



THIS MATTER IS NOT SCHEDULED FOR A BALLOT VOTE

A DECISIONAL MEETING FOR THIS MATTER IS SCHEDULED ON: October 16, 2024

TO: The Commission
Alberta E. Mills, Secretary

DATE: September 25, 2024

THROUGH: Jessica L. Rich, General Counsel
Austin C. Schlick, Executive Director

FROM: Daniel R. Vice, Assistant General Counsel, Regulatory Affairs
David M. DiMatteo, Attorney, Regulatory Affairs

SUBJECT: Draft Final Rule: Safety Standard for Infant Support Cushions

Staff is forwarding to the Commission a briefing memorandum and draft final rule recommending that the Commission promulgate a final rule, 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, to establish a safety standard for infant support cushions. The standard would address the risk of death and injury from suffocation, entrapment, and falls associated with infant support cushions. The draft final rule would: (1) establish mandatory performance and labeling requirements for infant support cushions; (2) amend CPSC regulations regarding third party conformity assessment bodies to include the safety standard for infant support cushions in the list of notices of requirements (NORs); and (3) identify infant support cushions as a category of durable infant or toddler product subject to consumer registration requirements.

Please indicate your vote on the following options:

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

(Signature)

(Date)

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

(Signature)

(Date)

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

(Signature)

(Date)

IV. Take other action specified below.

(Signature)

(Date)

Attachment: Draft Final Rule: 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. 2023-0047]

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 [INSERT DATE 180 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The incorporation by reference of the publication listed in this rule is approved by the Director of the Federal Register as of [INSERT DATE 180 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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

SUPPLEMENTARY INFORMATION:

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 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;

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.

- 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 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. 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.” 15 U.S.C. 2056a(b)(2).

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.

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 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.” 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

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.

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

⁴ Erin M. Mannen et al; Consumer Prod. Safety Comm’n. Pillows Product Characterization and Testing. (2022). <https://www.cpsc.gov/content/Pillows-Product-Characterization-and-Testing>.

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

⁵ The Commission voted (X-X) to publish this final rule.

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 section 1243.2 has been revised to change the term “infant product” to “infant support cushion.”
- For clarity, 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.
- To avoid ambiguity, a new definition of the term “sidewall” has been added in section 1243.2 which is defined as “any vertical wall at the edge of the occupant support surface.”
- For accuracy and consistency, a reference to “infant pillow” in section 1243.3(d) has been changed to “infant support cushion”.
- The final rule removes proposed section 1243.3(e) regarding side height as this requirement is redundant with the maximum incline angle limits in the rule. The final rule rennumbers the

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.

paragraphs following proposed section 1243.3(e) to reflect this change. The rule also 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 sections 1243.4(e)(2), 1243.4(e)(3), and 1243.4(f) as well as the corresponding test methods in sections 1243.5(g), 1243.4(h), and 1243.4(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 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 in section 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 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. Additionally, section 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 this 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 Figure 2 and Figure 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 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 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;

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: https://www.cpsc.gov/s3fs-public/Briefing-Package-Notice-of-Proposed-Rulemaking-Safety-Standard-for-Infant-Support-Cushions.pdf?VersionId=rA60lesWHddS1.wrk_EvV00xeX75dsFc.

- 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 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 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

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

⁹ 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.

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 124¹² 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

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 <https://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: https://www.cpsc.gov/s3fs-public/Briefing-Package-Notice-of-Proposed-Rulemaking-Safety-Standard-for-Infant-Support-Cushions.pdf?VersionId=rA60lesWHddS1.wrk_EvV00xeX75dsFc.

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)* and (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

¹⁴ Notice of Availability and Request for Comment: Data Regarding Incidents Associated With Infant Support Cushions (April 23, 2024), available at: <https://www.federalregister.gov/d/2024-08605>.

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 closes on October 16, 2024.

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

¹⁵ See Tab B of 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. 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: <https://www.cpsc.gov/s3fs-public/CPSCStaffCommenttoBallotASTMF1521onInfantLoungers.pdf?VersionId=tGM05rvyA6WCUzQxHFCdKvHVxRLbtQLv>.

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 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 addresses 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 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 address 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.¹⁷ Incident data, as outlined in the incident data and hazard pattern section of the NPR and Tab A of Staff's NPR Briefing Package,¹⁸ 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 (1) mitigates the hazards associated with infant support cushions for all

¹⁷ ASTM F15.21 Infant Loungers Scope Task Group - Meeting Log, available at: <https://www.cpsc.gov/content/ASTM-F1521-Infant-Loungers-Scope-Task-Group-Meeting%E2%80%AFLog-1>.

¹⁸ 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.

infants, regardless of age, and (2) 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 recommend tummy time pillows for that activity.^{19,20}

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

¹⁹ 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>.

²⁰ American Academy of Pediatrics. (2017). Back to sleep, tummy to play. Retrieved August 28, 2018, from <https://www.healthychildren.org/English/ages-stages/baby/sleep/Pages/Back-to-Sleep-Tummy-to-Play.aspx>.

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 September 18, 2024, the Commission approved publication of a final rule for nursing pillows, which does not have a requirement for convertible products. Nursing pillows that meet the definition of infant lounger in section 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 section 1243.3(g) of the rule regarding convertible products already states, “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 section 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 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.²¹ 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

²¹ See Safety Standard for Infant Sleep Products, available at: <https://www.federalregister.gov/d/2021-12723>.

environment because they pose suffocation hazards.^{22, 23} 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.

²² Recommendations for Parents/Caregivers About the Use of Baby Products | FDA, available at: <https://www.fda.gov/medical-devices/baby-products-sids-prevention-claims/recommendations-parentscaregivers-about-use-baby-products>.

²³ Deaths prompt CPSC, FDA warning on infant sleep positioners | CPSC.gov, available at: <https://www.cpsc.gov/Newsroom/News-Releases/2010/Deaths-prompt-CPSC-FDA-warning-on-infant-sleep-positioners>.

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 section 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 section 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 section 1243.2.

Response: For consistency and clarity, the reference to “infant pillow” in section 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 section 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 section 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 vertical wall at the edge of the occupant support surface,” has been added to section 1243.2 of the final rule.

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 so 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 website²⁴ 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

²⁴ Safe Sleep – Cribs and Infant Products, available at: <https://www.cpsc.gov/SafeSleep>.

Staff’s NPR Briefing Package,²⁵ 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 safely 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

²⁵ See Tab D of 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.

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 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.²⁶

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

²⁶ 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.

infant sleep.²⁷ 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 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

²⁷ Injuries and Deaths Associated with Nursery Products Among Children Younger than Age Five, August 2023, available at: <https://www.cpsc.gov/content/Injuries-and-Deaths-Associated-with-Nursery-Products-Among-Children-Younger-than-Age-Five-12>.

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 “location likely to fail” also is 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 vertical 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 sections 1243.4(e)(2), 1243.4(e)(3), and 1243.4(f) and also adds “For products with a sidewall” to the beginning of the sentence before “perform” in the test methods in sections 1243.5(g), 1243.4(h), and 1243.4(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, section 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 section 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, section 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.²⁸ 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.²⁹

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

²⁸ Erin M. Mannen et al; Consumer Prod. Safety Comm’n. *Pillows Product Characterization and Testing*. (2022). <https://www.cpsc.gov/content/Pillows-Product-Characterization-and-Testing>.

²⁹ 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

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-in hemispherical probe oriented at an angle, determined according to the test method in section 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 section 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 section 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 Figure 2 and Figure 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 must be tested with the slipcover installed on the product, the definition of infant support cushion in section 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, section 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.”³⁰ 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 section 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 section 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.

³⁰ Fors Marsh Group’s, 2022 “Consumer Product Safety Commission (CPSC): Sleep Warnings Final Report”, available at: <https://www.cpsc.gov/s3fs-public/Consumer-Product-Safety-Commission%E2%80%93Sleep-Warnings-Final-Report.pdf?VersionId=MfJcAAip4YNWVf.RllvXQtwNN7chjHyt>.

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 section 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 section 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 section 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 section 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 section 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 section 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.”

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 section 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 CPSIA section 104. The Initial Regulatory Flexibility Analysis (IRFA)³¹ 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 2022.³²

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.

³¹ See Tab E of 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.

³² See Tab A of 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.

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].” *Id.* 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 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 (Dec. 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 F.4th 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 section 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 vertical 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 section 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 section 1243.3(e) regarding side height. Measuring the height of the product is unnecessary and thus

duplicative because the maximum incline angle test in section 1243.5(d)(7) already accounts for the height of the product remaining under 2 inches. The final rule renumbers the paragraphs following section 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 section 1243.4 that establishes requirements for firmness. In section 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 section 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 section 1243.3(e) regarding side height, the final rule 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 response to a comment from Safe Infant Sleep, the following language has been added after the first sentence of section 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 section 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, section 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 both sections 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 section 1243.6(d)(7) as described below. We also add a new Figure 3 Warning for Tummy Time Product in section 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 section 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 section 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 section 1243.6(d)(7) is required as depicted in proposed Figure 2 and new Figure 3. Additionally, the final rule clarifies in section 1243.6(d)(7) that the content and format as depicted in Figure 2 and new Figure 3 as applicable, are required.

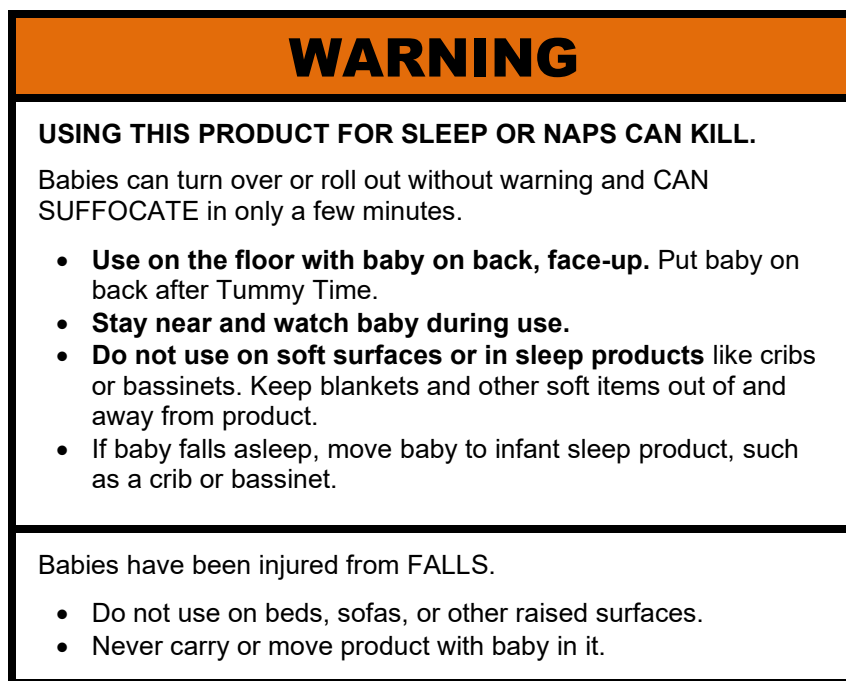
- Note 4 to section 1243.6 (e) has been removed from the rule as unnecessary because the final rule clarifies that the required content and format of the warning labels in Figure 2 and new Figure 3, as applicable, are to be used as written.
- In Figure 2 and new Figure 3, a black line has been inserted 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 and new Figure 3 from section 1243.6 of the final rule.

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

WARNING
<p>USING THIS PRODUCT FOR SLEEP OR NAPS CAN KILL.</p> <p>Babies can turn over or roll out without warning and CAN SUFFOCATE in only a few minutes.</p> <ul style="list-style-type: none">• 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.
<p>Babies have been injured from FALLS.</p> <ul style="list-style-type: none">• Do not use on beds, sofas, or other raised surfaces.• Never carry or move product with baby in it.

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



Additionally, in response to a comment from the Joint Consumer Advocate Commenters, section 1243.6(e) of the final rule adds the following language “Slipcovers, sold on or together with the product, are required to contain a warning with the content and format depicted in Figure 2 or Figure 3, as applicable, to paragraph (d (7))” after the first sentence of that paragraph. 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 American National Standards Institute (ANSI) ANSI Z535.4, *Product Safety Signs and Labels*. 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. Finally, under section 1243.7 any instructions provided in addition to those required by section 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, *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 16 CFR 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 Web site 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: (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. In the NPR, the Commission proposed to amend 16 CFR part 1130 to include “Infant Support Cushions” as durable infant or toddler products. Section 16 CFR 1300.2(a)(21) is being finalized as proposed in the NPR.

X. Incorporation by Reference

The rule incorporates by reference ANSI Z535.4–2011, *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 (OFR), 1 CFR part 51, Part VII.H of this preamble summarizes the requirements of the ANSI Z535.4–2011 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 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. Once the rule takes effect, a read-only copy of ANSI Z535.4–2011 will be available for viewing, at no cost, on the ANSI website at: <https://ibr.ansi.org/Standards/nema.aspx>. Interested persons may purchase a copy of ASTM D3359-23 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. 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: <https://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; 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). 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,³³ 750 employees for manufacturers (NAICS code 314120)

³³ The size standards are in listed in the Code of Federal Regulations. *See* 13 CFR part 121.

and 100 to 150 employees for wholesalers (NAICS codes 424350, 423990, and 424990).³⁴

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.³⁵ 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.

³⁴ 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.

³⁵ See for example: <https://www.cpsc.gov/Business--Manufacturing/Testing-Certification/Childrens-Product-Certificate>; and <https://www.cpsc.gov/Business--Manufacturing/Business-Education/Durable-Infant-or-Toddler-Products/FAQs-Durable-Infant-or-Toddler-Product-Consumer-Registration>.

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” 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 2024³⁶ 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

³⁶ <https://www.bls.gov/news.release/eccc.t02.htm>. The estimated costs in the link reflect the employers’ cost for salaries, wages, and benefits for civilian workers.

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 ($\$16,000 \text{ costs} \div 1 \text{ percent of revenue}$), 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.³⁷

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.

³⁷ 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.

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.

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 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: 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)(20).

The addition reads 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.

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.* 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 [INSERT THE

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 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 vertical 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

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 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.

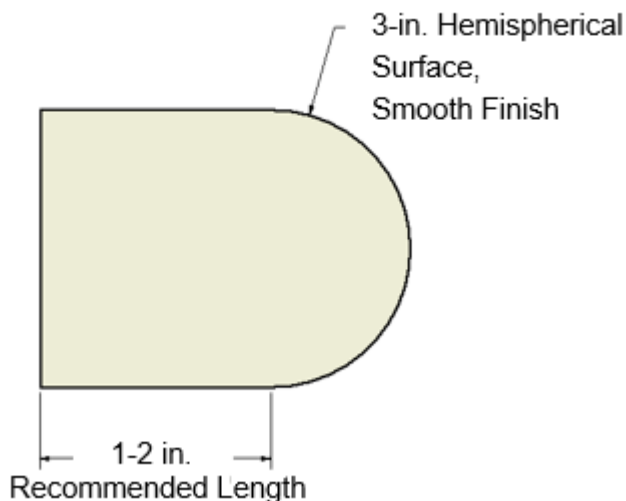
(b) *Seam strength*. When tested in accordance with § 1243.5(j), fabric/mesh seams and points of attachment shall not fail such that a small part, sharp point, or sharp edge is presented, as required in § 1243.3(a) and (b).

(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 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 Newtons (N).

Figure 1 to paragraph (e)(1) - 3-in Head Probe



(2) *Sidewall firmness.* For products with a sidewall, when the three-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 three-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 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

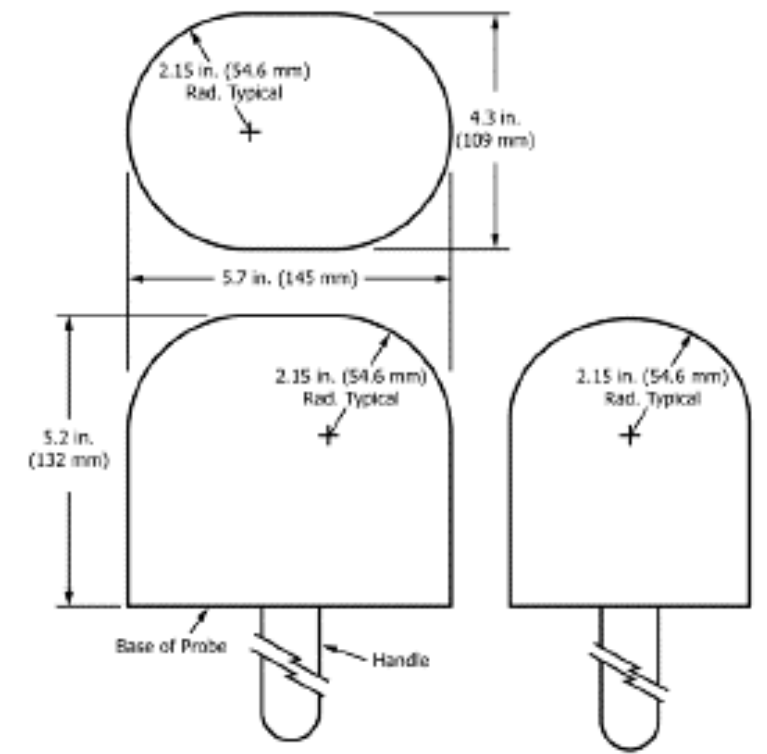
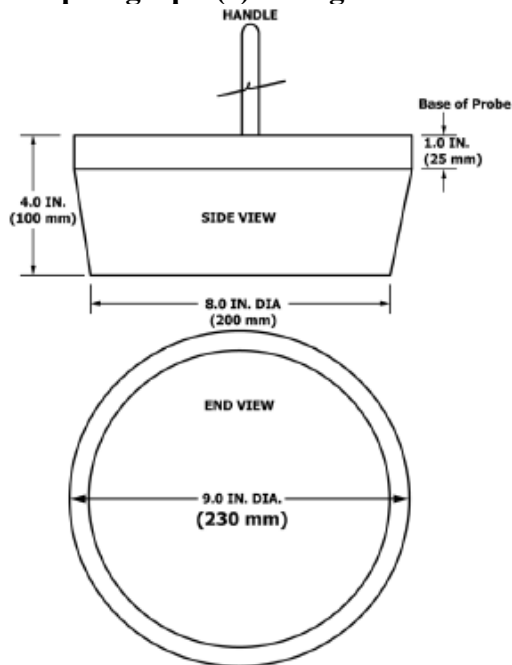


Figure 3 to paragraph (c) - Large Head Probe



(d) *Maximum incline test*—(1) Equipment shall include: (i) Digital protractor with accuracy

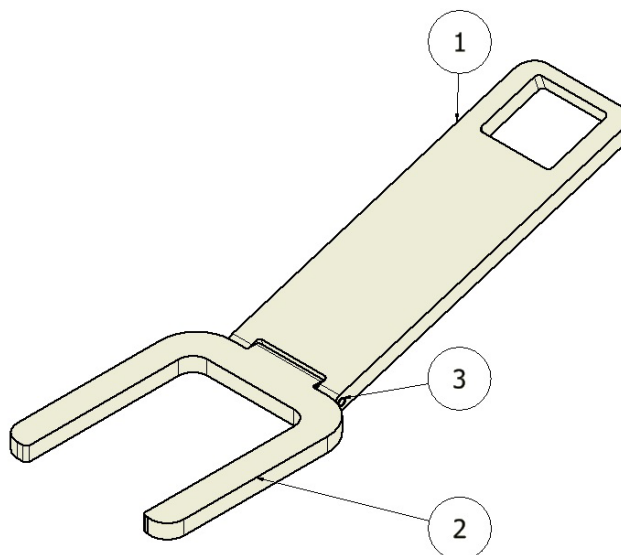
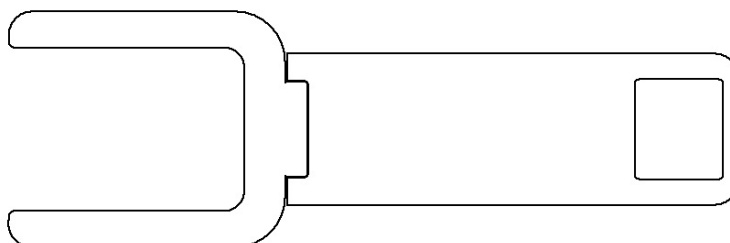
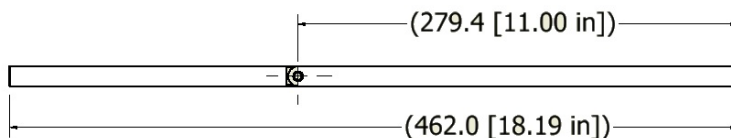
+/- 1 degree;

(ii) Hinged weight gauge–newborn, requirements for part masses and assembly (figure 4 to this paragraph (d)(1)(ii));

Figure 4 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)

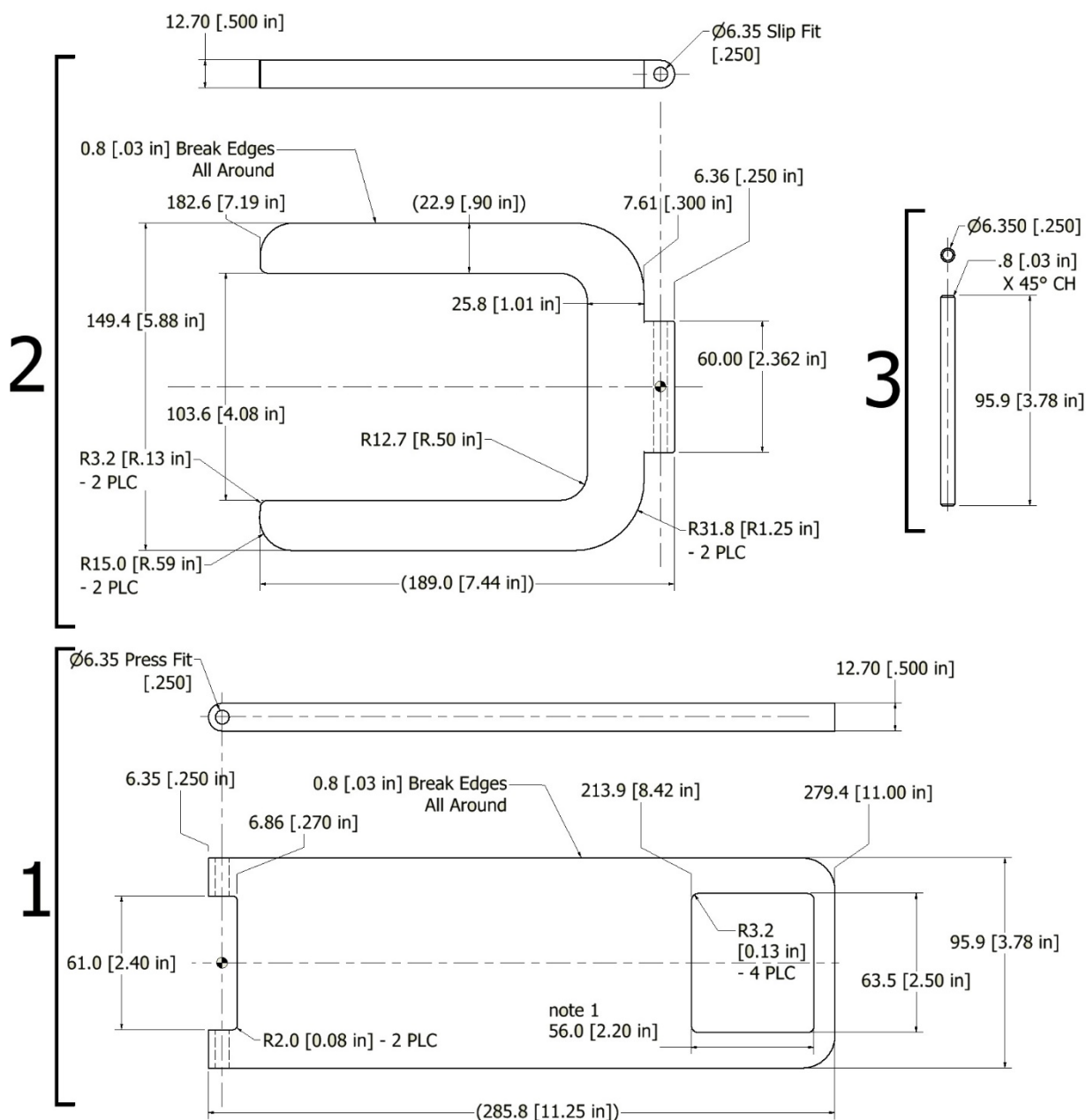
Note 1. Part mass is calculated as Volume divided by the density for mild steel of 7.85 g/cm³ (0.283 lbs/in³).



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(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



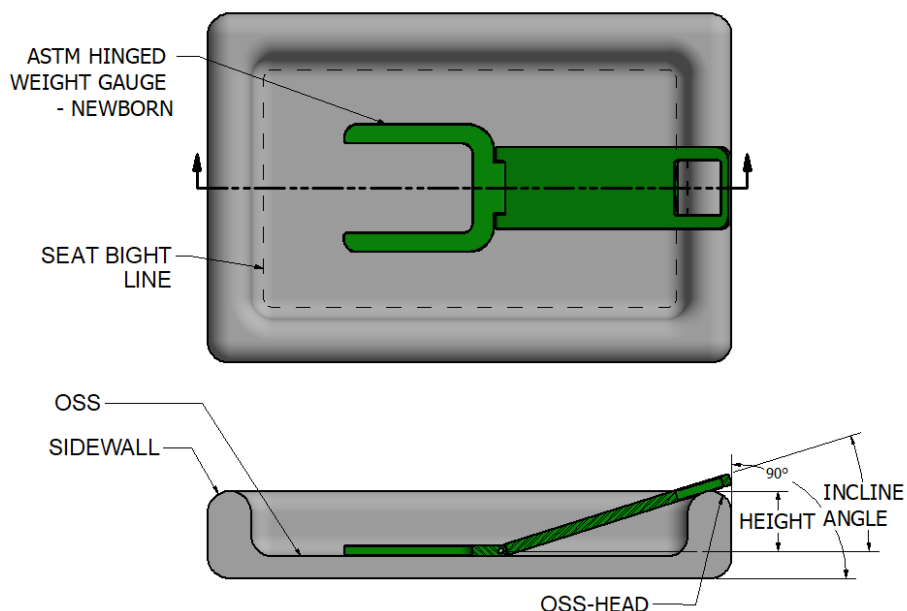
(iv) A test base that is horizontal, flat, firm, and smooth.

(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) 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 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. 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 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.

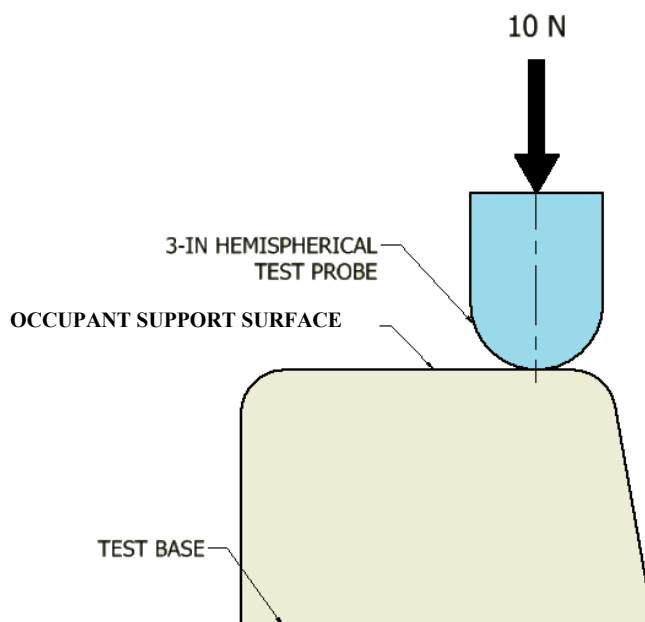
(8) Record the final force and deflection when the deflection has reached 1.00 inches or when the force has exceeded 10.0 N.

(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 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 8 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.

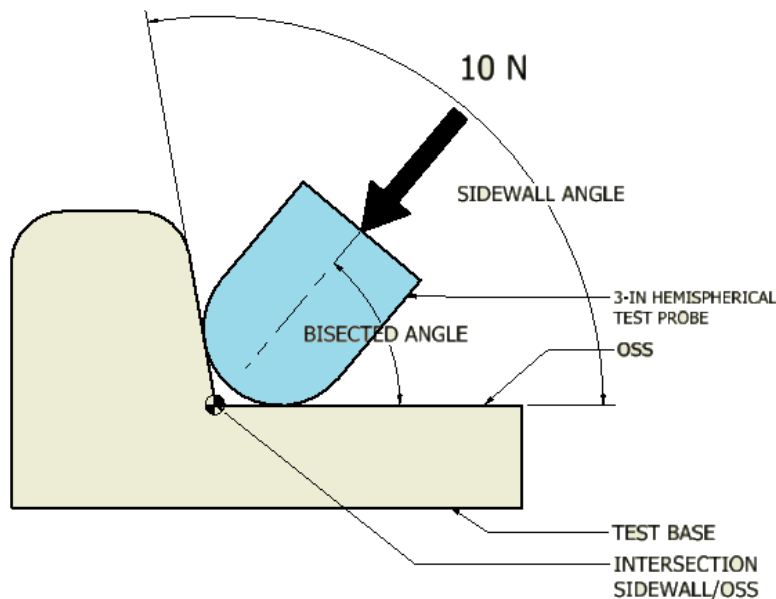
(2) The first test location shall be at the location of maximum product thickness parallel to the test base.

(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 8 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 9 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.

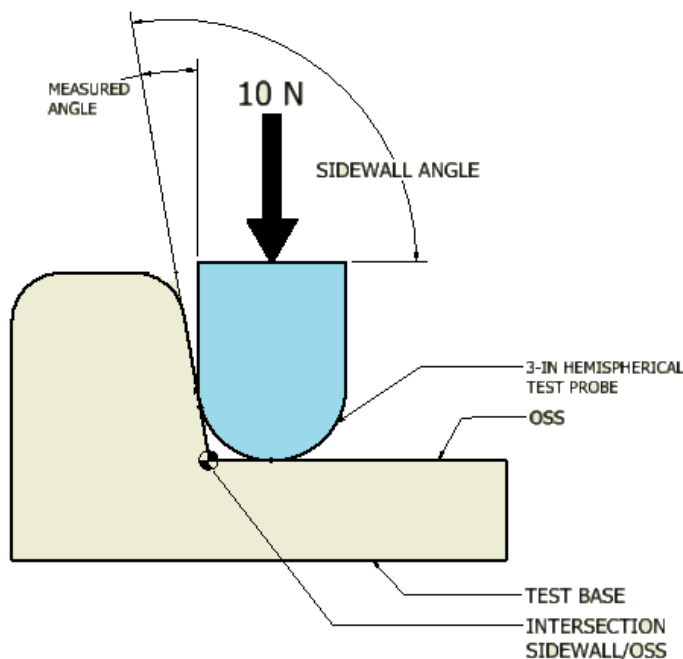
(2) After 30 seconds, determine whether the sidewall is in contact with the cylindrical side of the three-inch head probe. If the sidewall contacts the cylindrical part of the probe, the sidewall angle is equal to or less than 90 degrees.

(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 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.

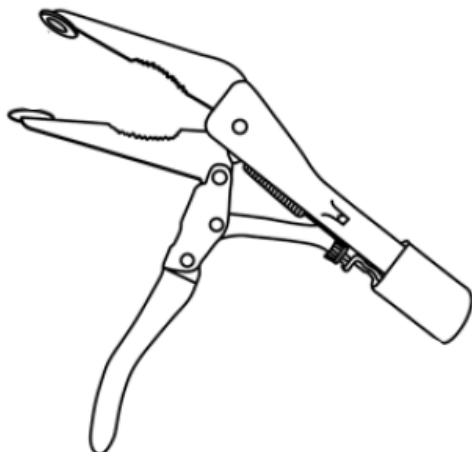
Figure 9 to paragraph (i) – Test Fixture Configuration for Sidewall Angle Measurement



(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 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) 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-inch (0.4 N-m) torque over 5 seconds in a clockwise rotation to 180 degrees or until 4 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 5 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) 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

WARNING
<p>USING THIS PRODUCT FOR SLEEP OR NAPS CAN KILL.</p> <p>Babies can turn over or roll out without warning and CAN SUFFOCATE in only a few minutes.</p> <ul style="list-style-type: none">• 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.
<p>Babies have been injured from FALLS.</p> <ul style="list-style-type: none">• Do not use on beds, sofas, or other raised surfaces.• Never carry or move product with baby in it.

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

WARNING
<p>USING THIS PRODUCT FOR SLEEP OR NAPS CAN KILL.</p> <p>Babies can turn over or roll out without warning and CAN SUFFOCATE in only a few minutes.</p> <ul style="list-style-type: none">• 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.
<p>Babies have been injured from FALLS.</p> <ul style="list-style-type: none">• Do not use on beds, sofas, or other raised surfaces.• Never carry or move product with baby in it.

(e) *Warning statements.* Each product shall address 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 Figure 3 to paragraph (d)(7) 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 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) through (6), except that section 6.4 and sections 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 February 1, 2023; approved for § 1243.5.

(2) [Reserved]

Alberta E. Mills,

Secretary,
Consumer Product Safety Commission.



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

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 positioners¹ 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 124⁴ 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

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.



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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 Package⁵.

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 Swings⁶. 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

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 rennumbers 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.

