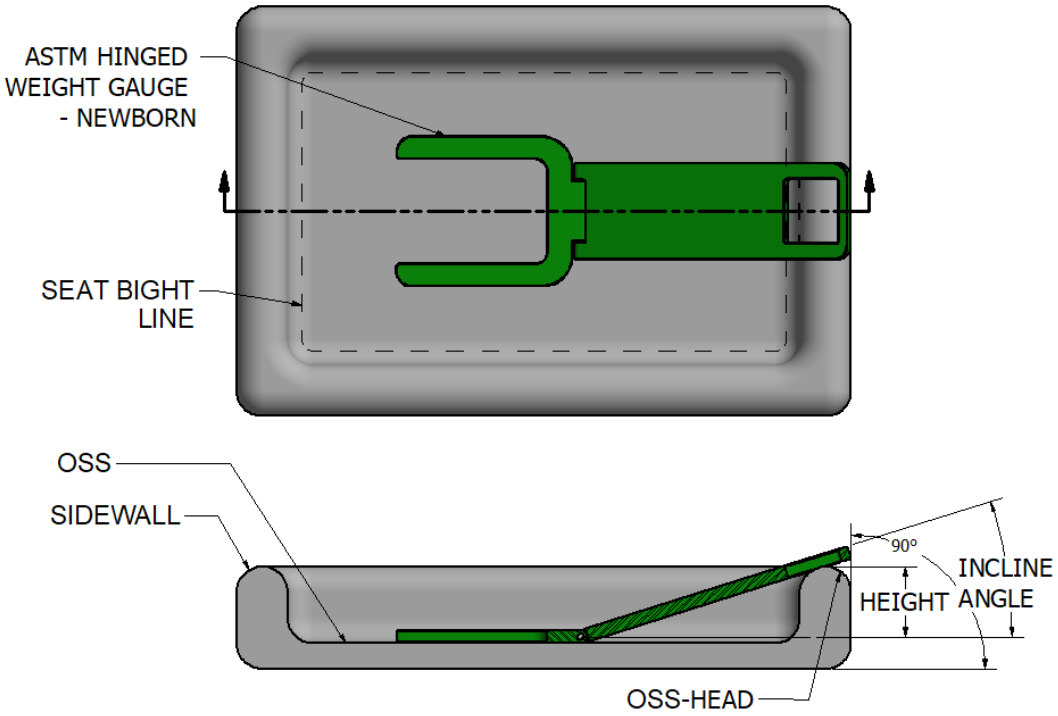

Figure 4. Test Fixture Configuration to Measure Incline Angle on an Infant Support Cushion Product

(e) Firmness Test Setup

(1) Equipment.

(i) Force gauge with accuracy +/- 0.05 N (0.01 lb).

(ii) Distance gauge with accuracy +/- 0.01 in. (0.03 cm).

(2) Align the axis of the 3-in head probe (Figure 1) with a force gauge and parallel to a distance measurement device or gauge.

(3) Use a lead screw or similar device to control movement along a single direction.

(4) Support the firmness fixture to a test base such that the head probe does not deflect more than 0.01 in. (0.025 cm) under a 10 N (2.2 lb) load applied in each orientation required in the test methods.

(f) *Occupant Support Surface Firmness Test Method*. Perform the following steps to determine the occupant support surface firmness of the product as received from the manufacturer. Figure 5.

(1) Orient the axis of the 3-in. head probe perpendicular to the surface of the product at each test location that is oriented greater than 5 degrees relative to the test base or align the axis of the probe perpendicular to the test base (vertically) at each test location that is oriented equal to or less than 5 degrees to the test base.

(2) The first test location shall be at the location of maximum thickness of the surface being tested, perpendicular to the test base.

(3) Lay the product, with the occupant support surface facing up, on a test base that is horizontal, flat, firm, and smooth.

(4) Prevent movement of the product in a manner that does not affect the force or deflection measurement of the product surface under test. Provide no additional support beneath the product.

(5) Advance the probe into the product and set the deflection to 0.0 in. when a force of 0.1 N (0.02 lb) force is reached.

(6) Continue to advance the head probe into the product at a rate not to exceed 0.1 inch per second and pause when the force exceeds 10.0 N (2.24 lb), or the deflection is equal to 1.00 in. (2.54 cm).

(7) Wait 30 seconds. If the deflection is less than 1.00 in. and the force is 10.0 N or less, repeat steps § XXXX.5(f)(6) and § XXXX.5(f)(7)).

(8) Record the final force and deflection when the deflection has reached 1.00 in. or when the force has exceeded 10.0 N.

(9) If the maximum thickness of the OSS is greater than 1.0 in (2.54 cm), perform additional tests, space permitting, at the geometric center of the OSS, at four locations along the product's longitudinal and lateral axes therefrom, 1.5 in (3.8 cm) towards center from the intersection of the sidewall and OSS, and at one location most likely to fail.

(10) Repeat the occupant support surface firmness tests on any other occupant support surface and in all intended and feasible configurations that could affect an occupant support surface, such as the folding or layering of parts of the product.

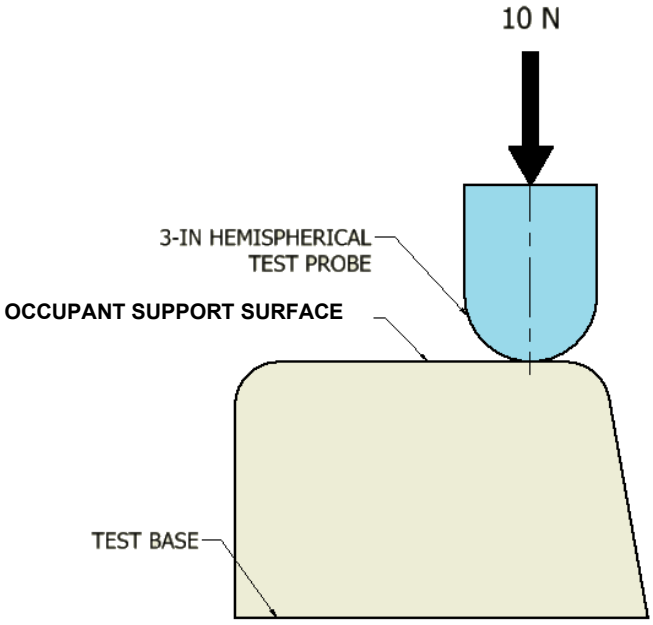

Figure 5. Test Configuration for Occupant Support Surface Firmness Test

(g) Sidewall Firmness Test Method. For sidewalls, perform the steps in § XXXX.5(f)(1) through § XXXX.5(f)(8) to determine the sidewall firmness of the product as received from the manufacturer and then perform the following,

(1) Perform a minimum of four additional tests, located at intervals not to exceed 6 in. along the entire top perimeter of the sidewall, starting from the maximum side height location, and at one additional location most likely to fail.

(2) Repeat the sidewall firmness test in all the intended or feasible configurations that could affect the sidewall firmness, such as the folding or layering of parts of the product.

(h) Intersection of Sidewall and Occupant Support Surface Firmness. Perform the following steps to determine the intersection firmness of the product as received from the manufacturer (Figure 6),

(1) Orient the axis of the 3-in head probe perpendicular to the sidewall perimeter at an angle from horizontal that bisects the angle determined in Sidewall Angle with the axis directed at the intersection of the occupant support surface and the sidewall (Figure 4).

(2) The first test location shall be at the location of maximum product thickness parallel to the test base.

(3) Perform the steps in § XXXX.5(f)(3) through § XXXX.5(f)(8).

(4) Perform a minimum of four additional tests, located at intervals not to exceed 6 in. along the entire inside perimeter of the intersection of the sidewall and OSS, and at one additional location most likely to fail.

(5) Repeat the intersection of sidewall and occupant support surface firmness test in all

the intended or feasible configurations that could affect the intersection firmness, such as the folding or layering of parts of the product.

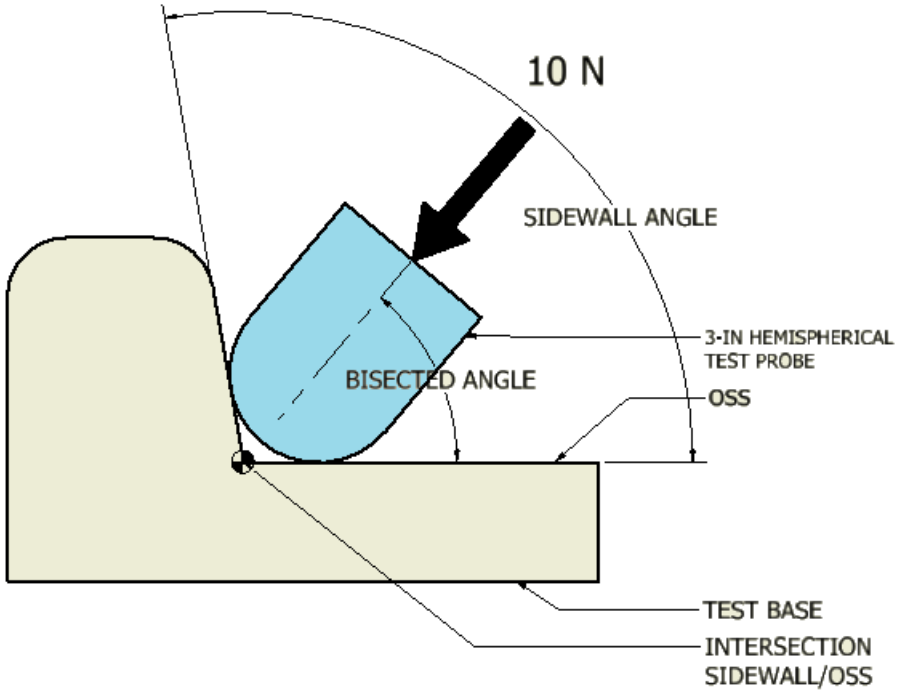

Figure 6. Test Configuration for Intersection of Sidewall and Occupant Support Surface Firmness

(i) *Sidewall Angle Determination.* Perform the following steps to determine if the angle between the sidewall and OSS is 90 degrees or less, or to measure the angle above 90 degrees. Figure 7.

(1) Orient the 3-in (7.62 cm) diameter hemispherical head probe vertically and place over the OSS with the cylindrical surface of the probe tangent to the intersection of the sidewall and the OSS. Advance the probe into the product until a downward force of 10 N (2.2 lb) force is reached. Figure 5.

(2) After 30 s, determine whether the sidewall is in contact with the cylindrical side of the 3-in head probe. If the sidewall contacts the cylindrical part of the probe, the sidewall angle is equal to or less than 90 degrees.

(3) For sidewall angles greater than 90 degrees, calculate the sidewall angle as 90 degrees plus the measured angle between the cylindrical side of the 3-in head probe and the sidewall.

(4) Determine a minimum of four sidewall angles at locations not to exceed 6 in (15.2 cm) intervals along the intersection of the sidewall and OSS.

(5) Measure the angle with a protractor or gauge placed to the depth of and in contact with the cylindrical side of the three-inch probe side and the sidewall.

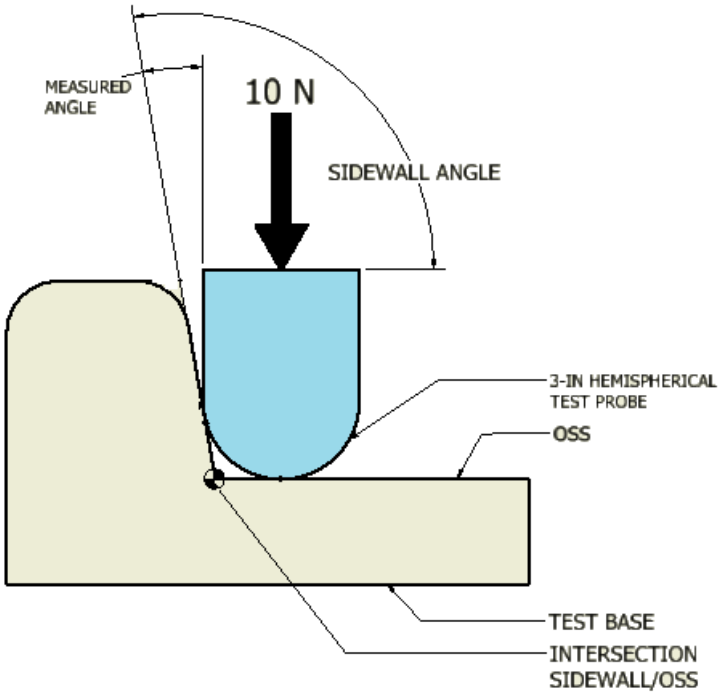

Figure 7. Test Fixture Configuration for Sidewall Angle Measurement

(j) *Seam Strength Test Method*.

(1) *Equipment*. Clamps with 0.75 in. (1.9 cm) diameter clamping surfaces capable of holding fabric and with a means to attach a force gauge. Figure 8, or equivalent. A force gauge, accuracy +/- 0.5 lb (1.1 N).

(2) Clamp the fabric of the infant support cushion on each side of the seam under test with the 0.75 in. clamping surfaces placed not less than 0.5 in. (1.2 cm) from the seam.

(3) Apply a tension of 15 lb (67 N) evenly over 5 s. and maintain for an additional 10 s.

(4) Repeat the test on every distinct seam and every 12 in. (15 cm) along each seam.

(k) *Removal of Components Test Method*.

(1) For torque and tension tests, any suitable device may be used to grasp the component that does not interfere with the attachment elements that are stressed during the tests.

(2) Torque Test. Gradually apply a 4 lb-in. (0.4 N-m) torque over 5 s. in a clockwise rotation to 180 degrees or until 4 lb-in. has been reached. Maintain for 10 s. Release and allow component to return to relaxed state. Repeat the torque test in a counterclockwise rotation.

(3) Tension Test. For components that can reasonably be grasped between thumb and forefinger, or teeth, apply a 15 lb (67 N) force over 5 s., in a direction to remove the component. Maintain for 10 s. A clamp such as shown in Figure 9 may be used if the gap between the back of the component and the base

material is 0.04 in. (0.1 cm) or more.

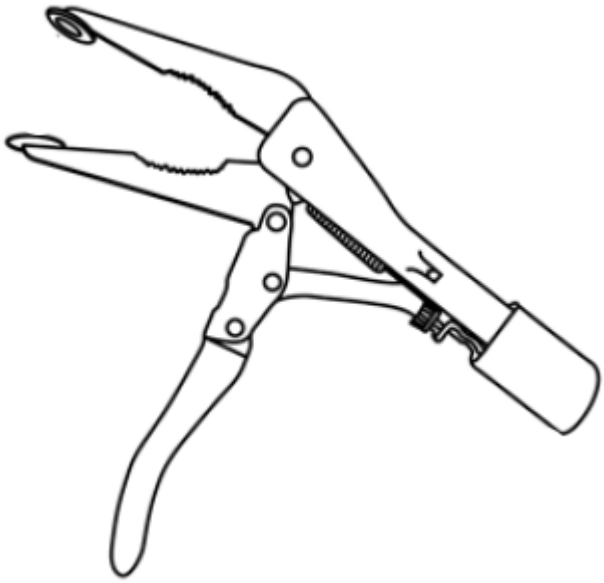

Figure 8. Seam Clamp

Figure 9. Tension Test Adapter Clamp

§ XXXX.6 Marking and Labeling

(a) Each product and its retail package shall be marked or labeled clearly and legibly to indicate the following:
  (1) The name, place of business (city, state, and mailing address, including zip code), and telephone number of the manufacturer, distributor, or seller.
  (2) A code mark or other means that identifies the date (month and year as a minimum) of manufacture.
  (3) The marking or labeling in XXXX.6(a)(1) and (2) are not required on the retail package if they are on the product and are visible in their entirety through the retail package. When no retail packaging is used to enclose the product, the information provided on the product shall be used for determining compliance with XXXX.6(a)(1) and (2). Cartons and other materials used exclusively for shipping the product are not considered retail packaging.

(b) The marking and labeling on the product shall be permanent.

(c) Any upholstery labeling required by law shall not be used to meet the requirements of this section.

(d) Warning Design for Product:
  (1) The warnings shall be easy to read and understand and be in the English language at a minimum.
  (2) Any marking or labeling provided in addition to those required by this section shall not contradict or confuse the meaning of the required information or be otherwise misleading to the consumer.
  (3) The warnings shall be conspicuous and permanent.
  (4) The warnings shall conform to ANSI Z535.4–2011, American National Standard for Product Safety Signs and Labels, sections 6.1–6.4, 7.2–7.6.3, and 8.1, with the following changes.
    i. In sections 6.2.2, 7.3, 7.5, and 8.1.2, replace “should” with “shall.”
    ii. In section 7.6.3, replace “should (when feasible)” with “shall.”
    iii. Strike the word “safety” when used immediately before a color (for example, replace “safety white” with “white”).
    NOTE — For reference, ANSI Z535.1, American National Standard for Safety Colors, provides a system for specifying safety colors

  (5) The safety alert symbol and the signal word “WARNING” shall be at least 0.2 in. (5 mm) high. The remainder of the text shall be in characters whose upper case shall be at least 0.1 in. (2.5 mm), except where otherwise specified.

NOTE — For improved warning readability, typefaces with large height-to- width ratios, which are commonly identified as “condensed,” “compressed,” “narrow,” or similar should be avoided.

  (6) Message Panel Text Layout:
    i. The text shall be left-aligned, ragged-right for all but one-line text messages, which can be left-aligned or centered.

NOTE — Left-aligned means that the text is aligned along the left margin, and in the case of multiple columns of text, along the left side of each individual column.

    ii. The text in each column should be arranged in list or outline format, with precautionary (hazard avoidance) statements preceded by bullet points. Multiple precautionary statements shall be separated by bullet points if

paragraph formatting is used.

(7) An example warning in the format described in this section is shown in Figure 12.

(e) Warning Statements — Each product shall have warning statements to address the following at a minimum.

NOTE — "Address" means that verbiage other than what is shown can be used as long as the meaning is the same or information that is product-specific is presented.

USING THIS PRODUCT FOR SLEEP OR NAPS CAN KILL.
Babies can turn over or roll out without warning and CAN SUFFOCATE in only a few minutes.

- **Use only with an AWAKE baby.**
- **Stay near and watch baby during use.** If baby falls asleep, remove baby as soon as possible and place baby on a firm, flat surface such as a crib or bassinet.
- **Use only on floor,** with baby face-up on back. Do not use on soft surfaces or in sleep products like cribs and bassinets.
- Keep blankets and other soft bedding or items out of product.

Babies have been injured from FALLS.

- Do not use on beds, sofas, or other raised surfaces.
- Never carry or move product with baby in it.

5) § XXXX.7 Instructional Literature

(a) Instructions shall be provided with the product and shall be easy to read and understand and shall be in the English language at a minimum. These instructions shall include information on assembly, maintenance, cleaning, and use, where applicable.

(b) The instructions shall address the following additional warnings:
(1) Read all instructions before using this product.
(2) Keep instructions for future use.
(3) Do not use this this product if it is damaged or broken.
(4) Instructions shall indicate the manufacturers recommended maximum weight, height, age, developmental level, or combination thereof, of the occupant for which the infant support is intended. If this product is not intended for use by a child for a specific reason, the instructions shall so state this limitation.

(c) The cautions and warnings in the instructions shall meet the requirements specified in XXXX.6(d)(4), XXXX.6(d)(5), and XXXX.6(d)(6), except those sections 6.4 and 7.2–7.6.3 of ANSI Z535.4 – 2011, American National Standard for Product Safety Signs and Labels, need not be applied. However, the signal word and safety alert symbol shall contrast with the background of the signal word panel, and the cautions and warnings shall contrast with the background of the instructional literature.

NOTE Y1 —For example, the signal word, safety alert symbol, and the warnings may be black letters on a white background, white letters on a black background, navy blue letters on an off-white background, or some other high-contrast combination.

(d) Any instructions provided in addition to those required by this section shall not contradict or confuse the meaning of the required information or be otherwise misleading to the consumer.

PARTS LIST			
ITEM	DESCRIPTION	MASS (1)	VOLUME
Assembly		3.378 ± .02 kg (7.447 ± .05 lb)	
1	Upper Plate	2.275 kg (5.016 lb)	289.8 cm^3 (17.68 in^3)
2	Lower Plate	1.079 kg (2.379 lb)	137.4 cm^3 (8.385 cm^3)
3	Pin	0.024 kg (0.053 lb)	3.03 cm^3 (0.185 in^3)

Note 1. Part mass is calculated as Volume divided by the density for mild steel of 7.85 g/cm^3 (0.283 lb/in^3).

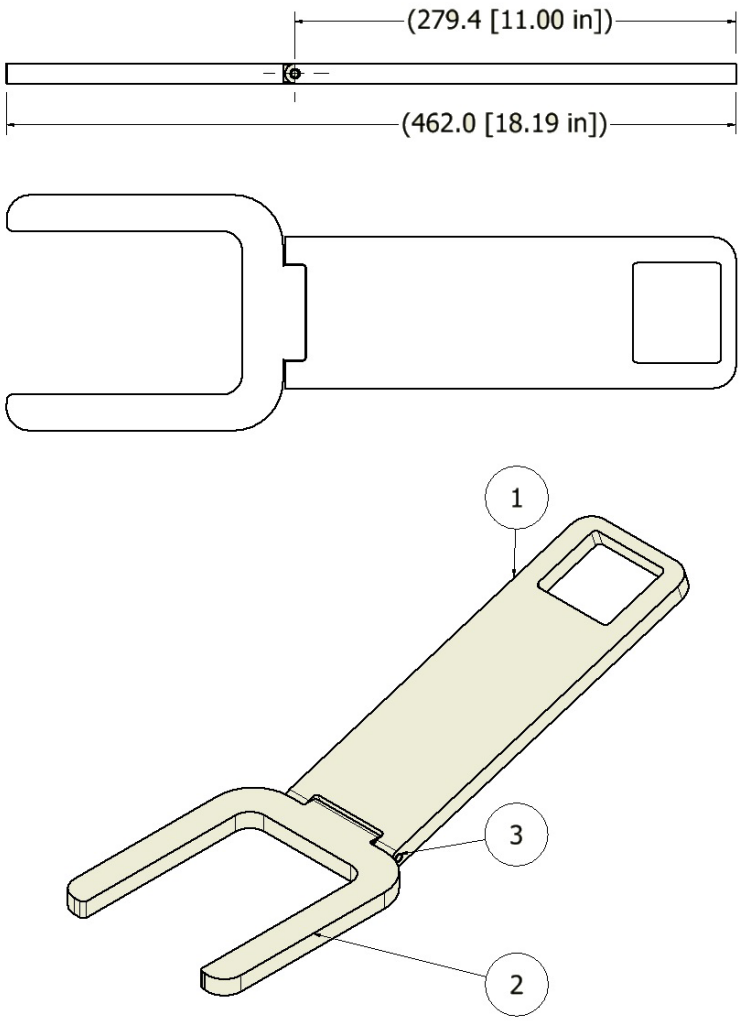

Figure 10. Hinged Weight Gauge–Newborn Assembly Drawings and Parts List

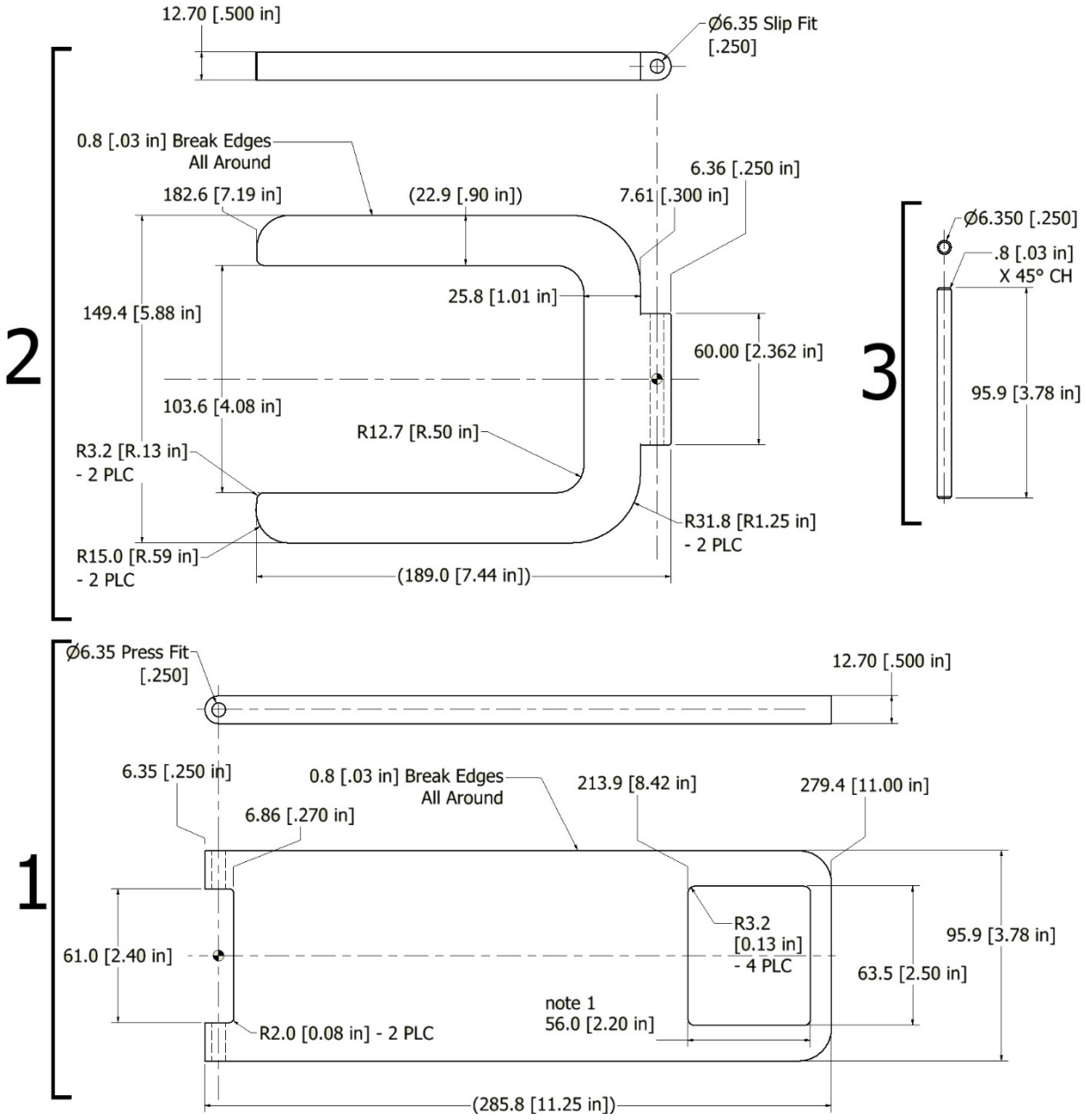

Figure 11. Hinged Weight Gauge–Newborn Part Drawings

Figure 12. Example of Warning