



## Vote Sheet

**TO:** The Commission  
Alberta E. Mills, Secretary

**THROUGH:** Austin C. Schlick, General Counsel  
Jason K. Levine, Executive Director

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

**SUBJECT:** Notice of Proposed Rulemaking: Safety Standard for Infant Support Cushions

**DATE:** November 8, 2023

---

**THIS MATTER IS NOT SCHEDULED FOR A BALLOT VOTE.**

**A DECISIONAL MEETING FOR THIS MATTER IS SCHEDULED ON: November 29, 2023.**

Pursuant to the Danny Keysar Child Product Safety Notification Act, section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), 15 U.S.C. § 2056a, which requires the Commission to promulgate consumer product safety standards for durable infant or toddler products, the Office of the General Counsel is forwarding for the Commission's consideration a staff briefing package recommending publication in the *Federal Register* of the attached draft notice of proposed rulemaking to establish a Safety Standard for Infant Support Cushions. To implement the requirements of section 104, the draft proposed rule includes mandatory performance and labeling requirements that address suffocation, entrapment, and fall hazards associated with infant support cushions.

Please indicate your vote on the following options:

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

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Date)

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

---

---

---

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Date)

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

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Date)

IV. Take other action specified below.

---

---

---

---

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Date)

Attachment: Notice of Proposed Rulemaking: Safety Standard for Infant Support Cushions.

**Billing Code 6355-01-P**

**CONSUMER PRODUCT SAFETY COMMISSION**

**16 CFR Parts 1112, 1130, and 1243**

**[CPSC Docket No. 2023-XXXX]**

**Safety Standard for Infant Support Cushions**

**AGENCY:** Consumer Product Safety Commission.

**ACTION:** Notice of proposed rulemaking.

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

**DATES:** Submit comments by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**ADDRESSES:** Comments related to the Paperwork Reduction Act aspects of the marking, labeling, and instructional literature requirements of the proposed rule should be directed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: CPSC Desk Officer, FAX: 202-395-6974, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov).

Other comments, identified by Docket No. CPSC-2023-XXXX, may be submitted electronically or in writing, as follows:

*Electronic Submissions:* Submit electronic comments to the Federal eRulemaking Portal at: <https://www.regulations.gov>. Follow the instructions for submitting comments. Do not submit through this website: confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. CPSC typically does not accept comments submitted by email, except as described below.

*Mail/Hand Delivery/Courier/Confidential Written Submissions:* CPSC encourages you to submit electronic comments by using the Federal eRulemaking Portal. You may, however, submit comments by mail, hand delivery, or courier to: Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone: (301) 504-7479.

*Instructions:* All submissions received must include the agency name and docket number for this proposed rulemaking. CPSC may post all comments without change, including any personal identifiers, contact information, or other personal information provided, to: [www.regulations.gov](https://www.regulations.gov). If you wish to submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public, you may submit such comments by mail, hand delivery, or courier, or you may email them to: [cpsc-os@cpsc.gov](mailto:cpsc-os@cpsc.gov).

*Docket:* For access to the docket to read background documents or comments received, go to: <http://www.regulations.gov>, insert the docket number, CPSC- 2023-XXXX, into the “Search” box, and follow the prompts.

**FOR FURTHER INFORMATION CONTACT:** Stefanie Marques, Ph.D., Project Manager, Directorate for Health Sciences, U.S. Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; email: [smarques@cpsc.gov](mailto:smarques@cpsc.gov); telephone: (301) 987-2581.

## **SUPPLEMENTARY INFORMATION:**

### **I. Background and Statutory Authority**

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

The Commission is issuing this notice of proposed rulemaking (NPR) to establish a consumer product safety rule for infant support cushions to further implement section 104 of the CPSIA. The proposed rule defines an “infant support cushion” as “an infant product that is filled with or comprised of resilient material such as foam, fibrous batting, or granular material or with a gel, liquid, or gas, and which is marketed, designed, or intended to support an infant’s weight or any portion of an infant while reclining or in a supine, prone, or recumbent position.” This includes infant pillows, infant loungers, nursing pillows with a lounging function, infant props or cushions used to support an infant for activities such as “tummy time,” and other similar products.

CPSC staff identified at least 79 reported fatalities involving infant support cushions from January 1, 2010 through December 31, 2022, as well as 125 nonfatal incidents or reports involving these products within the same time period. There were 17 deaths in 2020, and at least 17 more in the potentially incomplete data from 2021. More than 80 percent of the fatalities

associated with these products involved infants three months old and younger. In more than 60 percent of the fatalities, the official cause of death was either asphyxia or probable asphyxia, and these incidents typically involved use of an infant support cushion placed in or on a sleep-related consumer product such as an adult bed, futon, crib, bassinet, play yard, or a on a couch. For the nonfatal incidents, the most common circumstances involved an infant falling from an infant support cushion placed on a raised surface such as a bed or a sofa or the threat of asphyxia or entrapment.

This proposed rule addresses the risk of death and injury associated with infant support cushions primarily due to suffocation, entrapment, and fall hazards. The proposed rule would address positional asphyxiation hazards by requiring that all surfaces be sufficiently firm that they are unlikely to conform to an infant's face and occlude the airways, and by setting a maximum incline angle that would prevent hazardous positioning of an infant's head and neck along the surfaces of the product. The proposed rule would set a side angle requirement that addresses the risk of entrapment between the sidewall and the occupant support surface. It addresses fall hazards by effectively limiting sidewall height to discourage caregivers from mistakenly believing these products to be safe for unattended infants. The proposed rule also requires a strongly worded, conspicuous, and permanent on-product warning.

Consistent with section 104(b)(1)(A) of the CPSIA, CPSC consulted with manufacturers, retailers, trade organizations, laboratories, consumer advocacy groups, consultants, and the public to develop this rule, including through participation in the juvenile products subcommittee

meetings of ASTM.<sup>1</sup> Currently, however, no voluntary or mandatory safety standard for infant support cushions exists to address the hazards posed by these products.

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

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

Manufacturers of children’s products also must comply with product registration requirements, as well as testing and certification requirements for children’s products that are codified in 16 CFR parts 1107 and 1109. Section 14(a)(3) of the Consumer Product Safety Act

---

<sup>1</sup> CPSC formally began the consultation process for this rulemaking in December 2021, via a letter from CPSC staff requesting that ASTM form a working group to develop a voluntary standard to reduce the risk of death and injury from hazards associated with infant pillow products, including nursing pillows. In response, ASTM formed two subcommittees intended to develop two separate voluntary standards: the F15.16 Infant Feeding Supports subcommittee, intended to develop a standard for nursing pillows; and the F15.21 Infant Loungers subcommittee. CPSC staff has been actively participating in both ASTM subcommittees to develop voluntary standards that address hazards associated with these products.

(CPSA) requires the Commission to publish an NOR for the accreditation of third party conformity assessment bodies (test laboratories) to assess conformity with a children's product safety rule to which a children's product is subject. The proposed rule would be a children's product safety rule that requires issuance of an NOR.

## **II. The Product Category**

### *A. Infant Support Cushions*

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

Illustrative pictures of infant support cushions can be found in Tab C of staff's briefing package for this proposed rule.<sup>2</sup> A non-exhaustive list of examples of infant support cushions includes:

- head positioner pillows;
- flat baby loungers;
- crib pillows;
- wedge pillows for infants;
- infant sleep positioners, unless regulated by the Food and Drug Administration (FDA) as medical devices;
- stuffed toys marketed for use as an infant support cushion;
- infant "tummy time" or "lounging" pillows, whether flat or inclined;
- multi-purpose pillows marketed for both nursing and lounging;

---

<sup>2</sup> Staff Briefing Package: Staff's Draft Proposed Rule for Infant Support Cushions, (November \_\_, 2023) (Staff's NPR Briefing Package), available at: [\[INSERT LINK\]](#)

- anti-rollover pillows with or without straps that fasten the pillow to the infant;
- infant “self-feeding” pillows that hold a bottle in front of the face of a reclining or lying infant;
- pads and mats; and
- accessory pillows and other padded accessories, often marketed for use with an infant car seat, stroller, or bouncer, but not sold with that product and therefore not included in the mandatory safety standard for those products.

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

Illustratively, the following products are not infant support cushions within the scope of this proposed rule:

- Pillows not marketed or intended for use by infants, such as adult bed and throw pillows;
- nursing pillows if subject to Commission’s proposed nursing pillow rule 88 FR 65865 (Sept. 26, 2023) if that rule is finalized, unless they are also marketed for lounging;
- crib and play yard mattresses that are in scope of the play yard and crib mattress standard in 16 CFR part 1241;
- purely decorative nursery pillows, such as those personalized with a baby’s name and birthdate, that are not for infant use;
- stuffed toys (unless they meet the definition of an infant support cushion in this proposed rule);
- padded seat liners that are sold with a rocker, stroller, car seat, infant carrier, swing, highchair, or bouncer that are specifically designed to fit that product; and
- sleeping accommodations, which are regulated under the Commission’s infant sleep product rule at 16 CFR part 1236.

#### *B. Market Description*

Most types of new infant support cushions are sold online, including from general online retailers, online sites for “big box” stores, online baby products sites, and online marketplaces for hand-crafted items. A few types of infant support cushions, however, are also available from brick-and-mortar baby specialty stores and general retail stores, particularly crib pillows and

baby loungers. Prices for new infant support cushions average roughly \$30 and range from less than \$15 for a simple head positioner pillow or crib pillow to more than \$250 for a lounger with a removable cover or a large stuffed toy marketed for sleep. Several thousand manufacturers and importers, including hundreds of handcrafters and direct foreign shippers, supply infant support cushions to the U.S. market. *See Staff's NPR Briefing Package, Tab E.*

Infant support cushions may be re-used for multiple children or sold for use after an infant outgrows the product. Commission staff observed that used infant support cushions are widely available on secondary marketplaces such as eBay and Mercari. In June 2023, for example, staff found listings on Mercari for used changing pads, large stuffed toys marketed for infant sleep, crib wedge pillows, baby neck pillows, baby sleep positioners, baby loungers, baby sleep mats, baby "pillow chairs," infant "self-feeding" pillows, baby/toddler bean bag chairs, and crib pillows.

### *C. Infant Cushion/Pillow Ban*

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

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

16 CFR 1500.18(a)(16). This proposed rule for infant support cushions does not change the FHSA ban. That ban was limited to products with the specific hazard presented by loosely filled granular material such as polystyrene beads or pellets, and those products will continue to be

banned under the FHSA. Infant support cushions that are not subject to the ban are within the scope of this proposed rule and would be required to comply with the performance requirements of this proposed rule.<sup>3</sup>

### **III. Incident Data and Hazard Patterns**

CPSC staff searched the Consumer Product Safety Risk Management System (CPSRMS)<sup>4</sup> and National Electronic Injury Surveillance System (NEISS)<sup>5</sup> databases for fatalities, incidents, and concerns associated with infant support cushions and involving infants up to 12 months old, reported to have occurred between January 1, 2010 and December 31, 2022. Tab A of Staff's NPR Briefing Package describes the incident and hazard patterns associated with infant support cushions.

Commission staff identified 79 fatal incidents and 125 nonfatal incidents and consumer concerns reported to CPSC from 2010-2022. Of the 125 non-fatal reports, 22 consisted of emergency-department-treated injuries, three involved hospital admissions, 46 reports involved

---

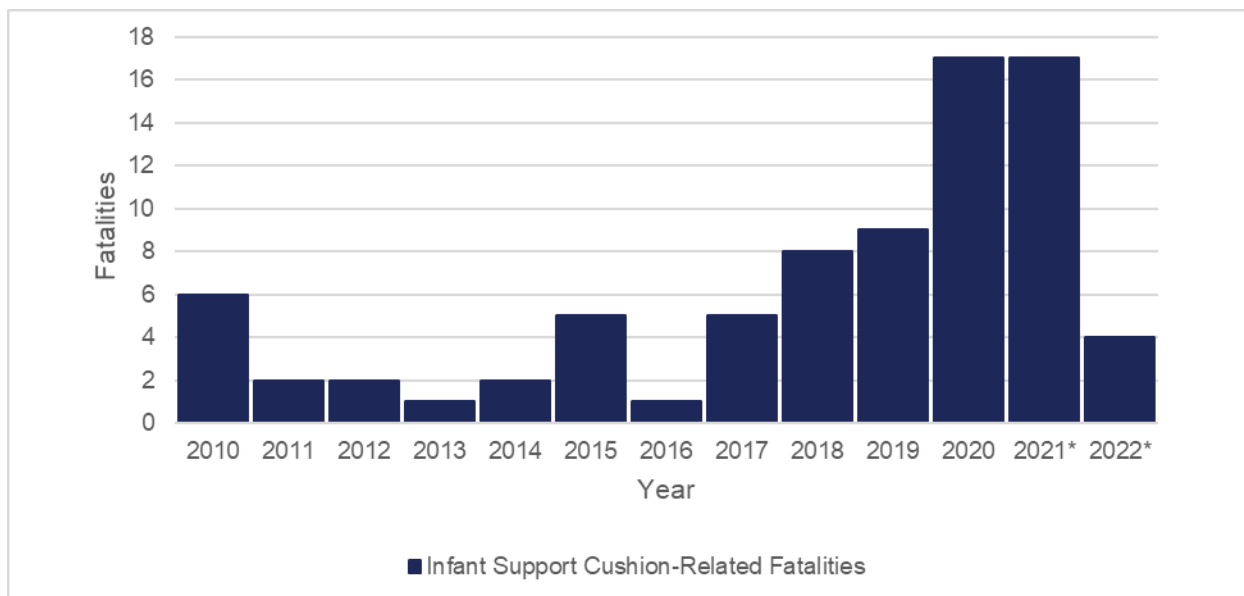
<sup>3</sup> An exemption to the infant pillow ban applies to Boston Billow nursing pillows and substantially similar nursing pillows that are designed to be used only as nursing aids for breastfeeding mothers. 16 CFR 1500.86(a)(9). The exemption applies specifically to the FHSA ban and is not applicable to this proposed rule or to the proposed standard for nursing pillows.

<sup>4</sup> 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.

<sup>5</sup> NEISS is a statistically valid surveillance system for collecting injury data. NEISS is based on a nationally representative probability sample of hospitals in the U.S. and its territories. Each participating NEISS hospital reports patient information for every emergency department visit associated with a consumer product or a poisoning to a child younger than five years of age. The total number of product-related hospital emergency department visits nationwide can be estimated from the sample of cases reported in the NEISS. See <https://www.cpsc.gov/Research--Statistics/NEISS-Injury-Data>.

no injury, and for 52 reports the disposition was either unknown or unspecified. Table 1 provides the distribution of fatal incidents by year.

**Table 1: Infant Support Cushion-Related Fatalities Reported by Year for Children 12 Months of Age or Younger: 2010-2022**



Source: CPSRMS and NEISS databases.

Asterisks (\*) indicate that reporting is ongoing for CPSRMS; the years 2021–2022 are considered incomplete.

Table 2 summarizes the number of reported fatalities related to infant support cushions for victims 12 months and younger by age in months and by gender. As reflected in Table 2, 80 percent of the fatalities with a known age were infants in the zero to three month age range. Among the 76 fatalities for which the sex is known, half were male and half were female.

**Table 2: Infant Support Cushion-Related Fatalities for Victims Ages 12 Months and Younger and Sex: 2010 -2022**

Age (In Months)	Total (% of Total)	Male (% of Total)	Female (% of Total)	Unknown (% of Total)
Total	79 (100%)	38 (48%)	38 (48%)	3 (4%)
1	26 (33%)	12 (15%)	14 (18%)	0
2	19 (24%)	10 (13%)	9 (11%)	0
3	18 (23%)	8 (10%)	10 (13%)	0
4	7 (9%)	4 (5%)	3 (4%)	0
5	3 (4%)	1 (1%)	0	2 (3%)
6	1 (1%)	0	1 (1%)	0

7	2 (3%)	1 (1%)	1 (1%)	0
8	0	0	0	0
9	0	0	0	0
10	1 (1%)	1 (1%)	0	0
11	1 (1%)	1 (1%)	0	0
12	0	0	0	0
Unknown	1 (1%)	0	0	1 (1%)

Source: CPSRMS and NEISS databases. Percentages may not add to 100 due to rounding; the years 2021–2022 are considered incomplete.

The official cause of death reported by the medical examiner in the majority of the 79 reported fatalities 49 (62 percent) was asphyxia or probable asphyxia; 13 (17 percent) were determined to be due to sudden unexpected infant death (SUID) events; 12 (15 percent) had an undetermined cause of death; and for five (six percent), no medical examiner's report was available. Nearly all reported fatalities (75 of 79) involved placement of the infant support cushion on another sleep-related consumer product. For the remaining four fatalities, the placement of the infant support cushion was either undetermined or unknown.

In the 125 nonfatal incidents associated with infant support cushions that involved children ages 12 months and younger and occurred between January 1, 2010 and December 31, 2022, three infants were admitted to the hospital and 22 infants were reported to have been treated and released from an emergency department. In 52 of these nonfatal incidents, the severity of the injury was unspecified or unknown, and in 46 of the incidents no injury was reported. Table 3 summarizes the disposition of the nonfatal incident reports associated with infant support cushions and victims ages 12 months and younger.

**Table 3: Infant Support Cushion-Related Nonfatal Reports by Severity for Victims Ages 12 Months and Younger: 2010-2022**

Severity	Total Reports (% of Total)
<b>Total Non-Fatal Reports</b>	<b>125 (100%)</b>
Hospital Admissions	3 (2%)
Emergency Department Treated	22 (18%)

Left without being seen	1 (1%)
Seen by a Medical Professional	1 (1%)
Unspecified/Unknown	52 (42%)
No Injury Reported	46 (37%)

Source: CPSRMS and NEISS databases. Percentages may not add to 100 due to rounding; the years 2021–2022 are considered incomplete.

For the 46 reports for which no injury was reported, many of the descriptions in the incident reports indicated the potential for serious injury or death. Staff's analysis of the narratives associated with these incident reports indicated that in 29 reports (23 percent) of the incidents, an infant support cushion occupied by an infant had been placed on an elevated surface (such as an adult bed or couch) and the infant had fallen off; 27 (22 percent) specified threatened asphyxia; and 17 incidents (14 percent) involved various types of rashes caused by the product. Table 4 summarizes the hazard patterns for infant support cushion-related nonfatal incidents.

**Table 4: Infant Support Cushion-Related Non-Fatal Reports by Hazard Pattern for Victims Ages 12 months and Younger: 2010-2022**

Event	Number of Non-Fatal Reports (% of Total)
	Children (0 to 12 Months)
Fall	29 (23%)
Threatened Asphyxia	27 (22%)
Rash	17 (14%)
Limb Entrapment	1 (1%)
Mold	1 (1%)
Choking	1 (1%)
Near Strangulation	1 (1%)
Vomiting	1 (1%)
Consumer Complaints	47 (38%)
<b>Total Non-Fatal Reports</b>	<b>125 (100%)</b>

Source: CPSRMS and NEISS databases. Percentages may not add to 100 due to rounding; the years 2021–2022 are considered incomplete.

Staff, based on review of nonfatal incident and report data, identified falls and threatened asphyxia as the two major nonfatal hazard patterns associated with infant support cushions. In the case of falls, the reports revealed that in most incidents infant support cushions had been

placed on elevated surfaces including adult beds and couches. The injuries associated with falls include concussions, facial injuries, and scalp injuries.

In the case of threatened asphyxia, the narratives described scenarios of infants being rescued after being found hanging partially or completely off of the infant support cushion with their mouths and noses obstructed, with their heads wedged between sleep positioner side cushions, or having rolled to a face-down position that put them at risk of an obstructed airway.

#### **IV. International Standards for Infant Support Cushions**

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

The hardness test in BS 4578:1970 requires that a 100 mm diameter probe be placed in the center of the product with 10 newtons (N) of force for one minute. BS 1877-8:1974 requires that displacement of the pillow when the force is applied shall not exceed 25 percent of the

thickness. Staff assesses that the proportional approach used in this standard allows thicker pillows to have a greater displacement than thinner pillows, which does not sufficiently protect against the suffocation and asphyxia hazards associated with infant support cushions because that greater displacement could allow the product to obstruct the infant's airways.

## **V. Boise State University Contractor Report**

CPSC awarded a contract to Boise State University (BSU) for infant biomechanics and suffocation research and consultancy services. This research included an analysis of the risk of injury or death to infants associated with the use of nursing pillows and infant support cushions during activities such as feeding, nursing, sleeping, propping, and lounging. *See Staff's NPR Briefing Package, Tab C.*

BSU delivered its final report on June 30, 2022 (the BSU Final Report).<sup>6</sup> The BSU Final Report provides recommendations and conclusions related to the performance and design of infant support cushions, including the following.

*Firmness Testing.* The BSU Final Report recommends that all infant support cushions be required to undergo firmness testing because products that lack firmness are more likely to conform around an infant's nose and mouth and present a suffocation hazard. The report recommended testing all infant pillows for firmness using a three-inch diameter, anthropometry-based hemispheric probe that is geometrically similar to, and sized to represent the breadth of, an infant's face. The report recommends that the probe should be applied to the product at three locations: the location of maximum thickness, the location of minimum thickness, and a subjective location of interest (*i.e.*, another soft location most likely to result in failure). The

---

<sup>6</sup> Mannen, E. M., Davis, W., Goldrod, S., Lujan, T., Siddicky, S. F., Whitaker, B., & Carroll, J. (2022). *Pillows Product Characterization and Testing*. Prepared for the U.S. Consumer Product Safety Commission under contract no. 61320620D0002, task order no. 61320621F1015. Available at: <https://www.cpsc.gov/content/Pillows-Product-Characterization-and-Testing>.

force required to displace the probe one inch into the product at each location must exceed 10 N. Meeting this requirement would mean that the product has firmness comparable to crib mattresses.

*Airflow Testing.* The BSU Final Report recommends that products that do not pass firmness testing be required to pass an airflow test. Passing the airflow test would mean that the product has airflow characteristics comparable to current mesh crib liners, which the BSU researchers concluded would mitigate the suffocation hazard. However, the report recommends against requiring that airflow testing for products that pass the BSU Final Report's proposed firmness testing, because a firm product is unlikely to form a seal around an infant's nose and mouth.

*Sagittal-Plane Testing.* BSU developed prototype sagittal-plane testing devices to allow for more comprehensive assessments of infant positioning in and on infant support cushions.<sup>7</sup> The BSU Final Report recommends further research to determine appropriate worst-case positions for testing and to set threshold values for acceptable body positions that would not negatively impact infant breathing.

Tab C of Staff's NPR Briefing Package contains staff's summary of how the Commission's proposed rule reflects the conclusions and recommendations of the BSU Final Report.

## **VI. ASTM's Working Draft Standard**

There are no published U.S. voluntary standards for infant support cushions. ASTM is working toward a voluntary standard for infant loungers under Subcommittee F15.21 on Infant

---

<sup>7</sup> The sagittal plane is an anatomical plane that runs vertically through the human body, dividing it into left and right sections. It can be thought of as viewing the human body in profile.

Carriers, Bouncers, and Baby Swings.<sup>8</sup> In the draft voluntary standard, an “infant lounger” is a product “with a raised perimeter, a recess, or other area that is intended to be placed on the floor and to provide a place for an infant to sit, lie, recline, or rest, while supervised by an adult.” That draft definition would govern only a subset of the products covered by this proposed rule, which includes infant positioners, nursing products with dual use for lounging, infant cushions, and other infant pillow-like products, as well as the infant loungers being considered by ASTM. Staff has been working with ASTM to develop performance requirements intended to address the primary hazards associated with infant loungers, but to date ASTM has not issued a ballot on a standard for infant loungers.

ASTM’s draft voluntary standard includes general requirements typically found in other ASTM juvenile product standards, such as requirements addressing lead content, small parts, hazardous sharp edges or points, and toy accessories that are attached to, removable from, or sold with the products. The ASTM draft also specifies that if the lounger can be converted to another product it shall comply with the applicable requirements of that product’s standard. The general requirements of the draft infant lounger standard also state that the sidewall height of the product shall be less than four inches when measured according to the sidewall height measurement test method specified in the draft standard. The draft voluntary standard further includes the following performance requirements:

- *Stability*: The product shall not tip over and shall retain the CAMI dummy<sup>9</sup> when tested in all manufacturers’ use positions.
- *Infant Restraints*: The product shall not have a restraint system.
- *Fabric/Mesh Integrity*: This requirement is intended to address product integrity issues such as seam failures and material breakage.

---

<sup>8</sup> See Staff’s NPR Briefing Package, Tab B. This ASTM standard is still in draft form and has not completed the full consensus process to be an approved standard and the draft language is subject to change.

<sup>9</sup> CAMI (Civil Aeromedical Institute) dummies, which are designated ASTM test devices, are based on child anthropometric data and come in multiple sizes. ASTM’s working draft references the six-month-old size.

- *Bounded Openings*: This requirement is intended to address potential entrapment hazards associated with openings in the product.
- *Occupant Support Surface*: This requirement is intended to address the thickness of, dimensions of, and potential gaps in the occupant support surface.
- *Occupant Support Surface Firmness*: This requirement uses an eight-inch diameter, disc-shaped “firmometer” probe and requires that there shall be no point where the feeler arm of the device, which hangs over the edge of a disc, comes in contact with the occupant support surface.
- *Sidewall Firmness*: The top of the sides of the product cannot be displaced more than one inch when a three-inch diameter hemispheric probe is applied to the product with 10 N of force.
- *Side Angle and Deflection*: To address potential entrapment hazards at the intersection of the side wall and occupant support surface, the angle between the sidewall and the occupant support surface of the infant support cushion shall be greater than 90 degrees.

The draft voluntary standard also includes marking, labeling, and instructional literature requirements, such as warning the consumer on the product about not using the product for sleep or naps, only using the product when the occupant baby is supervised, only using the product on the floor, keeping soft bedding out of the product, not using the product on raised surfaces, and not using the product to carry or move an infant. The draft standard requires the warnings to be “permanent” and “conspicuous.”

The product’s instructions must, among other requirements, indicate the manufacturer’s recommended maximum weight, height, age, developmental level, or combination of these attributes for any infant using the product, as well as any limitation on use of the product by a child for any specific unintended use.

## **VII. Description of the Proposed Mandatory Standard for Infant Support Cushions<sup>10</sup>**

To address established risks of death and injury associated with infant suffocations, asphyxiations, entrapments, and falls, and as section 104 of the CPSIA requires, the Commission

---

<sup>10</sup> See Staff’s NPR Briefing Package, Tab C

is issuing this proposed rule to establish mandatory performance and labeling requirements for infant support cushions.

The text of the proposed rule is based on an evaluation of incident data associated with infant support cushions, the ASTM working draft standard for infant loungers that is under development, and the recommendations of the BSU Final Report. The proposed rule is summarized below and explained in more detail in Tabs C and F of Staff's NPR Briefing Package.

#### *A. Scope and Definitions*

Section 1243.1 of the proposed rule explains that the rule would apply to infant support cushions, including infant positioners, nursing products with a dual use for lounging, infant loungers, infant props, or cushions used to support an infant for activities such as "tummy time," and other infant pillow-like products. It would exclude, however, products already regulated by other Commission mandatory standards for durable infant products, which are listed in 16 CFR 1130.2(a). The proposed rule would apply to all infant support cushions manufactured after the effective date of the rule.

Section 1243.2 of the proposed rule defines "infant support cushion" as:

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

The scope of "infant support cushions" is intended to encompass the products described in Part II above.

As noted previously, this proposed definition of "infant support cushions" includes, but is not limited to, the infant loungers that would be subject to ASTM's draft voluntary standard.

The proposed rule would define "infant lounger" as "a product with a raised perimeter or recess

that provides a place for an infant to sit, lie, recline or rest.” Because, however, incident data show that the suffocation, asphyxiation, and fall hazards this rule seeks to address are posed by other infant pillow-like products, in addition to those with a raised perimeter or recess, the proposed broader definition more effectively addresses the hazards posed by these products. For example, the proposed rule would apply to “infant positioners,” defined as a product intended to help keep an infant in a particular position while supine or prone.

As discussed above, ASTM is working concurrently on developing voluntary standards for both “infant feeding supports” and “infant loungers.” The draft ASTM standards address hazards posed by “dual use” products intended to be used both to feed an infant and to support a lounging infant by requiring such products to comply with both standards. Adopting ASTM’s approach, the proposed rule would apply to nursing pillows with a dual use for lounging, while excluding those nursing pillows that are solely intended to be used for nursing or feeding, along with other products already regulated by other Commission mandatory standards for durable infant products.

The Commission invites public comment on the scope of the proposed rule, including whether it addresses all products that pose the identified hazards and whether it is sufficiently clear and administrable. For example, the Commission invites public comment on whether it is appropriate to subject “dual use” products to both the proposed nursing pillow rule and the proposed infant support cushion rule (assuming that both are finalized), and what nursing products should be considered “dual use.”

#### *B. General Requirements*

The proposed rule includes many of the general requirements included in the ASTM draft standard for infant loungers to address sharp edges or points, small parts, and lead in paints. It

also requires that toy accessories that are attached to, removable from, or sold with the products comply with 16 CFR part 1250, which establishes a mandatory safety standard for toys, as well as requirements for the permanency of labels and warnings. However, while ASTM's draft standard for infant loungers would allow a maximum sidewall height of four inches, the Commission is concerned that this height may give consumers the mistaken impression that an infant can safely be left unattended in or on the product. For that reason, the proposed rule addresses the positional asphyxia hazard with a maximum incline requirement that effectively sets a lower limit on sidewall height, rather than the maximum side height requirement currently favored by ASTM. The Commission invites public comment on side height limit and incline angle requirements.

### *C. Proposed Performance Requirements*

#### *1. Firmness*

The Commission's proposed firmness requirements and associated test methods are consistent with those applicable to crib mattresses and more stringent than those currently included in ASTM's draft standard for infant loungers. As explained in Tab C of Staff's NPR Briefing Package, based upon the findings and recommendations in the BSU Final Report as well as staff's analysis of the incidents and hazard patterns associated with facial occlusion into infant support cushions, the proposed rule requires firmness testing at three locations: the

occupant support surface, the sidewall, and the intersection of the occupant support surface with the sidewall, as follows:

a. Occupant Support Surface (OSS) Firmness

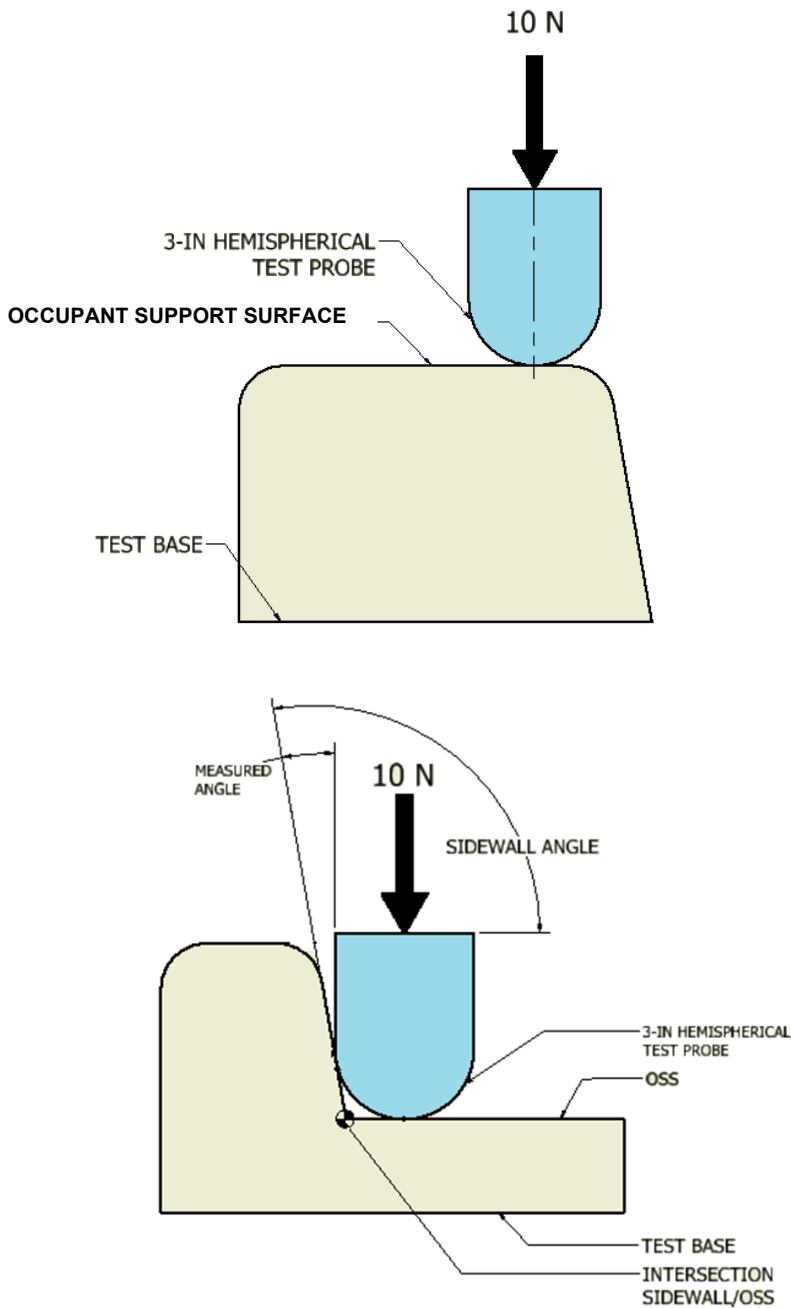
The proposed rule includes a firmness test for the occupant support surface<sup>11</sup> that is based on the BSU Final Report, with modifications to improve the test methodology. The firmness test is intended to reduce the likelihood that the OSS can conform to an infant's face and cause suffocation. The proposed rule requires that OSS firmness be tested using the three-inch diameter hemispheric probe developed by BSU, rather than the eight-inch firmometer probe in the ASTM draft standard. The three-inch probe is more consistent, in both size and shape, with the size and dimensions of an infant's head, enabling it to more accurately detect any material deformations and surface features that an infant's face may come in contact with on an infant support cushion. In addition, staff's testing showed that an eight-inch disc probe may not be as accurate as a three-inch hemispheric probe when used on certain models of infant support cushions with smaller dimensions or an OSS surface that is not completely flat, so that the eight-inch firmometer cannot fit well enough in the product to provide accurate measurement.

To meet the proposed rule's firmness requirement, the force required to displace the probe one inch into the OSS test location (as well as the two other test locations) must exceed 10 N (about 2.25 pounds), which indicates product firmness that is at least comparable to a crib mattress. Figure 1, below, illustrates the firmness test being applied to the OSS of an infant support cushion.

---

<sup>11</sup> The proposed rule uses ASTM's draft definition of an infant support cushion's "occupant support surface" or OSS as "the area that holds up and bears the infant or any portion of the infant."

**Figure 1: Firmness Test Applied to OSS or Sidewall**



Because an infant's head or face may rest on the sidewall of a product, as well as on the product's OSS, the proposed rule includes firmness requirements for any product sidewall.

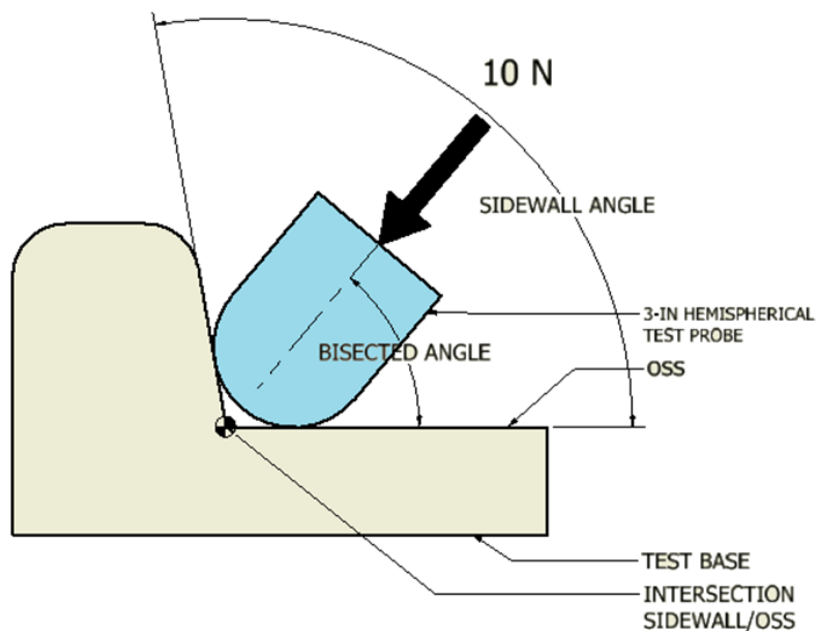
While the ASTM working draft also requires firmness testing of sidewalls, the proposed rule

requires testing a minimum of four sidewall locations, including the location of maximum sidewall height, and requires that the test locations include at least one location most likely to fail, rather than requiring that sidewalls be tested in six-inch increments around the product as stated in ASTM's draft. The differences from ASTM in testing protocol are intended to provide more accurate testing for both smaller head pillows and larger lounger products.

b. Intersection of OSS with Sidewall

To address the hazard of suffocation when an infant's face is surrounded on two sides by the OSS and a sidewall, the proposed rule includes firmness requirements based on testing the angle at which the two surfaces intersect, to ensure sufficient firmness to prevent the product from conforming to the infant's mouth or face and obstructing airways. It requires testing of firmness with the three-inch hemispherical probe positioned to bisect the angle formed where the two surfaces intersect, as shown in Figure 2.

**Figure 2: Test Configuration for Intersection of Sidewall and Occupant Support Surface Firmness**



The proposed rule's firmness requirements for the OSS/Sidewall intersection are similar to those in

ASTM's draft standard.

## 2. Sidewall Angle

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

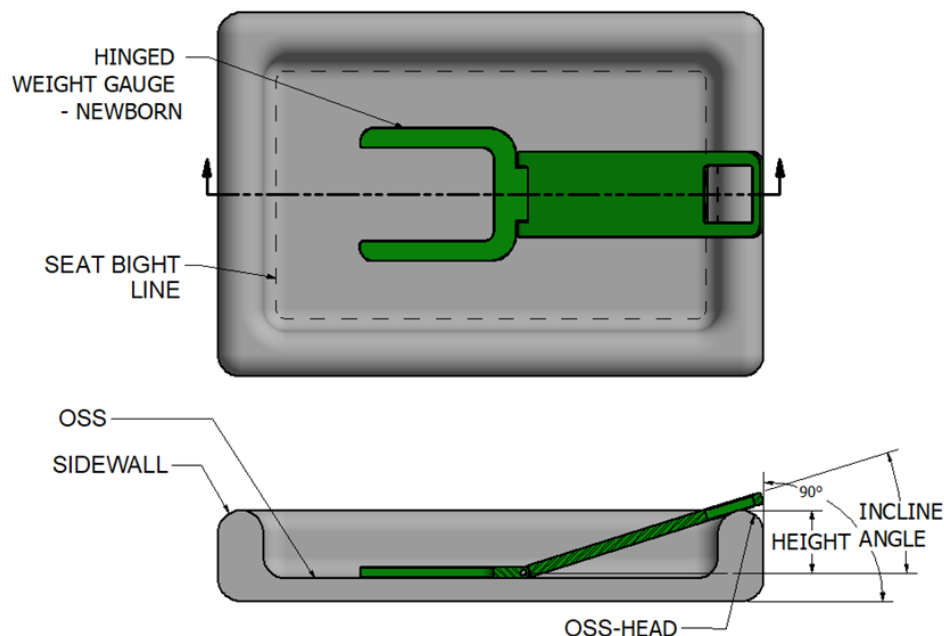
## 3. Maximum Incline Angle

The proposed rule, like ASTM's draft, requires that any incline of the OSS of an infant support cushion not exceed 10 degrees. This requirement is consistent with incline test of CPSC's *Safety Standard for Infant Sleep Products*, 16 CFR part 1236, and the ban of inclined sleepers for infants in the Safe Sleep for Babies Act, 15 U.S.C. 2057d, and similarly it addresses the hazards associated with inclined sleep products.

The proposed rule, however, differs from ASTM's maximum incline angle requirements and test procedures in order to improve test consistency across all infant support cushion

products and to address additional locations of potential inclined lounging, reclining, and sleep. The three ways in which the proposed rule modifies ASTM's proposed testing protocol are: (1) setting a maximum incline angle that applies not only to all of a manufacturer's recommended use positions, but also to all other infant cushion surfaces that can feasibly support an infant's head, including, for example, the angle from any sidewall to the OSS or from the sidewall to the floor; (2) use of a newborn hinged weight gauge, rather than an infant gauge; and (3) positioning the gauge differently throughout testing. Figure 3 below, shows the use of a hinged weight gauge to measure the incline on an infant support cushion with a sidewall. The proposed rule requires use of a newborn hinged weight gauge, rather than the heavier infant gauge specified in the ASTM draft, because infant support cushions are commonly used for newborns, who are at higher risk of suffocation.

**Figure 3: Test Fixture Configuration to Measure Incline Angle on an Infant Lounger**



#### 4. Sidewall Height

The proposed rule limits the height of any sidewall of an infant support cushion, as does ASTM's draft. However, the proposed rule addresses the hazards associated with relatively high sidewalls in a manner that is more closely tailored to the hazards, and applies to all of the products that fall within the scope of the proposed rule. These hazards are that caregivers may judge that an infant support cushion with relatively high sidewalls can safely contain an infant without supervision and is suitable for use on top of an adult bed or in a crib notwithstanding any contrary warnings, and that high sidewalls can cause hazardous positioning of the infant's neck when an infant's head is placed on top of the sidewall while their body is on a lower surface either inside or outside of the product. *See Staff's NPR Briefing Package, Tabs B and C.* While ASTM's draft sets a four-inch limit on sidewall height, the proposed rule addresses these hazards by limiting the maximum incline angle and provides testing protocols based on the type of product (for example, lounger-type products or head cushions). Using the test methodology prescribed in the proposed rule, sidewall heights, for products that have sidewalls, would be limited to approximately 1.9 inches.

The Commission invites public comments on the proposed rule's method for addressing hazards posed by sidewall heights via measurement of maximum incline angle and what methodology would most effectively address the identified fall and positional asphyxia hazards.

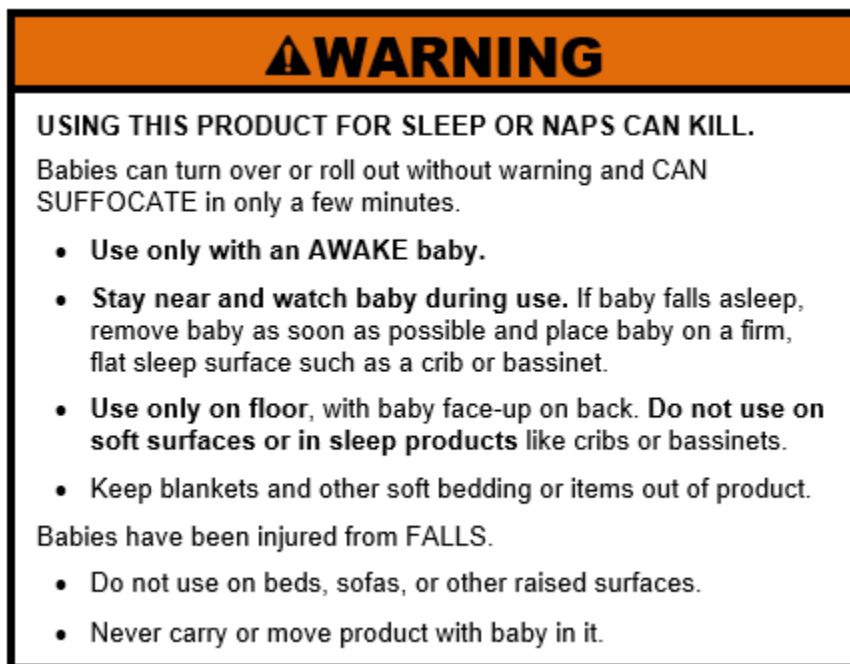
#### *D. Warning and Instructional Requirements*

Compared to the performance requirements described above, warnings are less effective in eliminating or adequately reducing exposure to hazards associated with infant support cushions. Nevertheless, prominent and well-designed warnings can provide consumers with important information about the hazards associated with these products and appropriate

behaviors to avoid the hazards. Thus, the proposed rule includes requirements for on-product warnings that address the primary hazards associated with infant support cushions.

The proposed rule includes warning content and format requirements similar to those in the ASTM draft standard. Figure 4 shows the warning statements and format that would be required on infant support cushions:

Figure 4: Example of Infant Support Cushion Warning



The proposed rule, like ASTM’s draft, requires on-product warning labels to be “conspicuous,” defined as “visible, when the product is in each manufacturer’s recommended use position, to a person while placing an infant into or onto the product.” Also, like ASTM’s draft, the proposed rule requires such warning labels to be “permanent,” with permanence requirements based on ASTM’s draft but better addressing the potential for consumers to attempt to remove on-product warning labels. The draft ASTM warning label for infant loungers indicates that the product should only be used on the floor, “with baby face-up on back.” This proposed rule would adopt ASTM’s draft language. However, this proposed rule for infant support cushions includes products that can be used for “tummy time,” for which infants are on their stomach. The Commission invites public comments in answer to the following questions:

Should manufacturers have flexibility to remove or change the “with baby face-up on back” language in the warning label? If so, in what circumstances?

The proposed rule incorporates by reference the following provisions of the American National Standards Institute (ANSI) warning format requirements published in sections 6.1–6.4 of ANSI Z535.4, *Product Safety Signs and Labels*, which include requirements related to safety alert symbol use, signal word selection, and warning panel format, arrangement, and shape; sections 7.2–7.6.3 of ANSI Z535.4, which include color requirements for each panel; and section 8.1 of ANSI Z535.4, which addresses letter style. *See Staff’s NPR Briefing Package, Tab D, 80–81.*

In addition to on-product warnings, the ASTM draft standard includes basic warning requirements for instructional literature that are the same as those in ASTM’s draft.

### **VIII. Proposed Amendment to 16 CFR Part 1112 to Include NOR for Infant Support Cushions**

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

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

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

## **IX. Product Registration Rule Amendment**

In addition to requiring the Commission to issue safety standards for durable infant or toddler products, section 104 of the CPSIA directed the Commission to issue a rule requiring that manufacturers of durable infant or toddler products establish a program for consumer registration of those products. 15 U.S.C. 2056a(d). Section 104(f) of the CPSIA defines the term "durable infant or toddler product" as "a durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years," and lists 12 distinct product categories. 15 U.S.C. 2056a(f). The product categories listed in section 104(f)(2) of the CPSIA represent a non-exhaustive list of durable infant or toddler product categories. Infant support cushions are not included in the statutory list of durable infant or toddler products.

In 2009, the Commission issued a rule implementing the consumer registration requirement. 74 FR 68668 (Dec. 29, 2009) (establishing 16 CFR part 1130). As section 104(d) of the CPSIA directs, the consumer registration rule requires each manufacturer of a durable infant or toddler product to provide a postage-paid consumer registration form with each product; keep records of consumers who register their products with the manufacturer; and permanently place the manufacturer's name and certain other identifying information on the product.

When issuing the consumer registration rule, the Commission identified six additional products as durable infant or toddler products: children's folding chairs; changing tables; infant bouncers; infant bathtubs; bed rails; and infant slings. 74 FR at 68669. The Commission explained that the specified statutory categories are not exclusive, and that the Commission is charged with identifying the product categories that are covered. "Because the statute has a broad definition of a durable infant or toddler product but also includes 12 specific product categories," the Commission noted, "additional items can and should be included in the definition, but should also be specifically listed in the rule." *Id.* at 68670.

The Commission proposes in this NPR to amend part 1130 to include "Infant Support Cushions" as durable infant or toddler products. Infant support cushions are a category of "durable infant or toddler product" for purposes of CPSIA section 104 because they: (1) are intended for use, and may be reasonably expected to be used, by children under the age of five years; (2) are products similar to other products listed in section 104(f)(2), such as crib mattresses and sling carriers; and (3) are commonly resold or "handed down" for use by other children over a period of years.

## **X. Incorporation by Reference**

Section 1243.6(d)(4) of the proposed rule incorporates by reference ANSI Z535.4–2011, *American National Standard for Product Safety Signs and Labels*, sections 6.1–6.4, 7.2–7.6.3, and 8.1, with modifications to further reduce the risk of injury associated with infant support cushions. In accordance with regulations of the Office of the Federal Register (OFR), 1 CFR part 51, Part VII.D of this preamble summarizes the provisions of ANSI Z535.4–2011 that the Commission proposes to incorporate by reference. The ANSI standard is reasonably available to interested parties in several ways. By permission of ANSI, the standard can be viewed as a read-only document during the comment period on this NPR, at:

<https://www.surveymonkey.com/r/DQVJYMK>. To download or print the standard, interested persons may purchase a copy of ANSI Z535.4–2011 from ANSI via its website, <https://www.ansi.org>, or by mail from ANSI, 25 West 43rd Street, 4th Floor, New York, NY 10036, telephone: (212)-642-4900. Alternatively, interested parties may inspect a copy of the standard at CPSC’s Office of the Secretary by contacting Alberta E. Mills, Commission Secretary, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone: (301) 504-7479; email: [cpsc-os@cpsc.gov](mailto:cpsc-os@cpsc.gov).

## **XI. Effective Date**

The Administrative Procedure Act (APA) generally requires that the effective date of a rule be at least 30 days after publication of the final rule. 5 U.S.C. 553(d). The Commission proposes an effective date of 180 days after publication of the final rule in the *Federal Register*, such that the requirements of the rule would apply to all infant support cushions manufactured after that date. This amount of time is typical for rules issued under section 104 of the CPSIA. It is also the period that the Juvenile Products Manufacturers Association (JPMA) typically allows

for products in their certification program to shift to a new standard once that new standard is published. Therefore, juvenile product manufacturers are accustomed to adjusting to new standards within this time. A 180-day effective date should also be sufficient for manufacturers to comply with this rule because the proposed requirements do not demand significant preparation by testing laboratories. For example, no new complex testing instruments or devices would be required to test infant support cushions for compliance with the proposed rule. The Commission invites comments, particularly from small businesses, that provide specific data addressing whether the proposed 180-day effective date period is appropriate.

## **XII. Regulatory Flexibility Act**

The Regulatory Flexibility Act ((RFA); 5 U.S.C. 601-612) requires that agencies review a proposed rule's potential economic impact on U.S. small entities, including small businesses. Section 603 of the RFA generally requires that agencies make an initial regulatory flexibility analysis (IRFA) available to the public for comment when the NPR is published. The IRFA must describe the impact of the proposed rule on small entities and identify significant alternatives that accomplish the statutory objectives and minimize any significant economic impact of the proposed rule on small entities. Staff prepared an IRFA for this rulemaking that appears at Tab E of the Staff's NPR Briefing Package. We summarize the IRFA below.

### *A. Reasons and Legal Basis for the NPR*

Part I of this preamble describes the reasons and legal basis for this NPR. As discussed in Parts VII-IX of this preamble, and detailed in Tab B of Staff's NPR Briefing Package, the proposed rule sets out mandatory requirements for infant support cushions to address the suffocation, entrapment, and fall hazards associated with these products; adds infant support

cushions to the list of products for which a registration card is required; and adds infant support cushions to the list of durable infant products for which an NOR is required.

*B. Small Entities to Which the Proposed Rule Would Apply*

As explained in Tab E to Staff's NPR Briefing Package, Commission staff has identified more than 2,000 suppliers of infant support cushions to the U.S. market, including manufacturers, importers, and foreign direct shippers. The majority of these suppliers are small businesses.

*C. Impact of the Proposed Rule on Small Manufacturers and Importers*

Most in-scope products on the market will require redesign to meet the requirements in the proposed rule, and redesign costs would be potentially significant for a substantial number of small firms, particularly small-volume home crafters, for the first year that a rule is effective. Staff considers a "significant" impact to be at least one percent of annual revenue, which is consistent with the regulatory flexibility analyses of other federal agencies. With an estimated 2,000 models to be redesigned, the total cost of redesign to the industry in the first year could be up to \$27 million. However, as discussed in Tab E of Staff's Briefing Package, suppliers may be able to cover these costs by implementing modest retail price increases which would reduce the rule's impact on individual small entities. For example, a firm supplying 5,000 infant support cushions per year could cover the entire cost of redesign by raising the retail price by \$2.70.

If issued, a final rule would require all manufacturers and importers of infant support cushions to meet additional third party testing requirements under section 14 of the CPSA. As specified in 16 CFR part 1109, entities that are not manufacturers of children's products, such as importers and wholesalers, may rely on the certificates of compliance provided by others.

However, manufacturers could pass on at least some of the cost of testing for compliance to U.S. importers and wholesalers.

Third party testing costs for infant support cushions are estimated to be \$500 to \$1,000 per model. The annual cost of samples for testing is estimated at around \$100, bringing the overall annual testing cost to an estimated \$600 to \$1,100 per model. The costs of testing per model would be similar for suppliers of all sizes, although larger firms may be more likely to qualify for volume discounts. As with redesign costs, these testing costs could largely be covered by modest retail price increases.

The hand crafters of infant support cushions with the smallest sales volumes may not have sufficient sales volume to cover these costs and may exit the market. However, consumers would likely not experience a significant loss of utility as there are many different products available from different suppliers.

#### *D. Other Federal Rules That May Duplicate, Overlap, or Conflict with the Proposed Rule*

The Commission has not identified any federal rules that duplicate, overlap with, or conflict with the proposed rule.

#### *E. Alternatives Considered to Reduce the Impact on Small Entities*

The Commission considered the following alternatives to the proposed rule to reduce the impact on small businesses. The Commission requests comments on these alternatives and other alternatives that could reduce the potential burden on U.S. small entities.

##### 1. Not Establishing a Safety Standard

The Commission considered not establishing a safety standard for infant support cushions. While this alternative would result in no regulatory impact on small entities, deaths

and injuries from the use of infant support cushions would likely continue to occur at similar rates as those observed during the period from 2010 through 2022. In 2020 alone, there were 17 fatalities involving infant support cushions. Another 17 fatalities have been recorded in the potentially incomplete data for 2021. *See* Staff NPR Briefing Package, Tab A.

## 2. Delay To Await Publication of a Voluntary Standard

The Commission considered delaying the draft proposed rule to allow possible publication of a voluntary standard. Although this alternative would delay any impact on small businesses, it would also allow the hazard to continue indefinitely, as there is no clear date at which ASTM or any other voluntary standards organization will adopt a relevant standard, nor any assurance that a voluntary standard, if published, would be complied with by industry or adequately address the identified hazards.

## 3. Earlier or Later Effective Date

The Commission is proposing an effective date 180 days after publication of the final rule in the *Federal Register*. An earlier effective date would achieve the safety benefits of the rule more quickly, but it would also increase the burden on small businesses to quickly redesign and test their products. In addition, a significantly earlier effective date could result in temporary shortages of infant support cushions due to a potential lack of availability of testing laboratory resources.

The Commission is not proposing a later effective date, which would somewhat reduce burdens on small suppliers, because 180 days has generally been sufficient time for suppliers to come into compliance with durable infant or toddler product rules. Additionally, six months from the change in a voluntary standard is the period that JPMA uses for its certification program, so compliant manufacturers are used to this time frame to comply with a modified

standard. Testing laboratories should have no difficulty preparing to test to the proposed new mandatory standards within a 180-day period.

#### *F. Impact on Testing Labs*

The proposed rule should not have a significant adverse impact on testing laboratories. Laboratories will not need to acquire complex or costly testing instruments or devices to test infant support cushions for compliance, and laboratories will decide for themselves, based on expected demand for their testing services, whether to offer testing services for infant support cushion compliance.

### **XIII. Environmental Considerations**

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

### **XIV. Paperwork Reduction Act**

This proposed rule contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA; 44 U.S.C. 3501–3521). In this document, pursuant to 44 U.S.C. 3507(a)(1)(D), we set forth:

- a title for the collection of information;
- a summary of the collection of information;
- a brief description of the need for the information and the proposed use of the information;
- a description of the likely respondents and proposed frequency of response to the collection of information;
- an estimate of the burden that shall result from the collection of information; and
- notice that comments may be submitted to the OMB.

*Title:* Safety Standard for Infant Support Cushions.

*Description:* The proposed rule would require each infant support cushion within the scope of the rule to meet the rule’s performance and labeling requirements. It would require suppliers to conduct third party testing to demonstrate compliance and provide the specified warning label and instructions. These requirements fall within the definition of a “collection of information,” as defined in 44 U.S.C. 3502(3).

*Description of Respondents:* Persons who manufacture or import infant support cushions.

*Estimated Burden:* We estimate the burden of this collection of information as follows:

**Table 7: Estimated Annual Reporting Burden**

Burden Type	Number of Respondents	Frequency of Response	Total Annual Responses	Hours per Response	Total Burden Hours
Labeling and instructions	2,000	1	2,000	2	4,000

While some infant support cushion products currently have labels, all of these products would have to meet the specific labeling requirements and instructions specified in the proposed rule, which provides the text and graphics for the required labels and instructions. Specialized expertise in graphics design would not be required to develop the warnings and instructions. Most reporting and recordkeeping requirements in this proposed rule would be new for all suppliers.

CPSC estimates there are 2,000 entities that would respond to this collection annually, the majority of which would be small entities. We estimate that the time required to create and/or modify labeling and instructions is about two hours per response. Therefore, the estimated burden associated with this collection is 2,000 responses × one response per year × two hours per response = 4,000 hours annually.

We estimate the hourly compensation for the time required to respond to the collection is \$37.88 (U.S. Bureau of Labor Statistics, “Employer Costs for Employee Compensation,” June 2023, Table 4, total compensation for all sales and office workers in goods-producing private industries: [https://www.bls.gov/news.release/archives/ecec\\_09122023.pdf](https://www.bls.gov/news.release/archives/ecec_09122023.pdf). Therefore, the estimated annual cost of the collection is \$151,520 (\$37.88 per hour x 4,000 hours = \$151,520).

Based on this analysis, the proposed standard for infant support cushions would impose a burden to industry of 4,000 hours at a cost of \$151,520.

*Comments.* CPSC has submitted the information collection requirements of this proposed rule to OMB for review in accordance with PRA requirements. 44 U.S.C. 3507(d). CPSC requests that interested parties submit comments regarding information collection to the Office of Information and Regulatory Affairs, OMB (see the **ADDRESSES** section at the beginning of this NPR). Pursuant to 44 U.S.C. 3506(c)(2)(A), the Commission invites comments on:

- whether the collection of information is necessary for the proper performance of CPSC’s functions, including whether the information will have practical utility;
- the accuracy of CPSC’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- ways to enhance the quality, utility, and clarity of the information to be collected;
- ways to reduce the burden of the collection of information on respondents, including the use of automated collection techniques when appropriate and other forms of information technology; and
- the estimated burden hours associated with label modification, including any alternative estimates.

## **XV. Preemption**

Section 26(a) of the CPSA, 15 U.S.C. 2075(a), provides that when a consumer product safety standard is in effect and applies to a product, no state or political subdivision of a state may either establish or continue in effect a standard or regulation that prescribes requirements for the performance, composition, contents, design, finish, construction, packaging, or labeling of such product dealing with the same risk of injury unless the state requirement is identical to the

federal standard. Section 26(c) of the CPSA also provides that states or political subdivisions of states may apply to the Commission for an exemption from this preemption under certain circumstances. Section 104(b) of the CPSIA refers to the rules to be issued under that section as “consumer product safety rules.” Therefore, if finalized, the preemption provision of section 26(a) of the CPSA would apply to this rule for infant support cushions.

## **XVI. Request for Comments**

The Commission seeks public comment on all aspects of the proposed rule. In particular, the Commission seeks comments on the scope of the proposed rule, with respect to both in scope and out of scope products, including comments on whether the proposed definition of “infant support cushion” is sufficient to include all infant support cushions that are not subject to the FHSA infant pillow ban, 16 CFR 1500.18(a)(16). The Commission would also welcome comments on the wording of proposed warning label as well as on whether the on-product warning label requirement included in the proposed rule should be applied to replacement covers for infant support cushions in addition to the cushions themselves. In addition, the Commission invites public comment on the proposed limit on sidewall height and whether the proposed rule’s incline angle requirements provide appropriate protection against positional asphyxiation. Finally, the Commission requests comments on the proposed effective date and the costs of compliance with, and testing to, the proposed rule.

Submit comments in accordance with the instructions in the **ADDRESSES** section at the beginning of this notice.

## **List of Subjects**

### **16 CFR Part 1112**

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

### **16 CFR Part 1130**

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

### **16 CFR Part 1243**

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

For the reasons discussed in the preamble, the Commission proposes to amend Title 16 of the Code of Federal Regulations as follows:

## **PART 1112—REQUIREMENTS PERTAINING TO THIRD PARTY CONFORMITY ASSESSMENT BODIES**

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

**Authority:** Pub. L. 110-314, section 3, 122 Stat. 3016, 3017 (2008); 15 U.S.C. 2063.

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

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

\* \* \* \* \*

(b) \* \* \*

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

\* \* \* \* \*

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

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

4. Amend § 1130.2 by adding paragraph (a)(21) to read as follows:

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

### **§ 1130.2 Definitions.**

\* \* \* \* \*

(a) \* \* \*

(21) Infant Support Cushions.

\* \* \* \* \*

5. Add part 1243 to read as follows:

## **PART 1243—SAFETY STANDARD FOR INFANT SUPPORT CUSHIONS**

Sec.

1243.1 Scope, purpose, application, and exemptions.

1243.2 Definitions.

1243.3 General requirements.

1243.4 Performance requirements.

1243.5 Test methods.

1243.6 Marking and labeling.

1243.7 Instructional literature.

1243.8 Incorporation by reference.

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

### **§ 1243.1 Scope, purpose, application, and exemptions.**

(a) *Scope and Purpose.* This consumer product safety standard prescribes requirements to reduce the risk of death and injury from hazards associated with *infant support cushions*, as defined in § 1243.2. This includes but is not limited to *infant positioners*, nursing products with a dual use for lounging, *infant loungers*, and infant props or cushions used to support an infant. All *infant support cushions* must be tested according to the requirements of § 1243.5 and comply with all requirements of this part 1243.

(b) *Application.* All infant support cushions manufactured after [insert effective date of

the final rule], are subject to the requirements of this part 1243.

(c) *Exemptions.* Products subject to another standard listed in 16 CFR 1130.2(a) are exempt from this part 1243. Nursing pillows that also meet the definition of *infant lounger*, however, are not exempt from this part 1243.

## **§ 1243.2 Definitions.**

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

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

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

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

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

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

## **§ 1243.3 General requirements.**

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

(b) *Small Parts.* There shall be no small parts as defined in 16 CFR 1501 before testing or presented as a result of testing.

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

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

(e) *Side Height*. The maximum side height for the product, measured from the OSS-body or test base, as appropriate, to the top of the sidewall, shall not exceed the maximum of the side heights determined in § 1243.5(d)(8).

(f) *Removal of Components*. When tested in accordance with § 1243.5(k), any removal of components that are accessible to an infant while in the product or from any position around the product shall not present a small part, sharp point, or sharp edge as required in § 1243.3(a) and § 1243.3(b).

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

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

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

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

(h) *Convertible Products*. If the infant support cushion can be converted into another product for which a consumer product safety standard exists, the product also shall comply with the

applicable requirements of that standard.

**§ 1243.4 Performance requirements.**

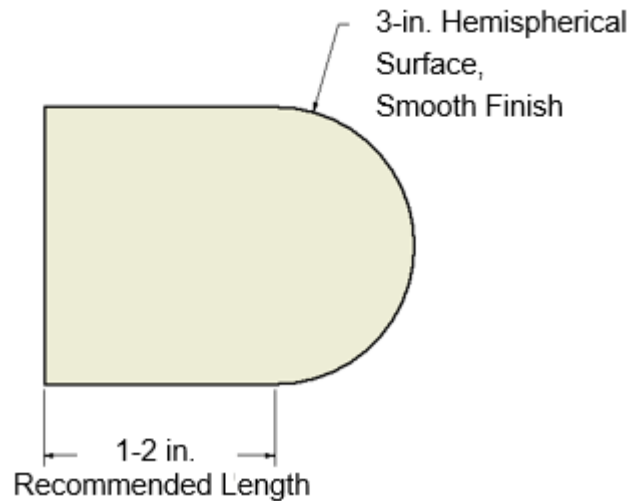
(a) *Restraint*. The product shall not include a restraint system.

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

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

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

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

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

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

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

(f) *Side Wall Angle.* Sidewall angle shall be greater than 90 degrees when determined according to the Sidewall Angle Determination, § 1243.5(i).

### **§ 1243.5 Test Methods.**

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

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

surface to which it is attached.

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

(3) A warning label attached by a seam shall be considered permanent if it does not detach when subjected to a 15-lbs (67-N) pull force applied in any direction using a 3/4-inch diameter clamp surface.

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

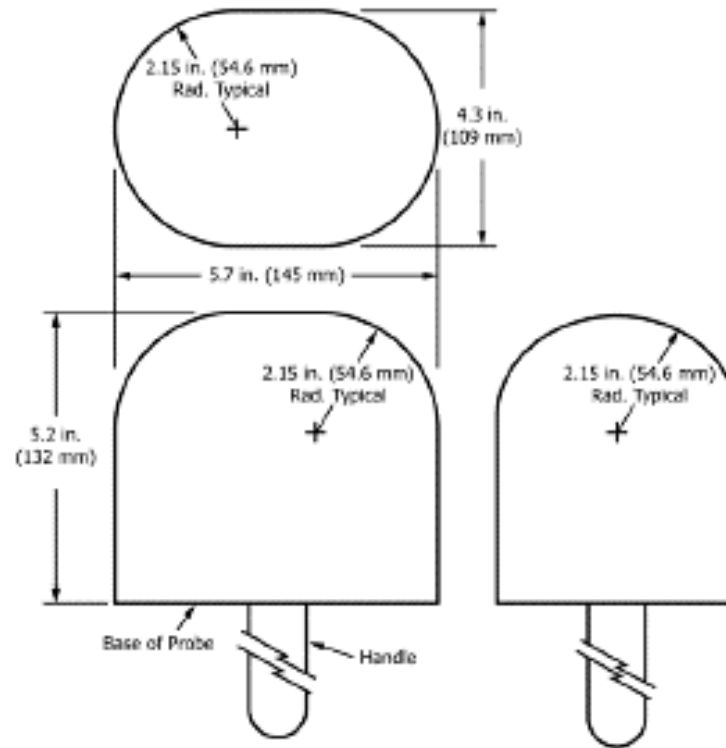
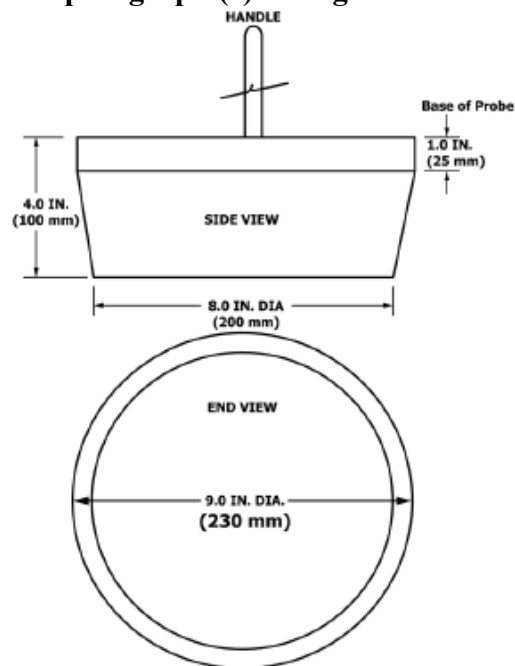
(i) Apply the tape test defined in Test Method B, Cross-Cut Tape Test of ASTM Test Methods D3359, eliminating parallel cuts.

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

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

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

(c) *Head Entrapment Test.* For all applicable openings, rotate the small head probe (Figure 2 to paragraph (c)) to the orientation most likely to fail and gradually apply an outward force from the occupant lounging area of 25 lbs (111 N). Apply the force to the probe in the direction most likely to fail within a period of 5 seconds and maintain it for an additional 10 seconds. If the small head probe can pass entirely through the opening in any orientation, determine if the large head probe (Figure 3 to paragraph (c)) can be freely inserted through the opening.

**Figure 2 to paragraph (c) - Small Head Probe****Figure 3 to paragraph (c) - Large Head Probe**

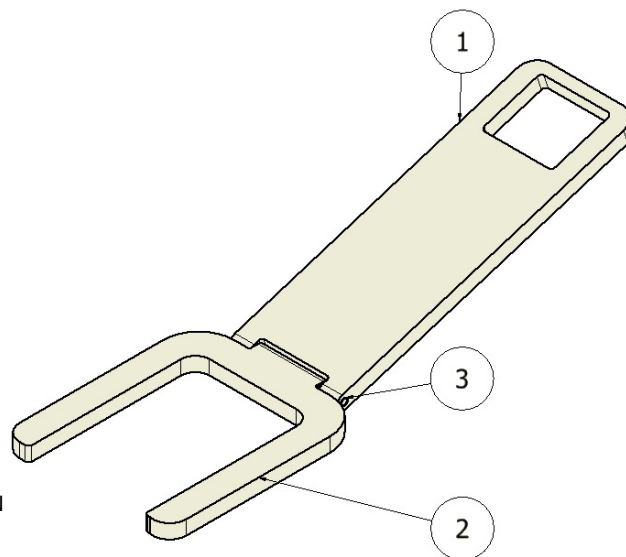
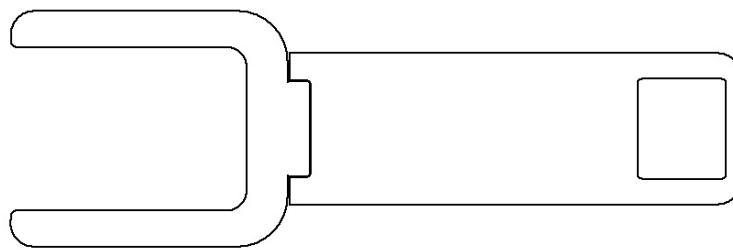
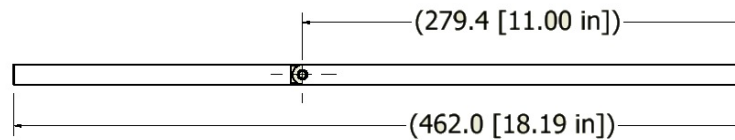
(d) *Maximum Incline Test.* (1) *Equipment:* (i) Digital Protractor with accuracy  $\pm 1$  degree;

(ii) Hinged Weight Gauge–Newborn, requirements for part masses and assembly (Figure 4 to this paragraph 5(d)(1)(ii)); (iii) Hinged Weight Gauge–Newborn, requirements for part dimensions (Figure 5 to this paragraph 5(d)(1)(iii)); and (iv) A test base that is horizontal, flat, firm, and smooth.

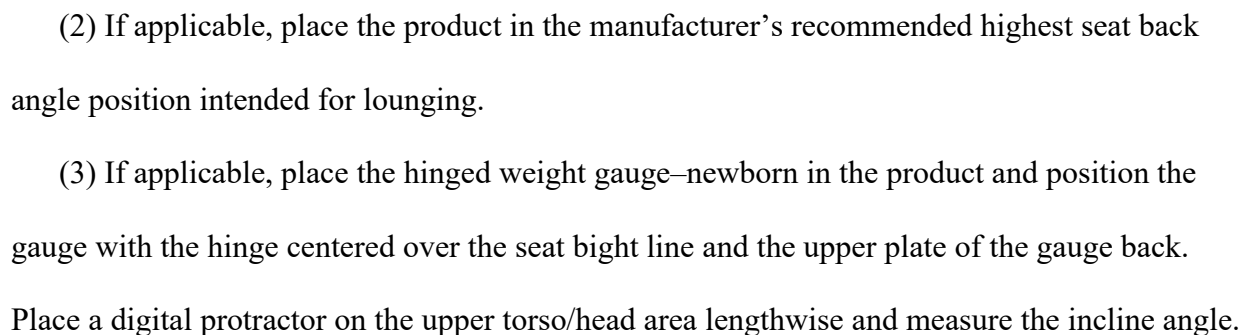
**Figure 4 to paragraph 5(d)(1)(ii) - Hinged Weight Gauge–Newborn, Requirements for Part Masses and Assembly**

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

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

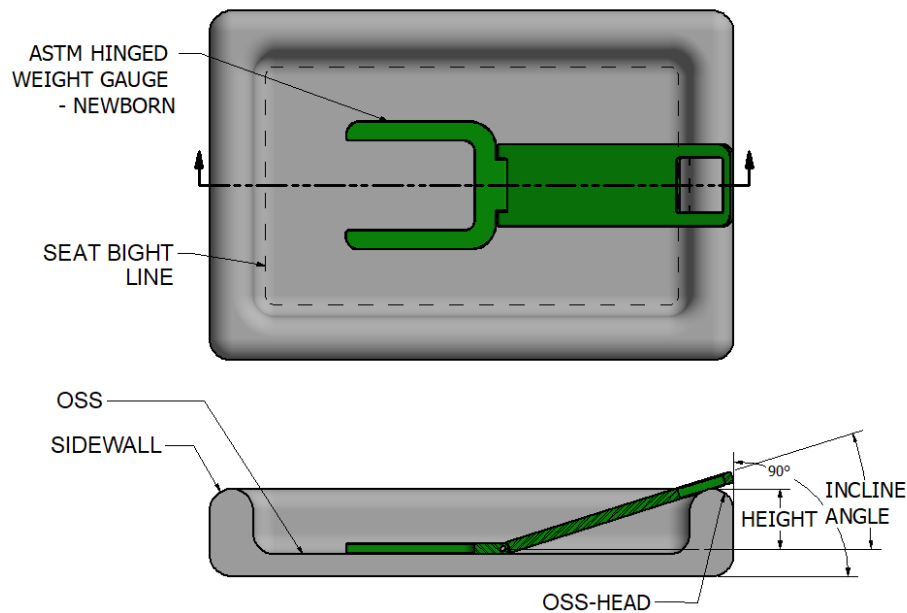


CLEARED FOR RELEASE  
UNDER CPSA 6(b)(1)



(4) Place the head/torso portion of the newborn hinged weight gauge on the product according to the manufacturer's recommended use position with the seat portion of the gauge, depending on the product design, allowed to lay freely on the product or on the test base (Figure 6 to paragraph (d)(4)).

**Figure 6 to paragraph (d)(4) - Test Fixture Configuration to Measure Incline Angle on an Infant Support Cushion Product**



(5) Move and rotate the newborn hinged weight gauge the minimum amount necessary such that the head/torso portion rests on an OSS that could foreseeably support an infant's head, and place the head/torso portion of the gauge according to all situations that apply: (i) In tests on products with an OSS for the infant's body, align the top edge of the head/torso portion of the gauge to coincide with a plumb line to the outermost edge of the OSS-head.

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

(6) If a product's seating bight area prevents reasonable positioning of the head/torso portion

to the outermost edge, then position the seat portion of the newborn hinged weight gauge as far forward as possible towards the outermost edge and allow the head/torso portion of the gauge to rest on the product.

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

(8) Remove the newborn gauge and determine the side height at the incline angle location, measured from the OSS-body or test base, as appropriate, to the top of the OSS-head.

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

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

(e) *Firmness Test Setup.* (1) *Equipment.* (i) Force gauge with accuracy  $\pm 0.05$  N (0.01 lbs); (ii) Distance gauge with accuracy  $\pm 0.01$  inches (0.03 cm).

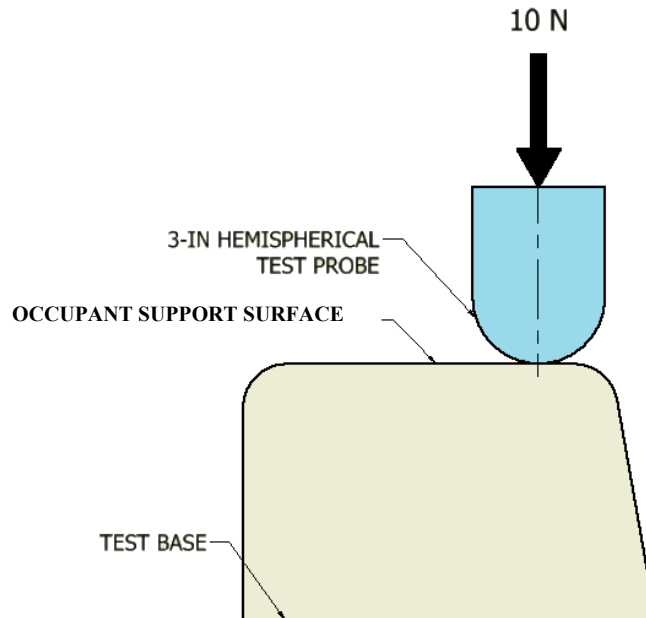
(2) Align the axis of the three-inch head probe (Figure 1 to paragraph (e)(1) of § 1243.4) with a force gauge and parallel to a distance measurement device or gauge.

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

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

(f) *Occupant Support Surface Firmness Test Method.* Perform the following steps to determine the occupant support surface firmness of the product as received from the manufacturer. See Figure 7 to paragraph (f).

**Figure 7 to paragraph (f) – Test Configuration for  
Occupant Support Surface Firmness Test**



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

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

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

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

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

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

(7) Wait 30 seconds. If the deflection is less than 1.00 inches and the force is 10.0 N or less, repeat steps § 1243.5(f)(6) and § 1243.5(f)(7)).

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

(9) If the maximum thickness of the OSS is greater than 1.0 inches (2.54 cm), perform additional tests, space permitting, at the geometric center of the OSS, at four locations along the product's longitudinal and lateral axes therefrom, 1.5 inches (3.8 cm) towards center from the intersection of the sidewall and OSS, and at one location most likely to fail.

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

(g) *Sidewall Firmness Test Method.* For sidewalls, perform the steps in § 1243.5(f)(1)-(8) to determine the sidewall firmness of the product as received from the manufacturer and then perform the following:

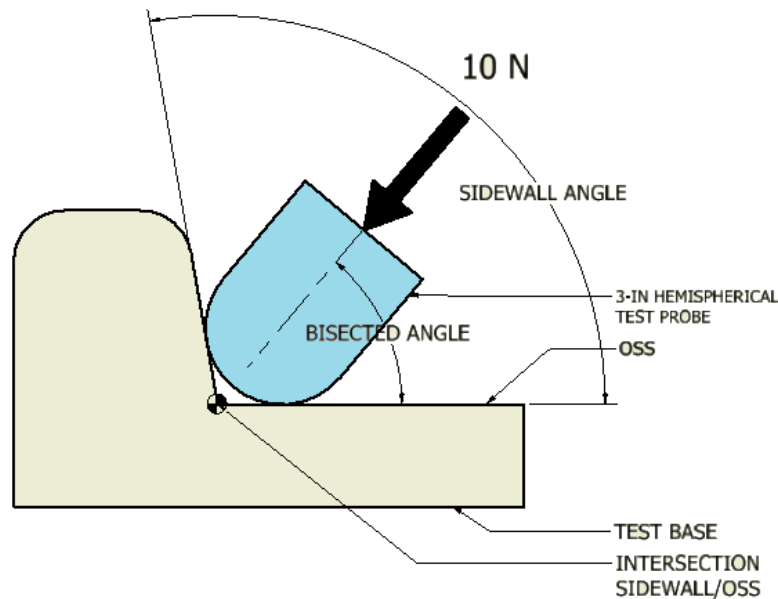
(1) Perform a minimum of four additional tests, located at intervals not to exceed six inches along the entire top perimeter of the sidewall, starting from the maximum side height location, and at one additional location most likely to fail.

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

(h) *Intersection of Sidewall and Occupant Support Surface Firmness.* Perform the following

steps to determine the intersection firmness of the product as received from the manufacturer (Figure 8 to paragraph (h)).

**Figure 8 to paragraph (h) - Test Configuration for Intersection of Sidewall and Occupant Support Surface Firmness**



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

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

(3) Perform the steps in § 1243.5(f)(3)-(8).

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

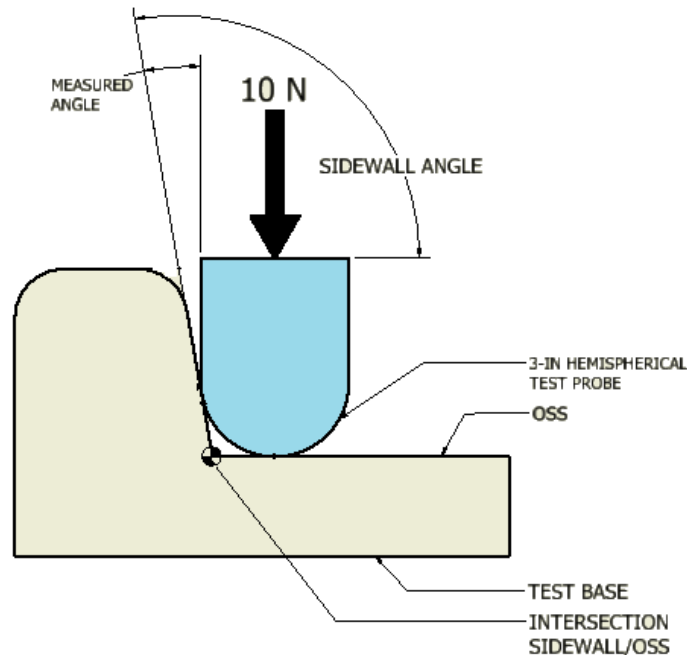
(5) Repeat the intersection of sidewall and occupant support surface firmness test in all the intended or feasible configurations that could affect the intersection firmness, such as the folding

or layering of parts of the product.

(i) *Sidewall Angle Determination.* Perform the following steps to determine if the angle between the sidewall and OSS is 90 degrees or less, or to measure the angle above 90 degrees.

See Figure 9 to paragraph (i).

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



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

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

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

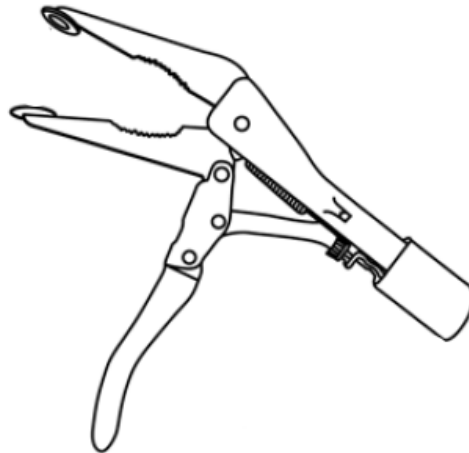
sidewall.

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

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

(j) *Seam Strength Test Method.* (1) *Equipment.* (i) Clamps with 0.75 inches (1.9 cm) diameter clamping surfaces capable of holding fabric and with a means to attach a force gauge. *See figure 10 to paragraph (j), or equivalent;* (ii) A force gauge, accuracy  $\pm 0.5$  lbs (1.1 N).

**Figure 10 to paragraph (j) – Seam Clamp**



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

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

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

(k) *Removal of Components Test Method.* (1) For torque and tension tests, any suitable device may be used to grasp the component that does not interfere with the attachment elements that are stressed during the tests.

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

(3) *Tension Test.* For components that can reasonably be grasped between thumb and forefinger, or teeth, apply a 15 lbs (67 N) force over five seconds, in a direction to remove the component. Maintain for 10 seconds. A clamp such as shown in Figure 11 to paragraph (k)(3) may be used if the gap between the back of the component and the base material is 0.04 inches (0.1 cm) or more.

**Figure 11 to paragraph (k)(3) - Tension Test Adapter Clamp**



#### **§ 1243.6 Marking and Labeling.**

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

(1) The name, place of business (city, state, and mailing address, including zip code), and

telephone number of the manufacturer, distributor, or seller.

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

(3) The marking or labeling in § 1243.6(a)(1) and (2) are not required on the retail package if they are on the product and are visible in their entirety through the retail package. When no retail packaging is used to enclose the product, the information provided on the product shall be used for determining compliance with § 1243.6(a)(1) and (2). Cartons and other materials used exclusively for shipping the product are not considered retail packaging.

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

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

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

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

(3) The warnings shall be conspicuous and permanent.

(4) The warnings shall conform to ANSI Z535.4–2011, American National Standard for Product Safety Signs and Labels, sections 6.1–6.4, 7.2–7.6.3, and 8.1, with the following changes.

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

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

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

Note 1 to paragraph (d)(4)(iii) — For reference, ANSI Z535.1, American National Standard for Safety Colors, provides a system for specifying safety colors.

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

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

(6) Message Panel Text Layout. (i) The text shall be left-aligned, ragged-right for all but one-line text messages, which can be left-aligned or centered. See Figure 12 to paragraph (d)(6) for examples of left-aligned text.

### Figure 12 to paragraph (d)(6) - Examples of Left-Aligned Text.

The text shown for these warnings is filler text, known as lorem ipsum, commonly used to demonstrate graphic elements.



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

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

(7) An example warning in the format described in this section is shown in Figure 13 to paragraph (d)(7).

**Figure 13 to paragraph (d)(7) – Example of Warning**



(e) *Warning Statements* — Each product shall address the warning statements shown on Figure 13 to paragraph (d)(7), at a minimum.

Note 4 to paragraph (e) — “Address” means that verbiage other than what is shown can be used as long as the meaning is the same or information that is product-specific is presented.

## **§ 1243.7 Instructional Literature.**

(a) Instructions shall be provided with the product and shall be easy to read and understand and

shall be in the English language at a minimum. These instructions shall include information on assembly, maintenance, cleaning, and use, where applicable.

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

(1) Read all instructions before using this product.

(2) Keep instructions for future use.

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

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

(c) The cautions and warnings in the instructions shall meet the requirements specified in § 1243.6(d)(4)-(6), except that sections 6.4 and 7.2–7.6.3 of ANSI Z535.4 – 2011, *American National Standard for Product Safety Signs and Labels*, need not be applied. However, the signal word and safety alert symbol shall contrast with the background of the signal word panel, and the cautions and warnings shall contrast with the background of the instructional literature.

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

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

### **§ 1243.8 Incorporation by Reference**

ANSI Z535.4-2011, *American National Standard for Product Safety Signs and Labels*, approved October 20, 2017, is incorporated by reference. The Director of the Federal Register

approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. This material is available for inspection at the U.S. Consumer Product Safety Commission and at the National Archives and Records Administration (NARA). Contact the U.S. Consumer Product Safety Commission at: the Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814, telephone (301) 504-7479, email: [cpsc-os@cpsc.gov](mailto:cpsc-os@cpsc.gov). For information on the availability of this material at NARA, email [fr.inspection@nara.gov](mailto:fr.inspection@nara.gov), or go to: [www.archives.gov/federal-register/cfr/ibr-locations.html](http://www.archives.gov/federal-register/cfr/ibr-locations.html). A free, read-only copy of the standard is available for viewing on the ANSI website at <https://ibr.ansi.org/Standards/nema.aspx>. You may also obtain a copy from American National Standards Institute (ANSI), 25 West 43rd Street, 4th Floor, New York, NY 10036, USA, telephone: (212) 642-4900, [www.ansi.org](http://www.ansi.org).

---

Alberta E. Mills, Secretary  
Consumer Product Safety Commission



## Staff Briefing Package

# Staff's Draft Proposed Rule for Infant Support Cushions

November 8th, 2023

For additional information, contact:

Stefanie Marques, Ph.D.  
Infant Support Cushions Rulemaking Project Manager  
Directorate for Health Sciences  
Office of Hazard Identification and Reduction  
Email: [smarques@cpsc.gov](mailto:smarques@cpsc.gov)

U.S. Consumer Product Safety Commission  
5 Research Place  
Rockville, MD 20850

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



# Table of Contents

<b>Table of Contents.....</b>	<b>1</b>
<b>Briefing Memorandum .....</b>	<b>2</b>
<b>I. Introduction .....</b>	<b>Error! Bookmark not defined.</b>
<b>II. Background .....</b>	<b>5</b>
<b>III. Incident Data.....</b>	<b>8</b>
<b>IV. Hazard Pattern Identification.....</b>	<b>9</b>
<b>V. Contractor Report .....</b>	<b>10</b>
<b>VI. International Standards for Infant Pillows .....</b>	<b>11</b>
<b>VII. Draft ASTM Voluntary Standard for Infant .....</b>	<b>12</b>
<b>VIII. Staff's Proposed Rule.....</b>	<b>14</b>
<b>IX. Potential Small Business Impact .....</b>	<b>20</b>
<b>X. Compliance Recall Information .....</b>	<b>21</b>
<b>XI. Product Registration Rule Amendment.....</b>	<b>21</b>
<b>XII. Notice of Requirements .....</b>	<b>22</b>
<b>XIII. Recommended Effective Date.....</b>	<b>22</b>
<b>XIV. Staff Conclusion and Recommendations .....</b>	<b>23</b>
<b>TAB A: Infant Support Cushion-Related Fatalities, Injuries, and Noninjury Incidents, 2010 – 2022.....</b>	<b>29</b>
<b>TAB B: Health Science Staff's Assessment on Infant Pillow-Related Deaths, Injuries, and Potential Injuries .....</b>	<b>37</b>
<b>TAB C: Staff Recommended Performance Requirements for the Notice of Proposed Rulemaking for Infant Support Cushions.....</b>	<b>46</b>
<b>TAB D: Human Factors Review of Incident Data and Recommended Requirements for Infant Support Cushions .....</b>	<b>74</b>
<b>TAB E: Initial Regulatory Flexibility Analysis for the Draft Proposed Rule to Establish a Mandatory Safety Standard for Infant Support Cushions .....</b>	<b>89</b>
<b>TAB F: Recommended Regulatory Text for the Draft Proposed Rule .....</b>	<b>104</b>

## Briefing Memorandum



# Memorandum

**TO:** The Commission  
Alberta E. Mills, Secretary  
Austin C. Schlick, General Counsel  
Jason Levine, Executive Director  
DeWane Ray, Deputy Executive Director of Operations

**DATE:** November 8,  
2023

**FROM:** Duane E. Boniface, Assistant Executive Director,  
Office of Hazard Identification and Reduction  
  
Stefanie Marques, Infant Support Cushions Rulemaking Project  
Manager,  
Directorate for Health Sciences

**SUBJECT:** Staff's Draft Proposed Rule for Infant Support Cushions

## I. Introduction

This briefing package presents staff's draft proposed rule for infant support cushions under the Danny Keysar Child Product Safety Notification Act, *i.e.*, section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA). Infant support cushions are products marketed, designed, or intended to support an infant's weight or any portion of an infant while reclining or in a supine, prone, or recumbent position. Some of these products are marketed for use inside a crib or other sleep product but are not sleeping accommodations themselves.

Staff has identified 79 fatal incidents and 125 nonfatal incidents and consumer concerns reported to the U.S. Consumer Product Safety Commission (CPSC) from January 1, 2010, through December 31, 2022, associated with infant support cushions and involving infants up to 12 months of age.

Section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), requires the U.S. Consumer Product Safety Commission (CPSC) to:

- 1) examine and assess voluntary safety standards for certain infant or toddler products; and
- 2) promulgate mandatory consumer product safety standards that are substantially the same as the voluntary standards or more stringent than the voluntary standards, if the Commission determines that more stringent standards would further reduce the risk of injury associated with these products.

15 U.S.C. § 2056a(b). The Commission must continue promulgating safety standards for infant and toddler products until it “has promulgated standards for all such product categories.” 15 U.S.C. § 2056a(b)(2).

Section 104(f) of the CPSIA defines “durable infant or toddler products” as “durable products intended for use, or that may be reasonably expected to be used, by children under the age of 5 years.” 15 U.S.C. § 2056a(f). Section 104(f)(2) sets forth a non-exhaustive list of durable infant or toddler products that fall within the definition. 15 U.S.C. § 2056a(f)(2). Although infant support cushions are not specifically listed, they are “durable infant or toddler products” because they are durable products used by infants to support their weight while reclining or in a supine, prone, or recumbent position.

Section 104 of the CPSIA requires the Commission to consult with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts to examine and assess the effectiveness of any relevant voluntary standards. This consultation process has been ongoing with CPSC staff’s participation in the juvenile product subcommittee meetings of ASTM International. ASTM subcommittee members represent producers, users, consumers, government, and academia.<sup>1</sup> Staff began the consultation process that led to this rulemaking in December 2021, in a letter to ASTM requesting that ASTM form a working group under the F15 committee to develop a voluntary standard containing performance requirements to reduce the risk of death and injury from hazards associated with infant support cushions, including nursing pillows. ASTM formed two subcommittees to develop two separate voluntary standards:

- 3) the F15.16 Infant Feeding Supports subcommittee,<sup>2</sup> intended to develop a standard for nursing pillows and other infant feeding supports, and
- 4) the F15.21 Infant Loungers subcommittee, intended to develop a standard for infant loungers, including nursing pillows intended for lounging.

Since then, staff has been actively participating with both ASTM subcommittees to develop voluntary standard requirements that address the associated hazards; however, neither subcommittee has published their respective standards.

Staff considers infant loungers to be a type of infant support cushion, therefore this briefing package summarizes staff’s assessment of the performance and other requirements under consideration by the ASTM F15.21 Infant Loungers subcommittee for its voluntary standard as well as staff’s work to develop requirements for infant support cushions.

This Briefing Package presents staff’s recommendations for a draft proposed rule for infant support cushions, provides staff’s analysis of the draft ASTM standards, and discusses the impact of this proposed rule on small businesses as required by the Regulatory Flexibility Act. Staff recommends updating 16 C.F.R. part 1130 to include infant support cushions as “durable infant or toddler products” requiring consumer registration cards under section 104(b) of the

<sup>1</sup> ASTM International website: [www.astm.org](http://www.astm.org), About ASTM International.

<sup>2</sup> The ASTM F15.16 Infant Feeding Supports subcommittee was initially called the Feeding and Infant Support Products subcommittee.

CPSIA and updating 16 C.F.R. part 1112 to include a Notice of Requirements (NOR) for infant support cushions.<sup>3,4</sup>

## II. Background

### A. Infant Pillow Ban

In 1992, pursuant to the Commission's authority under the Federal Hazardous Substances Act (FHSA), the Commission banned certain infant cushions and infant pillows. Specifically, 16 C.F.R. § 1500.18(a)(16) bans any article known as an "infant cushion" or "infant pillow," and any other similar article, which has *all* of the following characteristics:

- Has a flexible fabric covering;
- Is loosely filled with granular material, including but not limited to, polystyrene beads or pellets;
- Is easily flattened;
- Is capable of conforming to the body or face of an infant; and
- Is intended or promoted for use by children under 1 year of age.

The ban was intended to address a specific type of product; an infant bean bag cushion designed in the 1980s that, due to its size and shape, was being used as a mattress during a time when the recommended position for infant sleep was to place infants face down, prone. Therefore, the characteristics of pillows that fall under the ban were oriented to a particular product. For at least some period, this rule kept pillows that conformed to infants' faces and presented a suffocation hazard off the market. However, staff's assessment is that the infant pillow ban is not sufficient to remove potentially hazardous products available in today's market. In recent years, CPSC staff has become concerned about the increase in products promoted as infant support cushions that do not fall within the scope of the infant pillow ban, particularly those using non-granular fill materials, and the potential suffocation hazards that these products present to infants. Staff's proposed rulemaking does not disturb the FHSA infant pillow ban, but instead proposes performance standards for infant support cushions pursuant to section 104 of the CPSIA.

### B. Products and the Market

Most infant support cushions on the market today are "loosely filled" or simply "filled" with some type of cushy foam or soft fibrous batting, rather than a "granular material," and are therefore not within the scope of the FHSA ban. As a result, many soft products marketed as infant support cushions have been used in infant sleep environments where they create asphyxiation and suffocation hazards.

The proposed rule defines an "infant support cushion" as "an infant product that is filled with or comprised of resilient material such as foam, fibrous batting, or granular material or with a gel,

<sup>3</sup> Staff's assessment of the performance and other requirements under consideration by the ASTM F15.16 Infant Feeding Supports subcommittee for its voluntary standard, and staff's recommendations for a draft proposed rule for nursing pillows intended to position and support an infant during supervised feeding, such as breastfeeding, nursing, or bottle feeding are addressed under a separate rulemaking activity, and separate staff briefing package for nursing pillows.

<sup>4</sup> [https://www.regulations.gov/document/CPSC\\_FRDOC\\_0001-1332](https://www.regulations.gov/document/CPSC_FRDOC_0001-1332)

liquid, or gas, and which is marketed, designed, or intended to support an infant's weight or any portion of an infant while reclining or in a supine, prone, or recumbent position. (Figure 1). This includes products such as infant loungers that may have walls around their perimeters, infant positioners, nursing products used for lounging, infant cushions and props. The proposed rule would not apply to removable padding or padded seat liners sold as part of products primarily used to transport, entertain, or feed infants. It also would not apply to infant products subject to other infant product rules listed at 16 CFR 1130.2(a), including infant sleeping accommodations, which are already regulated by CPSC's infant sleep products standard, 16 C.F.R. part 1236. In other words, if an infant cushion product is not subject to another CPSC durable infant product rule and is marketed, designed, or intended to support an infant's weight or any portion of an infant for reclining or lying in a supine, prone, or recumbent position, it would be required to comply with the proposed infant support cushions rule.



**Figure 1. Examples of the various types of infant support cushions**

The products in scope would include but are not limited to:

- Head positioner pillows
- Flat baby loungers
- Crib pillows
- Wedge pillows for infants
- Infant sleep positioners, unless regulated by the FDA as medical devices<sup>5</sup>
- Stuffed toys marketed for use as infant support cushions
- Infant “tummy time” or “lounging” pillows, whether flat or inclined
- Multi-purpose pillows marketed for both nursing and lounging

<sup>5</sup> The FDA discourages the use of infant sleep positioners and has not approved pillow products for preventing sudden infant death syndrome (SIDS). See <https://www.fda.gov/consumers/consumer-updates/do-not-use-infant-sleep-positioners-due-risk-suffocation>

- Anti-rollover pillows with or without straps that fasten the pillow to the infant
- Infant “self-feeding” pillows that hold a bottle in front of the face of reclining or lying infant<sup>6</sup>.
- Pads and mats
- Accessory pillows and other padded accessories, often marketed for use with an infant car seat, stroller, or bouncer, but not sold with that product and therefore, not included in the mandatory safety testing for those products.

Some of these products are currently marketed for use inside a crib or other infant sleep product, notwithstanding the American Academy of Pediatrics’ (AAP’s) recommendation that soft objects, such as pillows and excess bedding, should not be placed in an infant’s sleep environment.<sup>7</sup> In addition, the CPSC and FDA have warned against using infant positioning products in an infant’s sleep environment, out of concern for the potential suffocation hazards these products pose. Based on the AAP, CPSC, and FDA’s consistent recommendations regarding infants, pillows, and soft bedding, the draft proposed rule does not encourage infant support cushions to be used for sleep or in a sleep environment. However, because infants sleep a majority of the day and tend to fall asleep in products intended for lounging or periods of rest, and based on the incident data, staff concludes it reasonably foreseeable that caregivers will continue to use infant support cushions in an infant sleep environment. Therefore, staff proposes a performance standard to reduce the asphyxiation and suffocation hazards that, based on incident data, these products pose.

The following products are out of scope:

- Pillows not marketed or intended for use by infants, such as adult bed pillows
- Nursing pillows that are marketed only for feeding and are not marketed, intended, or foreseeably used for lounging, if they meet the requirements of the Commission’s proposed nursing pillow rule 88 FR 65865 (Sept. 26, 2023) if that rule is finalized
- Crib and play yard mattresses that are in scope of the play yard and crib mattress standard in 16 C.F.R. part 1241
- Purely decorative nursery pillows, such as those personalized with the baby’s name and birthdate, if they are not intended, or marketed for infant use.
- Stuffed toys (unless they meet the definition of an infant support cushion in this proposed rule)
- Padded seat liners that are sold with a rocker, stroller, car seat, infant carrier, swing, highchair or bouncer that are specifically designed to fit that product
- Sleeping accommodations, which are regulated under the Commission’s infant sleep product rule at 16 CFR part 1236.

In general, products that are clearly intended to keep an infant engaged while awake or that can only be used when supervised by a caregiver would be considered out of scope of this proposed rule. In addition, free-standing products marketed or intended to provide sleeping accommodations for infants up to five months of age are within the scope of the “Safety

<sup>6</sup> These products are banned in the UK due to suffocation and pneumonia hazards. <https://www.gov.uk/product-safety-alerts-reports-recalls/product-safety-alert-baby-self-feeding-pillows-slash-prop-feeders-psa3>

<sup>7</sup> American Academy of Pediatrics, Sleep-Related Infant Deaths: Updated 2022 Recommendations for Reducing Infant Deaths in the Sleep Environment., <https://publications.aap.org/pediatrics/article/150/1/e2022057990/188304/Sleep-Related-Infant-Deaths-Updated-2022>

Standard for Infant Sleep Products” (16 C.F.R. part 1236), and therefore do not fall within the scope of this proposed safety standard. Staff recommends that the Commission invite comments from the public on whether the scope of this proposed rule is appropriate, or instead should be expanded or narrowed.

Staff cannot precisely determine the annual sales volume of infant support cushions, given the variety of products in scope of this rule and the large number of suppliers. Most types of infant support cushions are sold primarily online, rather than primarily in brick-and-mortar stores. Prices for new infant support cushions range from less than \$15 for a simple head positioner pillow or crib pillow to more than \$250 for a lounger with a removable cover or a large stuffed toy marketed for sleep, with the average price at roughly \$30. Infant support cushions are supplied by several thousand manufacturers and importers, including hundreds of handcrafters and direct foreign shippers. There is also a considerable market in secondhand items, particularly for the more expensive items such as loungers and large stuffed toys marketed for sleep. In addition, caregivers frequently save and reuse infant support cushions for more than one child, and manufacturers of some infant support cushions sell replacement covers that facilitate use over many years.

### **III. Incident Data**

As staff of CPSC’s Directorate for Epidemiology, Division of Hazard Analysis (EPAH) discusses in Tab A, staff’s search of the Consumer Product Safety Risk Management System (CPSRMS) and National Electronic Injury Surveillance System (NEISS) databases identified 79 fatal incidents and 125 nonfatal incidents and concerns reported to CPSC from January 1, 2010, through December 31, 2022—a period of 13 years—associated with infant support cushions as defined above, and involving infants up to 12 months of age (i.e. 365 days old). The data obtained from NEISS did not meet the minimum criteria to enable staff to compute a national estimate of the number of emergency department-treated injuries to infants involving infant support cushions. Thus, these cases are included with the other reported incident data. Because reporting is ongoing, the number of reported fatalities and nonfatal incidents and concerns during the specified timeframe might change in the future, especially for years 2021 and 2022. More detailed analyses of the incident data can be found in the EPAH staff memorandum in Tab A, as well as the memoranda in Tabs B and D, prepared by staff of the Directorate for Health Sciences (HS), and staff of the Directorate for Engineering Sciences, Division of Human Factors (ESHF), respectively.

#### **A. Fatalities**

CPSC staff identified 79 reported fatalities involving infant support cushions from January 1, 2010, through December 31, 2022. Given the anecdotal and incomplete nature of the data, staff discourages inferences based on year-over-year changes. However, more than three times as many fatalities occurred in the 2016-2022 period (61 fatalities) compared to the 2010-2015 period (18 fatalities), which is a concerning reporting trend, especially considering incident data from 2021 and 2022 may be incomplete.

Although staff reviewed incident data for children 12 months and younger, almost 81% of the infant pillow-related fatalities involved infants 3 months old and younger, a vulnerable age bracket. In 49 of the fatalities (62%), the official cause of death was asphyxia/probable

asphyxia. The decedent was placed on an infant support cushion in the following scenarios typically involving another sleep-related consumer product: 34 fatalities (43%) in an adult bed, 1 fatality in an air mattress (1%), 11 fatalities (14%) in a crib, 13 incidents in a bassinet or the bassinet portion of a play yard (15%), 8 fatalities (10%) inside a play yard or non-full sized crib, 3 fatalities (4%) on top of a couch/futon, 4 fatalities (5%) on either a mat or on the floor, and 1 fatality (1%) inside a toddler bed. Four (4) fatalities (5%) involved an undetermined or unknown scenario.

## B. Non-Fatalities

CPSC staff identified 125 nonfatal incidents or reports involving infant support cushions for children 12 months old and younger that occurred from January 1, 2010, through December 31, 2022. Three of these incidents (2%), resulted in hospital admission, and 22 incidents (18%) were Emergency Department treated. Using reported information, that varied widely due to the self-reporting nature of the reports, staff was able to further characterize the nonfatal incidents into the following scenarios: 29 reports (23%), involved the victim falling off the infant support cushion that was placed on raised surfaces (e.g. beds and sofas) 27 reports (22%) involved the victim having a threatened asphyxia event while using the infant support cushion, 17 reports (14%) involved the victim developing a rash after using the infant support cushion; reports of limb entrapment, mold, choking, entanglement /entrapment and vomiting associated with the use of the infant support cushion all had one report each (each 1%). Forty-seven of the nonfatal reports were consumer complaints (38%).

## IV. Hazard Pattern Identification.

As staff of CPSC's Directorate of Health Sciences (HS) discusses in Tab B, positional asphyxia/suffocation is a serious risk factor associated with the use of infant support cushions. HS staff identified four major types of positional asphyxia/suffocation hazards associated with infant support cushions:

***Remaining on product with nose and mouth occluded-*** HS staff identified 23 (29%) fatal incidents where the victim remained on the infant pillow and suffocated due to their nose and mouth being occluded. The narratives in those incidents indicate that the victim was placed supine on the infant pillow, or in an unstable side position and later found prone on the infant pillow with nose and mouth occluded by the infant pillow and/or by other soft bedding present in the sleep setting. These incidents suggest that the infants' unexpected movement on the infant pillow resulted in the occlusion of their nose and mouth either by the infant pillow itself or other soft bedding. An infant can suffocate/asphyxiate against an object that partially or fully obstructs the nose and mouth and prevents breathing. Death as the result of asphyxia can occur in as little as 3 minutes.

***Use as an in-bed sleeper/bassinet to facilitate bedsharing hazard-*** HS staff identified 27 fatal incidents (34%) where the victim was sharing a sleeping environment such as an adult bed, couch, or air mattress with caregivers and/or siblings. Bedsharing exposes the infant to a potentially fatal asphyxia hazard from overlay of the caregiver or suffocation from extraneous adult bedding; however, many narratives specifically describe scenarios where the infant pillow was being used as an in-bed sleeper/bassinet to facilitate bedsharing. Due to the complexity of

this unsafe sleep environment, victims were found in a variety of positions while using the infant pillow, including prone and supine on the pillow, partially off the infant pillow, completely off the infant pillow and wedged between the adult bed and the wall/or the outside surface of another children's product.

**Hyperextension hazard-** HS staff identified 2 fatal incidents (3%) where the victim's neck was hyperextended. Neck hyperextension is a hazardous position that can result if an infant's unsupported head is tilted backwards over the top of the product; if sustained in this position and the infant's head is below the level of the infant's heart, respiration will be significantly impaired which could lead to oxygen desaturation and death. In one incident the victim was found to have moved further up on the infant pillow, resulting in the infant's head falling off the pillow and resting on a comforter while the infant's body remained on the pillow. In the second incident, the infant partially rolled off the pillow which resulted in their head over the back of the pillow with their neck hyperextended.

**Rolling off product into hazardous setting-** HS staff identified 14 fatal incidents (18%) not associated with the bedsharing incidents described above where the infant rolled or slid off the infant pillow into a hazardous environment, such as wedge entrapment hazard or soft bedding hazard. Several incidents involved the victim using the infant pillow on an adult bed, rolling off the infant pillow and becoming wedged between parts of an adult bed or wedged between the adult bed and a wall; other wedging incidents resulted from the victim using the infant pillow in an infant sleep product such as a crib, bassinet, or play yard, rolling off the infant pillow and becoming wedged between the infant pillow and the side of the infant sleep product. In other incidents, the victims rolled off infant support cushions face down onto soft bedding that was placed in the sleep setting; in two incidents involving soft bedding the victims slid off the infant support cushions and remained supine (face up) but were suffocated by adult pillows placed in the sleep setting that covered the victims' nose and mouth.

## V. Contractor Report

In September 2020, Commission staff awarded a contract to Boise State University (BSU) for infant biomechanics and suffocation research and consultancy services.<sup>8</sup> One task order under this contract was for research on pillows intended for infant care and use and included an analysis of the risk of injury or death to infants associated with the use of infant pillows, including nursing pillows and other types of pillows marketed as aiding infants during activities such as feeding, nursing, sleeping, propping, and lounging.<sup>9</sup> On June 30, 2022, BSU delivered their final report which included development and testing on an appropriate test probe and performance requirements recommendations for infant pillows<sup>10</sup>.

### A. Test probe development

BSU compared the effectiveness of 11 different probes for potential use in implementing their recommended performance requirements. The goal of this probe development process was to

<sup>8</sup> Contract No. 61320620D0002. The key personnel for performance under this contract are Dr. Erin M. Mannen, Ph.D. (Principal Investigator), and Dr. John Carroll, MD (Co-Investigator).

<sup>9</sup> Task Order No. 61320621F1015.

<sup>10</sup> [Pillows Product Characterization and Testing | CPSC.gov](https://www.cpsc.gov/Document-Details/61320621F1015)

identify a probe that could produce consistent and accurate airflow measurements. The probes ranged in complexity from simple disc probes to different sized hemispheric probes, to probes modeled on an infant's airway. Ultimately BSU recommended a 3-inch hemispheric probe, because it was geometrically similar to an infant's face, relatively easier to manufacture, and produced air flow rates that were consistent with physiological values reported in previous infant research. Although selection of the appropriate probe was based mainly on its airflow measurements, BSU determined that this probe was also appropriate for firmness testing.

## **B. Firmness testing**

Based on its characteristics, described above, BSU recommended that all infant pillows be tested for firmness using the 3-inch hemispheric probe. The recommended test involves using the probe in three different locations: the location of maximum thickness, the location of minimum thickness, and a subjective location of interest (*i.e.*, another soft location that seems most likely to result in failure). At each location the probe is lowered onto the product and displaces the product surface by 1 inch; the resulting force measured from this displacement must exceed 10 Newtons (N) (which is approximately 2.25 pounds force). This requirement is consistent with the firmness requirement currently applicable to crib mattresses<sup>11</sup> in order to reduce a suffocation hazard. BSU tested 13 infant pillow products using this recommended firmness performance test, and none of them exceeded 10 N (2.25 pounds) force to cause a 1-inch displacement on any of the three locations tested. Thus, each pillow failed to meet this proposed requirement.

## **C. Other Recommended Requirements**

In their final report, BSU also discussed requirements for airflow testing, and sagittal-plane<sup>12</sup> testing for infant pillows. BSU developed an airflow test that would determine whether a product had airflow characteristics comparable to mesh crib liners, however BSU suggested that this test should not be required if a product passes BSU's recommended firmness test. BSU also developed a novel multi-hinged sagittal-plane testing device, which they determined provides a better visual representation of infants positioning on an infant pillow than a single-hinged gauge testing fixture; however, consistent placement of the sagittal plane testing device was a concern, and BSU concluded that further research was needed to determine appropriate worst-case positioning of the testing device.

## **VI. International Standards for Infant Pillows**

Other than CPSC's Infant Pillow Ban under the FHSA discussed above, the only other current standards that address infant pillows are the following British Standards:

<sup>11</sup> BSU found that sample crib mattresses tested using the hemispheric probe required more than 10 N (2.25 pounds) to displace the probe 1 inch. A force of 10 N also approximates the weight of an infant's head.

<sup>12</sup> The sagittal plane is the plane that runs lengthwise the body, dividing it into right and left.

- **BS 1877-8:1974, Specification for domestic bedding —Part 8: pillows and bolsters for domestic use (excluding cellular rubber pillows and bolsters)**
- **BS 4578:1970, Specification for methods of test for hardness of, and for air flow through, infants' pillows**

The scope of BS 1877-8:1974 includes both adult pillows and cot pillows (infant pillows) and recommends that cot pillows be filled firmly enough to prevent infants' heads from sinking into the products and that the pillow covering not be loose enough to be drawn into the infant's mouth. BS 1877-8:1974 has requirements for cot pillow size, filling, and covering. Cot pillows must be 58 x 38 cm (23 x 15 inches) and filled with curled hair, and their covering must be of open construction to allow air permeability. Both the filling and covering must meet performance requirements described in BS 4578:1970 for hardness and air permeability.

BS 4578:1970 sets out performance requirements for hardness and air permeability in addition to describing how to wash those pillows. The hardness test requires that a 100mm diameter probe be placed in the center of the product with 10N of force for 1 minute. BS 1877-8:1974 requires that displacement of the pillow when the force is applied shall not exceed 25% of the thickness. Staff's concern with this requirement is that the proportional approach used in this requirement allows thicker pillows to have a greater displacement than thinner pillows.

## **VII. Draft ASTM Voluntary Standard for Infant Loungers**

No published voluntary standards in the U.S. cover infant support cushions; however, ASTM is in the process of developing a voluntary standard for "Infant Loungers" under Subcommittee F15.21 on Infant Carriers, Bouncers, and Baby Swings. The working definition of infant loungers is that they are products "with a raised perimeter, a recess, or other area that is intended to be placed on the floor and to provide a place for an infant to sit, lie, recline, or rest, while supervised by an adult". As such, it would be a subset of the products covered by this proposed rule, which also includes infant positioners, nursing products with dual use for lounging, infant loungers, infant cushions, and other infant pillow-like products. On May 2, 2023, the Subcommittee discussed the draft standard for infant loungers, but so far, ASTM has not issued a ballot on the draft standard for Infant Loungers. CPSC staff has been working with ASTM to develop performance requirements intended to address the primary hazards associated with infant loungers.

ASTM's draft voluntary standard includes general requirements typically found in other ASTM juvenile product standards, such as requirements related to hazardous sharp edges or points, small parts, lead in paints, resistance to collapse, scissoring shearing and pinching, openings, protective components, toys accessories that are attached to, removable from, or sold with the products, and the permanency of labels and warnings, as well as the requirement that if the lounger can be converted to another product it shall comply with the applicable requirements of that product's standard. The general requirements of the draft infant lounger standard also state that the sidewall height of the product shall be less than 4 inches when measured according to the sidewall height measurement test method.

The draft voluntary standard also includes the following performance requirements:

- *Stability*: This requirement states that the product shall not tip over and shall retain the CAMI dummy when tested in all manufacturers use positions.
- *Infant Restraints*: This requirement states the product shall not have a restraint system.
- *Fabric/Mesh Integrity*: This requirement is intended to address product integrity issues such as seam failures and material breakage.
- *Bounded openings*<sup>13</sup>: This requirement is intended to address potential entrapment hazards.
- *Occupant Support Surface*: This requirement is intended to address the thickness, dimensions, and potential gaps of the occupant support surface.
- *Occupant Support Surface Firmness*: This requirement uses an 8-inch diameter “Firmometer” probe<sup>14</sup> and requires that there shall be no point where the feeler arm, which hangs over the edge of the disc, comes in contact with the occupant support surface.
- *Sidewall Firmness*: This requirement states that the top of the sides of the product cannot be displaced more than 1-inch when a 3-inch diameter hemispheric probe is applied to the product with a 10N of force.
- *Side Angle and Deflection*: This requirement states that the angle between the sidewall and the occupant support surface shall be greater than 90 degrees; this requirement is intended to address potential entrapment hazards at the intersection of the side wall and occupant support surface.

The draft voluntary standard also includes marking and labeling and instructional literature requirements. The marking and labeling requirements include requirements for warnings that must appear on infant loungers covered by the standard, that address hazards associated with infant loungers such as warning the consumer about using the product for sleep or naps, only using with an awake baby, only using when baby is supervised, only using the product on the floor, keeping soft bedding out of the product, not using the product on raised surfaces, and not using the product to carry or move an infant while in the product. The draft standard requires the warnings to be “permanent” and “conspicuous.”

In addition, the draft voluntary standard provides requirements for instructional literature to accompany products covered by the standard. These requirements state that the instructional literature that accompanies infant loungers must include warnings on the product, as well as the following additional warnings:

- Read all instructions before using this product.
- Keep instructions for future use.
- Do not use this product if it is damaged or broken.

---

<sup>13</sup> A completely bounded opening is defined as opening that exists due to the design of the product or created by accessory attached to the product that does not have any breaks in the perimeter of the opening.

<sup>14</sup> A Firmometer probe is a device that consists of a circular disk of a certain size and weight, with an attached “feeler arm” that extends over the edge of the disk.

The instructions also must indicate the manufacturer's recommended maximum weight, height, age, developmental level, or combination thereof, of the infant. If the product is not intended for use by a child for a specific reason, the instructions must state that limitation.

## VIII. Staff's Proposed Rule

Although CPSC staff has worked closely with ASTM in the development of the loungers requirements in the standard discussed above and drawn extensively from this work to develop requirements for infant support cushions, to protect against hazard patterns observed with incidents involving infant support cushions, staff determined that additions and modifications to the draft lounger standard were warranted.

### A. Scope and definition

Based on the incident data and hazards associated with infant support cushions, staff recommends the following scope and definition:

This consumer product safety standard prescribes requirements to reduce the risk of death and injury from hazards associated with *infant support cushions*. This includes but is not limited to *infant positioners*, *nursing products* with a dual use for lounging, *infant loungers*, and infant props or cushions used to support an infant.

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

### B. General Requirements

Staff concludes that the general requirements included in the draft ASTM voluntary standard for infant loungers such as requirements related to hazardous sharp edges or points, small parts, lead in paints, resistance to collapse, scissoring shearing and pinching, openings, protective components, toy accessories that are attached to, removable from, or sold with the products, and the permanency of labels and warnings, as well as the requirement that if the lounger can be converted to another product it shall comply with the applicable requirements of that product's standard, would also be necessary for infant support cushions, apart from the sidewall height requirement which staff addresses in a different manner. The ASTM infant loungers draft voluntary standard allows a maximum sidewall height of 4 inches for infant loungers, however CPSC staff is concerned that this side height might give consumers the impression that the infant support cushion is intended to safely contain the infant occupant. The draft proposed rule addresses hazards associated with infant support cushion products that do not provide sleeping accommodations and are not intended to or do not safely contain the infant user of the product. CPSC staff has developed proposed performance requirements for the maximum incline angle discussed below to address positional asphyxia concerns. These requirements would effectively limit the side height of infant support cushion products (because due to geometry, it would be difficult for a lounger with high sidewalls over 2 inches to meet the incline angle

requirement), but it does not specify a maximum side height. CPSC staff recommend that the Commission invite comments from the public on what is an appropriate side height that would not give the consumer the impression that an infant support cushion is intended to safely contain the infant and whether these incline angle requirements provide sufficient protection.

The General Requirements in ASTM's draft lounge standard include warning label permanence requirements that are consistent with other ASTM juvenile product standards. However, staff also recommends that the draft proposed rule include an additional warning-permanency requirement that would address so-called "free-hanging" labels; that is, labels that attach to the product at only one end of the label. Warning labels that are attached in that way are more likely to be torn or ripped off, or otherwise altered by the consumer, which eliminates the potential safety benefit of the warning for future users of the product. Thus, staff recommends that the draft proposed rule include the following additional requirement.

Warning labels that are attached to the fabric of infant support cushions with seams shall remain in contact with the fabric around the entire perimeter of the label, when the product is in all manufacturer-recommended use positions, when subjected to a 15-lbf (67N) pull force applied in any direction using a 3/4-in diameter clamp surface.

### **C. Performance requirements**

CPSC staff assessed that the draft requirements in the ASTM lounge standard for restraints, seam strength, and bounded openings are appropriate for the infant support cushion standard. ASTM draft requirements for restraints would not allow an infant support cushion to have a restraint system which could potentially pose an entanglement/strangulation hazard. Because infant support cushions are not intended to safely contain the infant, not allowing restraints is consistent with this intended purpose and staff finds the requirement necessary to prevent entanglement/strangulation hazards. The seam strength requirement ensures that all the seams of the infant support cushion bear the weight of the occupant, which is appropriate for infant support cushions that are intended to support the body or even a part of the infant's body. The bounded opening requirements ensure that any bounded opening in the product does not pose a head entrapment hazard; infant support cushions range in a variety of shape and sizes and some may include openings, so it is appropriate for infant support cushions to have this requirement.

In addition to incorporating these performance standards from ASTM's infant lounge draft standard, the draft proposed rule includes additional performance standards intended to address the specific safety hazards staff have found particular infant support cushion products to pose. Tab C discusses the extensive research and testing on infant pillow products by the staff of CPSC's Directorate for Laboratory Sciences, Division of Mechanical Engineering (LSM), to develop performance requirements for infant support cushions. These proposed requirements are as follows:

## i. Firmness

Staff developed firmness requirements differing from those in the ASTM draft Lounger standard. Staff proposes firmness requirements and associated test methods that are consistent with crib mattresses firmness requirements summarized below and described in greater detail in Tab C, which staff finds necessary for safety based on the work of BSU<sup>8</sup> and to address the incidents and hazard patterns described above with facial occlusion into infant support cushions:

### *Occupant Support Surface (OSS) Firmness*

Staff recommends an OSS firmness requirement that the OSS of any infant pillow must require more than 10 N force to deflect one inch with a 3-inch hemispheric probe following staff's recommended test procedure. In the ASTM draft lounger standard, the 8-inch firmometer probe is used for the OSS firmness requirement; however, CPSC staff has concerns about the accuracy of using this probe to measure the firmness of the OSS. Due to the variety of infant pillow styles, LSM staff observed that in some of support cushions tested, the OSS was more curved than horizontal, had button-like stitching that made the OSS irregular, or had a thin and flexible OSS that would make consistent positioning of the firmometer difficult. In addition, LSM staff noted that some infant support cushions have smaller OSS dimensions, in which ASTM's large 8-inch disc firmometer would not fit well enough to provide accurate measurement, and the large size of the firmometer probe could possibly mask OSS features that could potentially pose a suffocation hazard. Staff recommends the OSS firmness requirement for the NPR use the 3-inch hemispheric probe developed by BSU as described above, because the size and dimensions of this probe are more anthropometrically consistent with the size and dimensions of an infant's head, as compared to the 8-inch diameter firmometer, and the BSU-developed probe can more accurately detect the types of material deformations and surface features that an infant's face may come in contact with while on the infant support cushion.

To simplify and clarify test methods and to improve upon the ASTM test methodology, staff also recommends: (1) to conduct tests and measurements of loungers/support cushions vertically if the OSS is on average within 10 degrees of horizontal, and conduct tests and measurements perpendicular to the OSS if the OSS is tilted at an angle equal to or greater than 10 degrees (so that probe is always at a 90 degree angle to the OSS) ; and (2) to establish a vertical reference to the side of the 3-in probe and a horizontal reference to the top of that probe. Once the infant support cushion has been prepared for firmness testing, staff recommends performing the OSS firmness test both at the location of maximum OSS thickness and also at a location most likely to fail, using the following test procedure:

- a. Using a lead screw or similar device to control movement, advance the probe onto the product and set the deflection to 0.0 in when a force of 0.1 N (0.022 lb) force is reached.
- b. Continue to advance the head probe into the product at a rate not to exceed 0.1 in (0.25 cm) per second and pause when the force exceeds 10 N (2.2 lb), or the deflection is equal to 1.0 in (2.54 cm).

- c. After a 30 second pause, if the force is equal to or less than 10 N (2.2 lb) and the deflection is less than 1.0 in (2.54 cm), the probe shall be advanced further in a similar manner,
- d. Record the final force and deflection when the deflection has reached 1.0 in (2.54 cm) or when the force has exceeded 10 N (2.2 lb).
- e. If the maximum thickness of the OSS is equal to or greater than 1.0 in (2.54 cm), perform additional tests at the geometric center of the OSS and at four locations along the product's longitudinal and lateral axes therefrom, 1.5 in (3.8 cm) towards center from the intersection of the sidewall and OSS.

### *Sidewall Firmness*

For the sidewall firmness test, ASTM uses the 3-inch hemispheric probe developed by BSU to apply a force of 10N downwards on top of the side wall and requires that the product may not deflect 1 inch or greater under this force. This test method is similar to the one developed for firmness by BSU, and the OSS firmness test recommended by LSM staff above, because the force required for a 1-inch displacement should be greater than 10N to pass the firmness test. However, staff concludes ASTM's draft sidewall firmness test is not as accurate in measuring firmness as the test proposed in this rule. The ASTM method is the inverse of the staff proposed method; the ASTM test applies a fixed force and measures the deflection that force causes, while the staff proposed method applies force until a fixed deflection is achieved and measures the force required to reach the specified deflection, which results in a product firmness that is comparable to crib mattresses, and reduces the likelihood that the sidewalls of infant support cushions conform to infant's face and pose a suffocation hazard.

LSM staff does not consider the ASTM test requirement compatible with staff proposed test requirements. ASTM does not describe how the force is applied, and the force driving deflection method (ASTM) is not the same as deflection driving force (staff proposed) because the staff proposed test method requires a time delay before measuring deflection. A time delay is essential to allow the filling material of the infant pillow to adjust to the applied force, i.e., force decay, and relax to a stable reading, which increases the repeatability of the test method. Staff recommends for infant support cushions with sidewalls, the staff proposed test method because it accounts for the downward decay of test forces and enables precise control of deflection. After performing the OSS firmness test, LSM staff recommends also performing the sidewall surface firmness test a minimum of four times starting at the location of maximum sidewall height, and along the entire perimeter of the sidewall located at intervals not to exceed 6 in., including an additional test at a location most likely to fail using the procedure steps a. to d. from the OSS firmness test.

### *Intersection of Sidewall and Occupant Support Surface Firmness*

Staff recommends, for infant support cushions with sidewalls, consistent with the firmness requirements for OSS and for sidewall, that the force required for a 1.0-inch displacement at the intersection of the sidewall and OSS must be greater than 10N which is the force exerted by crib mattresses in firmness tests, when a 3-in (7.62 cm) diameter hemispheric probe is directed

at an angle to that intersection that bisects the angle between the OSS and the sidewall. A minimum of four sidewall firmness tests should be conducted, and at intervals not to exceed 6 in, to account for the various sizes of infant's heads that could encounter this area. In addition, staff recommends that the test locations include at least one location most likely to fail.

LSM staff observed that for some infant support cushions the intersection of the sidewall and the OSS had clear transition from the OSS to the sidewall with distinctive angle changes; however, in other infant support cushions tested the transition between the OSS and sidewall was more curved and not easily discerned especially for infant support cushions that had a more recessed OSS with a thicker outside perimeter. Despite the potential challenge to consistently determine a definitive intersection between the OSS and the sidewall, staff determined that having a firmness requirement at this intersection is appropriate for infant support cushions, because in addition to the firmness of the two mating surfaces, a firmness requirement at the intersection also addresses hazards of suffocation in product areas or configurations where parts join, sharply transition, or overlay other parts and that form internal or concave surfaces in which the face of the infant can contact simultaneously.

## **ii. Sidewall angle**

In the draft ASTM lounger standard, ASTM requires that the angle between the sidewall and the occupant support surface (OSS) be greater than 90 degrees to reduce potential entrapment hazards that could occur in these areas. The angle is measured with a protractor, or similar tool, every 4 in (10 cm) along the interior of the product. As discussed above, the OSS for infant support cushions is generally an irregular surface, making it challenging as an angular reference. Staff finds that for support cushions with a sidewall, a requirement of sidewall angle greater than 90 degrees is necessary to protect against entrapment of the infant between the sidewall and the OSS. In addition, staff recommends the 90-degree angle requirement for the sidewall be assessed with the cylindrical side of the 3-in probe, applied with a 10 N (2.2 lb) force and placed with the probe side tangent to the intersection of sidewall and OSS. Contact with the probe side by the product sidewall will constitute an angle equal to or less than 90 degrees and no contact will signify an angle greater than 90 degrees. Sidewall angle measurements should be taken, starting at the location of maximum sidewall height, and at intervals not to exceed 6 in (15.2 cm). to account for the various sizes of infant's heads that could encounter this area.

## **iii. Maximum Incline Angle**

In the draft ASTM lounger standard, ASTM proposes a requirement for "Maximum Seat Back Angle," which states that the angle of the seat back along the head-to-toe axis relative to the horizontal shall not exceed 10 degrees when tested with the infant hinged weight gauge.<sup>15</sup> The infant hinged weight gauge is positioned with the hinge aligned over the seat bight line<sup>16</sup> and

<sup>15</sup> A two-part, hinged, metal gauge to represent the approximate form and weight of an infant when lying prone or supine. This gauge is used in several ASTM infant safety standards.

<sup>16</sup> Seat bight: The intersection between the seat or occupant support surface and seatback or sidewall.

with the upper torso/head plate of the gauge on the seat back. The angle is measured with a digital protractor resting on the upper gauge area. Staff recommends that infant support cushions should have a maximum incline angle that shall not exceed 10 degrees, as in the CPSC infant sleep product rule<sup>17</sup>, the Safe Sleep for Babies Act, and based on addressing the hazards identified for inclined sleep products. However, staff recommends several modifications to the maximum incline angle requirements and test procedures in ASTM's proposed testing protocol to improve test consistency across all infant support cushion products and to address additional locations of potential inclined sleep.

The first modification is to apply the maximum seat back angle requirement not only to all of a manufacturer's recommended use positions, but also to all other infant cushion surfaces that can feasibly support an infant's head (OSS-head), including the angle from the sidewall (if present) to the OSS or from the OSS-head to the floor when no elevated sidewall is present or from sidewall to floor when an elevated sidewall is present, see figure 9 Tab C.

The second modification is to use a newborn hinged weight gauge. This newborn gauge is lighter than the infant counterpart and presents a worse-case scenario since the lighter newborn gauge would deflect less, creating more of a seat back angle, and consumers foreseeably would use infant products for newborns.

The third modification is a change to the placement of the gauge throughout testing. The torso/head portion of the gauge should, at times, be positioned so that it rests against the top surface of the product, with the top edge of the torso/head portion positioned plumb with the outer edge of the product, even if this positioning causes the hinge of the gauge to not align with the bight line of the product. It is staff's preliminary determination that these recommendations for positioning and using the newborn hinged weight gauge and the resulting maximum incline angle measurement better represents the positioning on or in the product for the youngest occupant. These recommended modifications of the maximum seat back angle requirement would also limit the heights of OSS-head surfaces for loungers and infant support cushions, which addresses staff's concern that higher sidewall heights give the consumer the impression the infant support cushion could safely contain an infant as discussed above. Also, the floor to OSS surface and floor to sidewall angle requirement protect against inclined sleep from the angle created by having an infant's head on the side of the pillow and body on the floor and limit the height of the side of the pillow, to address incidents and hazard patterns described above of positional asphyxia seen with support cushions (including loungers) used together with other sleep products.

## **D. Warning and Instructional Literature Requirements**

### **i. Marking and Labeling**

The draft ASTM voluntary standard for infant loungers includes marking and labeling requirements, which include requirements for warnings that must appear on infant loungers. CPSC staff worked with the ASTM infant lounger's subcommittee to develop the on-product warning requirements, which address the primary hazards associated with infant loungers, with particular emphasis on the potentially deadly consequences of using these products for sleep or naps. As staff of CPSC's Directorate for Engineering Sciences, Division of Human Factors

<sup>17</sup> <https://www.cpsc.gov/s3fs-public/Final-Rule-Safety-Standard-for-Infant-Sleep-Products.pdf>

(ESHF) discusses in Tab D, infant support cushions under the scope of this rule would also be expected to meet this requirement.

The ASTM draft lounger standard has accepted staff's recommendations for defining "conspicuous" as staff has in the draft proposed rule:

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

This definition allows for consumers using the infant support cushion from any position to visibly see the warning label.

The ASTM draft lounger standard also requires the warnings to be "permanent" and includes permanence requirements among the General Requirements for infant loungers. In Tab D, staff also discusses a recommended additional permanence requirement to reduce the potential for the warnings to be torn, ripped, or cut off.

## ii. Instructional Literature

The ASTM draft lounger standard includes requirements for instructional literature to accompany loungers. These requirements are based on the ASTM Ad Hoc Language Task Group recommended requirements for instructional literature and for the formatting of warnings in instructional literature, and CPSC staff worked with the ASTM Ad Hoc Language Task Group to develop these requirements. Thus, staff recommends adopting consistent instructional literature requirements in the draft proposed rule for infant support cushions.

## IX. Potential Small Business Impact

As staff of CPSC's Directorate of Economics (EC) discusses in its Tab E initial regulatory flexibility analysis pursuant to the Regulatory Flexibility Act, the draft proposed rule is expected to have a significant impact on a substantial number of small entities because currently there is no mandatory or voluntary performance standard for infant support cushions, therefore all the proposed requirements would be new for any small business in this market.

There are more than 2,000 suppliers, i.e., manufacturers, importers, and foreign direct shippers of infant support cushions to the U.S. market. Based on the U.S. Small Business Administration (SBA) size standards, most of these suppliers qualify as small. Most products on the market will require redesign to meet the requirements in the draft proposed rule. Staff considers one percent of annual revenue to be a "significant" economic impact on a company, consistent with regulatory flexibility analyses conducted by other federal government agencies. The cost of redesign and testing is likely to be significant for a substantial number of small U.S. firms, including small manufacturers and small importers. Small home crafters are a subset of small manufacturers; they will likely be significantly impacted by this rule.

Manufacturers of infant support cushions would be required to comply with the standards of this draft proposed rule and demonstrate this compliance through third-party testing. As specified in

16 C.F.R. part 1109, entities that are not manufacturers of children's products, such as importers and wholesalers, may rely on the certificate of compliance provided by others. Staff assumes that manufacturers will pass on at least some of the cost of testing for compliance to importers and wholesalers. Third-party testing will be a new cost for all suppliers, because infant support cushions are not currently required to be third-party tested. The performance requirements in this draft proposed rule require that products meet certain firmness criteria and incline requirements. While any product in scope of this rule could in theory be redesigned to meet the performance requirements in this rule, some suppliers may decide to remove their products from the market rather than redesign because they anticipate that there may not be a sufficient market for their redesigned products. In terms of small businesses, the impact of removing the product from the market instead of redesigning it could be significant as a result of a potentially large volume of lost sales.

The labeling and instructions requirements constitute a burden under the Paperwork Reduction Act. CPSC staff will submit an Information Collection Request to the Office of Management and Budget of the Executive Office of the President (OMB) for their approval and obtain an OMB control number for this information collection. Certificates of Conformance are already required for all children's products under OMB Control Number 3041-0159 and are not a new requirement of this NPR.

## **X. Compliance Recall Information**

Staff of CPSC's Office of Compliance (EXC) has not identified any recalls involving infant support cushions that are not intended to provide a sleeping accommodation, from January 1, 2010, through December 31, 2022.

## **XI. Product Registration Rule Amendment**

In addition to requiring the Commission to issue safety standards for durable infant or toddler products, section 104 of the CPSIA directed the Commission to issue a rule requiring that manufacturers of durable infant or toddler products establish a program for consumer registration of those products. Section 104(f) of the CPSIA defines the phrase "durable infant or toddler product" and lists examples of such products.

In 2009, the Commission issued a rule, commonly known as the product registration card rule, implementing product registration as section 104 required (16 C.F.R. part 1130). As part of that rule, the Commission added six products—children's folding chairs, changing tables, infant bouncers, infant bathtubs, bed rails, and infant slings—to the list of durable infant or toddler products that the CPSIA specifically identified.

Staff's draft proposed rule would add "infant support cushions" to the list of durable infant or toddler products requiring registration under section 104(b) of the CPSIA. Infant support cushions are a durable infant or toddler product because they are not disposable and have a useful life of up to a few years and are similar to other durable nursery products including crib mattresses and sling carriers, and because they are primarily intended to be used by children five years old or younger, and in this case, 12 months old or younger.

## **XII. Notice of Requirements**

Section 14(a) of the Consumer Product Safety Act (CPSA) requires that any children's product subject to a consumer product safety rule under the CPSA must be certified as complying with all applicable CPSC-enforced requirements. The children's product certification must be based on testing conducted by a CPSC-accepted third party conformity assessment body (test laboratory). The CPSA requires the Commission to publish a notice of requirements (NOR) for the accreditation of third-party test laboratories to determine compliance with a children's product safety rule. This proposed rule for infant support cushions, if issued as a final rule, would be a children's product safety rule that requires issuing an NOR.

The Commission rule, *Requirements Pertaining to Third Party Conformity Assessment Bodies*, 16 C.F.R. part 1112 establishes the requirements for accreditation of third-party testing laboratories to test for compliance with a children's product safety rule. The part 1112 rule also codifies all the NORs that the CPSC has published to date for children's product safety rules. All new children's product safety rules, such as the proposed rule for infant support cushions, would require an amendment to Part 1112 to create an NOR. Therefore, staff recommends that the Commission propose to amend Part 1112 to include infant support cushions in the list of children's product safety rules for which the CPSC has issued NORs.

As discussed in Tab E, EC staff concludes that there should be no adverse impact on testing laboratories as a result of the proposed rule. There are no new complex testing instruments, devices, or procedures that are required to test infant support cushions for compliance to this draft proposed rule. The testing devices include a probe, a distance measurement device, a force gauge, a hinged weight gauge, and a frame to hold the product and testing devices in place. Testing laboratories are not required to provide these testing services; only those laboratories that make the business decision to provide such services, based on expected demand for their services, will need to procure the testing devices and apply for CPSC-acceptance of their ISO accreditation.

For the same reasons, revising the NOR to add infant support cushions to the list of products subject to part 1112 would not have a significant adverse impact on small laboratories. Most laboratories are not small U.S. businesses. Companies in the lab testing industry include companies with hundreds of locations, including labs in Asia and Europe, and thousands of employees. Thus, the Commission could certify that the NOR for the infant pillow mandatory standard will not have a significant impact on a substantial number of small laboratories.

## **XIII. Recommended Effective Date**

The Administrative Procedure Act (APA) generally requires that the effective date of a rule be at least 30 days after publication of the final rule (5 U.S.C § 553(d)). Staff recommends a 180-day, or approximately 6-month, effective date. Staff generally considers 6 months to be sufficient time for laboratories to apply for accreditation for the proposed standard and suppliers to come into compliance with the proposed standard, and this amount of time is typical for other CPSIA section 104 rules. Six months is also the period that JPMA typically allows for products in their certification program to shift to a new standard once that new standard is published. Therefore,

juvenile product manufacturers are accustomed to adjusting to new standards within this time. A significantly earlier effective date could potentially result in shortages due to testing logistics, while a longer effective date could reduce the burden on small businesses to redesign their products quickly but would delay the safety benefits of the rule. Staff invites comments, particularly from small businesses, regarding the amount of time they will need to come into compliance.

#### **XIV. Staff Conclusion and Recommendations**

Staff recommends that the Commission issue the draft proposed rule for infant support cushions that includes the requirements discussed in Section VIII, which are provided in detail in Tab F and summarized as follows:

- General requirements and associated test methods that are consistent with the draft voluntary standard for infant loungers, with the exception of a maximum side height requirement, and with an additional warning permanence requirement to prevent “free-hanging” labels.
- Performance requirements and associated test methods that:
  - Add firmness requirements that apply to all surfaces that an infant may be exposed to while using the product, e.g., occupant support surface, sidewall, and the intersection of the sidewall and occupant support surface.
  - Add a side angle requirement to reduce potential entrapment hazards between the sidewall and occupant support surface.
  - Add a maximum incline angle requirement that will: (1) effectively limit the height of the sidewalls, discouraging the impression that the product can safely contain an infant; and (2) protect against unsafe sleep angles when the infant is within the product and when the infant’s head is elevated onto the side of the product while the infant’s body is on the floor.
- Warning and instructional requirements that include a strongly worded and conspicuous on-product warning.

Staff also recommends an effective date of 180 days after publication of the final rule to allow manufacturers to bring their products into compliance and to arrange for third party testing. Before labs can provide third party testing to verify conformity with the final rule, they will need to become ISO accredited to perform testing to the new standard and then apply to CPSC for acceptance of their accreditation for this rule. The draft proposed rule provided with this briefing package includes these recommended provisions.

## **TAB A: Infant Support Cushion-Related Fatalities, Injuries, and Noninjury Incidents, 2010 – 2022**

Draft



# Memorandum

**TO:** Stefanie Marques, Infant Support Cushions Rulemaking Project Manager,  
Directorate for Health Sciences

**THROUGH:** Steve Hanway, Associate Executive Director,  
Directorate for Epidemiology

**FROM:** Blake Smith, Mathematical Statistician,  
Directorate for Epidemiology Division of Hazard Analysis

**SUBJECT:** Infant Support Cushion-Related Fatalities, Injuries and Noninjury Incidents 2010-2022

**DATE:** November 8,  
2023

## I. Introduction

This memorandum characterizes the reported fatalities and nonfatal incidents associated with infant support cushions received by CPSC staff. Staff reviewed incidents reported to have occurred between January 1, 2010, and December 31, 2022.

For the reported fatal and nonfatal incidents, staff extracted and analyzed data from both the Consumer Product Safety Risk Management System (CPSRMS)<sup>1</sup> as well as the National Electronic Injury Surveillance System (NEISS).<sup>2</sup> The number of emergency department (ED)-treated injuries reported through NEISS that were within the scope of this analysis did not meet the publication criteria.<sup>3</sup> As such, a separate national estimate of ED-treated injuries associated with infant support cushions is not presented in this memorandum. However, the NEISS injury cases have been combined with the anecdotal data from CPSRMS and are part of the analysis presented in this memorandum. The data presented in this memorandum represent the minimum number of incidents associated with infant support cushions within the scope of the NPR during the relevant time period.

## Incident Data

CPSC staff extracted data concerning incidents that occurred between January 1, 2010, and December 31, 2022, where the victim's age was 12 months or younger. The data extraction took place on January 3, 2023, from the CPSRMS and NEISS databases for the following 12 infant support cushion-related product codes<sup>4</sup>: 4050 (Pillows, excluding water pillows), 1513 (Playpens and play yards), 1529 (Portable cribs), 1537 (Bassinets or cradles), 1542 (baby

<sup>1</sup> CPSRMS is the epidemiological database that houses all anecdotal reports of incidents received by CPSC, external cause-based death certificates purchased by CPSC, all in-depth investigations of these anecdotal reports, as well as investigations of select NEISS injuries. Examples of documents in CPSRMS include hotline reports, Internet reports, news reports, medical examiner's reports, death certificates, retailer/manufacturer reports, and documents sent by state/local authorities, among others.

<sup>2</sup> Data from the NEISS is based on a nationally representative probability sample of about 100 hospitals in the United States and its territories. The NEISS data can be used to derive national estimates of emergency department-treated injuries associated with infant pillows.

<sup>3</sup> Reporting criteria for NEISS require that the estimated number of injuries be 1,200 or higher, the sample size be 20 or larger, and the coefficient of variation be less than 33 percent.

mattresses or pads), 1543 (Cribs), 1552 (Cribs, Nonportable or Not specified), 1545 (Cribs, Not specified), 4010 (Mattresses, not specified), 4082 (Toddler beds), 1562 (Other soft baby carriers), and 4002 (Bedding, not specified). Staff also separately extracted a generic code (9101) because the reports under code 9101 are not clerically coded, and the products are not clearly identified. Reports under these codes required staff to search the narrative text using specific keywords. Staff excluded all incidents occurring outside of the U.S. except for incidents occurring at U.S. military bases in foreign countries. To prevent any double counting, when multiple reports of the same incident were identified, staff consolidated and counted them as one incident.

CPSC staff then reviewed the data to ensure each product involved in an incident met the criteria of an infant support cushion as described in the draft proposed rule.<sup>5</sup> The emergency department treated injuries (NEISS) and non-fatal incidents (CPSRMS) were then combined to form one non-fatal incidents dataset. The same was done for emergency department fatalities (NEISS) and fatal incidents (CPSRMS) to form a fatalities dataset. CPSC staff removed any duplicate reports to avoid double counting.

Staff identified a total of 204 incidents associated with the use of infant support cushions in the CPSC epidemiological databases from January 1, 2010, through December 31, 2022. These included 79 fatal incidents and 125 non-fatal reports. The dispositions of the 125 non-fatal reports consisted of 22 emergency department-treated injuries, 3 hospital admissions, 1 victim leaving before being seen, 1 victim seen by a medical professional, 46 reports where no injury occurred, and 52 reports with either an unknown or unspecified disposition.

Given the anecdotal nature of CPSRMS, the data are not necessarily representative of incidents that have occurred throughout the nation, nor are they a complete count of every incident that has happened around the U.S. during the given timeframe. Instead, the reported incidents addressed in this memorandum represent a minimum for the number of incidents or fatalities that have occurred during the given timeframes.

In addition, because data collection is ongoing, CPSC may receive additional reports for the period covered in this memorandum in the future. As an incident is investigated and new information becomes available, or as other associated reports are received, the initial information is either corroborated or contradicted. If new information contradicts initial information, it may cause the currently reported incident numbers to change.

## II. Results

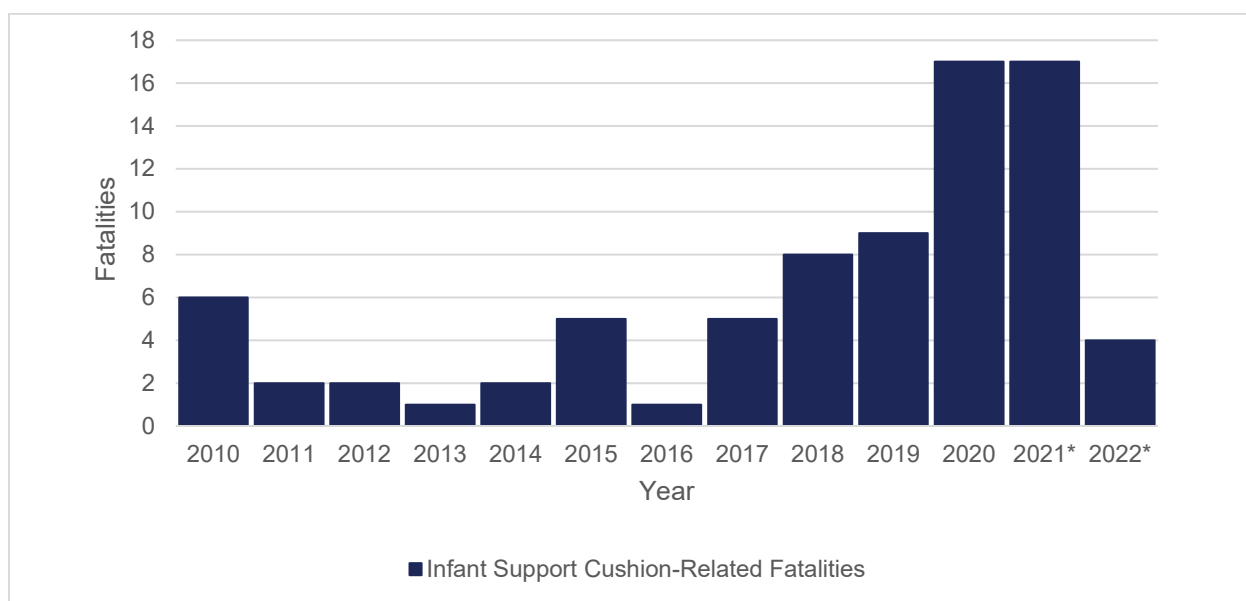
### Fatal Reports

CPSC staff is aware of 79 reported fatalities involving infant support cushions among children ages 12 months and younger. These deaths occurred between January 1, 2010, and December 31, 2022. Given the anecdotal nature and the ongoing reporting of the CPSRMS data, inferences based on year-over-year increases/decreases are discouraged.

---

<sup>5</sup> For CPSRMS incidents, staff relied on all available information, including product make/model, descriptions/pictures from in-depth investigations when available, to determine if an incident was in-scope. For NEISS incidents, staff mostly relied on the injury narrative for any description of the product to determine whether the report was in-scope.

Figure 1: Infant Support Cushion-Related Fatalities Reported by Year for Children 12 Months of Age or Younger: January 1, 2010–December 31, 2022.



Source: CPSRMS and NEISS databases.

Asterisks (\*) indicate that reporting is ongoing for CPSRMS; the years 2021–2022 are considered incomplete.

Among the fatalities with known gender, males accounted for 38 fatalities (48 percent of the total) and females also accounted for 38 fatalities (48 percent of the total). Three fatalities involved an unknown gender (4 percent of the total). Infant support cushion-related fatalities in the 0-3 months age range accounted for 81 percent of all fatalities with a known age. Table 2 summarizes the number of reported infant support cushion-related fatalities for victims 12 months and younger by age in months and by gender.

**Table 2: Infant Support Cushion-Related Fatalities for Victims Ages 12 Months and Younger by Age in Months and Gender: January 1, 2010–December 31, 2022**

Age (In Months)	Total (% of Total)	Male (% of Total)	Female (% of Total)	Unknown (% of Total)
Total	79 (100%)	38 (48%)	38 (48%)	3 (4%)
1	26 (33%)	12 (15%)	14 (18%)	0
2	19 (24%)	10 (13%)	9 (11%)	0
3	18 (23%)	8 (10%)	10 (13%)	0
4	7 (9%)	4 (5%)	3 (4%)	0
5	3 (4%)	1 (1%)	0	2 (3%)
6	1 (1%)	0	1 (1%)	0
7	2 (3%)	1 (1%)	1 (1%)	0
8	0	0	0	0
9	0	0	0	0
10	1 (1%)	1 (1%)	0	0
11	1 (1%)	1 (1%)	0	0
12	0	0	0	0

Unknown	1 (1%)	0	0	1 (1%)
---------	--------	---	---	--------

Source: CPSRMS and NEISS databases.

Percentages may not add to 100 due to rounding.

Reporting is ongoing for CPSRMS; the years 2021–2022 are considered incomplete.

Of the reported fatalities, 49 had an official cause of death as ruled by a Medical Examiner (ME) of asphyxia/probable asphyxia (62% of the total), 13 were determined to be sudden unexpected infant death (SUID) events (17% of the total), 12 had an undetermined cause of death (15% of the total), and the medical examiner's report was unavailable for 5 fatalities (6% of the total).

The scenario-specific information that indicated the placement of the decedents can be described as follows:

- 34 decedents were placed on infant support cushions in an adult-sized bed.
- 13 decedents were placed on an infant support cushion in a bassinet or bassinet portion of a play yard.
- 11 decedents were placed on an infant support cushion in a crib.
- 8 decedents were placed on an infant support cushion inside a play yard.
- 3 decedents were placed on an infant support cushion on top of a couch or futon.
- 4 decedents were placed on an infant support cushion on either a mat or on the floor.
- 1 decedent was placed on an infant support cushion inside a toddler bed.
- 1 decedent was placed on an infant support cushion in an air mattress.

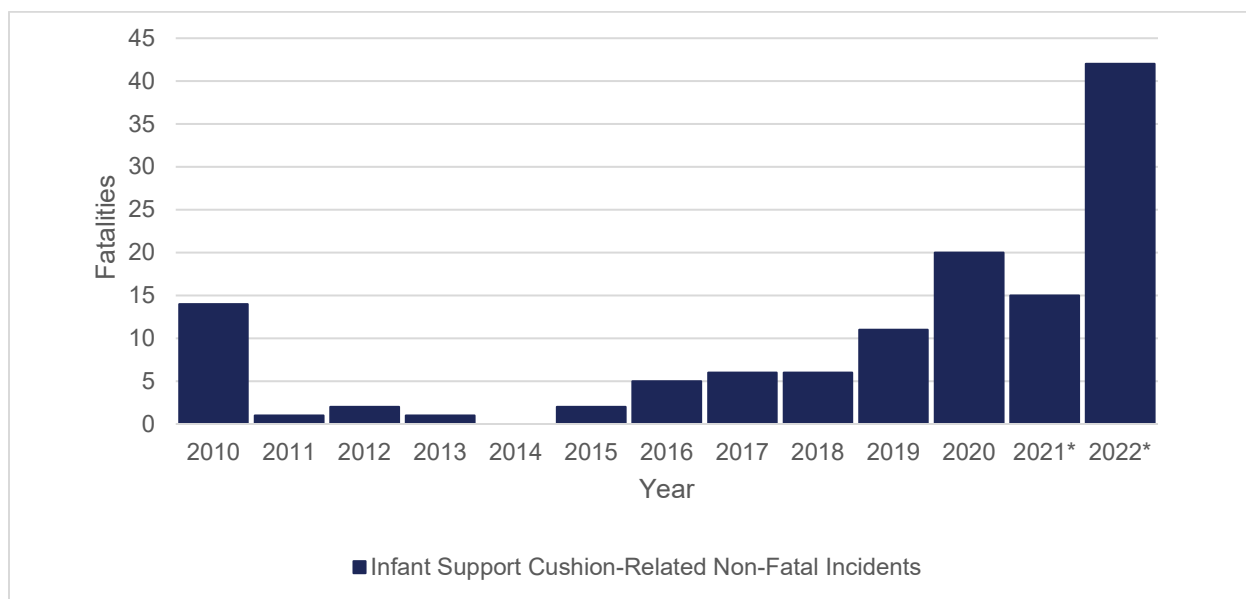
There were 4 fatalities for which the placement was either undetermined or unknown.

### Nonfatal Reports

CPSC staff identified 125 reported nonfatal infant support cushion-related reports for children ages 12 months and younger that occurred between January 1, 2010, and December 31, 2022.<sup>6</sup> Given the anecdotal nature and the ongoing reporting of the CPSRMS data, inferences based on year-over-year increases/decreases are discouraged.

<sup>6</sup> Nonfatal incident reports submitted to CPSC come from reports entered into CPSC's CPSRMS database no later than 1/3/2023 and include completed NEISS investigations. All of the investigation reports based on NEISS injuries that occurred from 2010-2022 appear in the reported nonfatal incidents.

Figure 2: Infant Support Cushion-Related Non-fatal Reports by Year for Children 12 Months of Age or Younger: January 1, 2010–December 31, 2022.



Source: CPSRMS and NEISS databases.

Asterisks (\*) indicate that reporting is ongoing for CPSRMS; the years 2021–2022 are considered incomplete.

Table 3 summarizes the number of reported non-fatal infant support cushion-related reports for victims 12 months and younger by month and gender. The reports in the non-fatal dataset are anecdotal and the reporting should be considered incomplete. Thus, the number of incidents identified should be considered a minimum.

**Table 3: Infant Support Cushion-Related Non-fatal Reports for Victims Ages 12 Months and Younger by Month and Gender: January 1, 2010–December 31, 2022**

Age Group (In Months)	Total (% of Total)	Male (% of Total)	Female (% of Total)	Unknown (% of Total)
Total	125 (100%)	27 (22%)	32 (26%)	66 (53%)
1	23 (18%)	10 (8%)	13 (10%)	0
2	12 (10%)	4 (3%)	6 (5%)	2 (2%)
3	5 (4%)	1 (1%)	3 (2%)	1 (1%)
4	8 (6%)	5 (4%)	3 (2%)	0
5	2 (2%)	1 (1%)	1 (1%)	0
6	3 (2%)	2 (2%)	1 (1%)	0
7	2 (2%)	0	2 (2%)	0
8	1 (1%)	0	1 (1%)	0
9	1 (1%)	0	1 (1%)	0
10	0	0	0	0
11	0	0	0	0
12	0	0	0	0
Unknown	68 (54%)	4 (3%)	1 (1%)	63 (50%)

Source: CPSRMS and NEISS databases.

Percentages may not add to 100 due to rounding.

*Reporting is ongoing for CPSRMS; the years 2021–2022 are considered incomplete.*

Table 4 provides a descriptive breakdown of the disposition of the infant support cushion-related non-fatal reports for Victims Ages 12 months and younger:

**Table 4: Infant Support Cushion-Related Nonfatal Reports by Severity for Victims Ages 12 Months and Younger: January 1, 2010–December 31, 2022**

Severity	Total Reports (% of Total)
<b>Total Non-Fatal Reports</b>	<b>125 (100%)</b>
Hospital Admissions	3 (2%)
Emergency Department Treated	22 (18%)
Left without being seen	1 (1%)
Seen by a Medical Professional	1 (1%)
Unspecified/Unknown	52 (42%)
No Injury	46 (37%)

*Source: CPSRMS and NEISS databases.*

*Percentages may not add to 100 due to rounding.*

*Reporting is ongoing for CPSRMS; the years 2021–2022 are considered incomplete.*

For the 46 reports that stated no injury occurred or provided no information about any injury, many of the descriptions indicated the potential for serious injury or even death.

Due to the self-reporting nature of the CPSRMS database, the descriptiveness and quality of incident narratives varied. Staff attempted to categorize the narratives to further analyze the reports. CPSC received 29 reports (23% of the total) of a victim being placed on various surfaces while on top of an infant support cushion and falling off, 27 reports involved a victim experiencing a scenario involving threatened asphyxia (22% of the total), and 17 reports that referenced a victim receiving various types of rashes from the product (14% of the total). Reports of limb entrapment, mold, choking, near strangulation, and vomiting all had one report each (1% of the total for each report). CPSC received 47 complaints (38% of the total) from consumers regarding infant support cushions in which no incident was clearly indicated. Table 5 illustrates the breakdown of non-fatal infant support cushion-related incidents by hazard pattern.

**Table 5: Infant Support Cushion-Related Non-Fatal Reports by Hazard Pattern for Victims Ages 12 months and Younger: January 1, 2010–December 31, 2022**

Event	Number of Non-Fatal Reports (% of Total)
	Children (0 to 12 Months)
Fall	29 (23%)
Threatened Asphyxia	27 (22%)
Rash	17 (14%)
Limb Entrapment	1 (1%)
Mold	1 (1%)
Choking	1 (1%)
Near Strangulation	1 (1%)
Vomiting	1 (1%)
Consumer Complaints	47 (38%)
<b>Total Non-Fatal Reports</b>	<b>125 (100%)</b>

Source: CPSRMS and NEISS databases.

Percentages may not add to 100 due to rounding.

Reporting is ongoing for CPSRMS; the years 2021–2022 are considered incomplete.

## **TAB B: Health Science Staff's Assessment on Infant Pillow-Related Deaths, Injuries, and Potential Injuries**



# Memorandum

**TO:** Stefanie Marques, Infant Support Cushions Rulemaking Project Manager,  
Directorate for Health Sciences

**DATE:** November 8, 2023

**THROUGH:** Mary Kelleher, Associate Executive Director  
Directorate for Health Sciences

**FROM:** Ashley Johnson, Ph.D., Physiologist  
Division of Pharmacology and Physiology Assessment,  
Directorate for Health Sciences

**SUBJECT:** Health Science Staff's Assessment on Infant Support Cushion-Related Deaths, Injuries, and Potential Injuries

## I. Introduction

In this memorandum, staff from the CPSC Directorate for Health Sciences (HS) provides an assessment and analysis on infant support cushion-related deaths, injuries, and potential injuries, including: a review of fatal and nonfatal incidents, the mechanisms and severity of injury associated with incidents, the hazard patterns associated with the use of infant support cushions, and a discussion of the most current medical literature pertaining to the pathophysiology of positional asphyxia.

## II. Discussion

Directorate for Epidemiology (EPA) staff conducted a search of CPSC databases<sup>1</sup> between January 1, 2010, and December 31, 2022, to identify incidents related to infant support cushions as defined in the draft proposed rule. This includes infant positioners, nursing products with dual use for lounging, infant loungers, and infant props or cushions marketed, designed, or intended to support an infant while reclining or lying in a supine, prone, or recumbent position. This does not include products intended to provide an infant sleep accommodation as defined by 16 C.F.R. part 1236 or products that exclusively support supervised nursing and feeding such as nursing products. Tab A contains information pertaining to data extraction criteria, scope of the data search, and tables/figures of reported fatal and nonfatal incidents (Smith, 2023). CPSC staff identified a total of 204 incidents associated with the use of infant support cushions. The data

---

<sup>1</sup> Data from NEISS are based on a nationally representative probability sample of approximately 100 hospitals in the United States and its territories. The NEISS reports capture one part of the treatment process (the emergency department visit), and typically do not show information on treatment after the initial visit.

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

included 79 reported fatal incidents and 125 reported nonfatal incidents, including 22 emergency department-treated injuries, 3 hospital admissions, 1 visit to a medical provider, 1 victim that visited an ER and left without being seen, 46 reports where no injury occurred, and 52 reports with either an unknown or unspecified disposition.

### *Nonfatal incidents/reports*

HS staff reviewed all 125 reported nonfatal incidents/reports associated with infant support cushions to identify the hazard patterns, including 22 emergency department-treated injuries, 3 hospital admissions, 1 visit to a medical provider, and 1 victim that visited an emergency department and left without being seen. The remaining 98 nonfatal incidents/reports either involved no injuries or the injuries and the level of care were not documented. The 125 nonfatal incidents/reports are further characterized in the epidemiology memorandum (Tab A, Smith, 2023). Products involved in nonfatal incidents/reports included loungers, large stuffed animal-shaped infant pillows, sleep positioners, wedges, tummy time pillows, and anti-flat head pillows. Where known, the average age of the infant was 2.7 months and at least 53 incidents/reports involved an infant under 6 months of age, a vulnerable age (see discussion below). Thirty-two (32) incidents/reports (26%) involved female victims, 27 incidents/reports (22%) involved male victims, and in 66 incidents/reports (53%) the gender was not known. Reports of nonfatal incidents/reports describe falls after being placed on infant support cushions (29 incidents, 23%); scenarios of threatened asphyxia after being placed on infant support cushions (27 incidents, 22%); various types of rashes received from infant support cushions (17 incidents, 14%); one report each (1%) of mold, choking, near strangulation, limb entrapment, and vomiting as a result of an infant pillow; and 47 consumer complaints (38%) about infant support cushions where no incident was clearly indicated.

Based on a review of nonfatal incident/report data, HS staff identified falls and threatened asphyxia as the two major nonfatal hazard patterns associated with infant support cushions.

- 1) *Falls*. Most reports did not specify the cause or manner of the fall, but infants and infant support cushions were placed on elevated surfaces in most fall incidents. These elevated surfaces included adult beds, bathroom and kitchen counters, chairs, tables (including kitchen tables, coffee tables, and side tables), and couches. In some incidents, infants were injured when they fell from the infant pillow onto the surface on which the pillow was placed. Injuries such as concussions, scalp injuries including hematomas and contusions, injuries to the face such as abrasions and lacerations, fractures, including skull fractures, and brain injuries can all result from falls.
- 2) *Threatened asphyxia*. The narratives describe scenarios of threatened asphyxia where victims were rescued after being found hanging partially off the infant pillow, completely off the infant pillow with mouth and nose obstructed, or with the infant's head wedged between the side cushions (in the case of sleep positioners). Infants were also found after sliding down into a vulnerable position on the infant pillow or after rolling to prone or unstable side positioning. Some narratives describe soft bedding, such as blankets and stuffed animals, that can be contributory causes to threatened asphyxia events.

Although most nonfatal incidents/reports did not report an injury, HS staff recognizes that infants placed on infant support cushions could potentially suffer injuries due to falls from elevated surfaces or injuries or death due to positional asphyxia/suffocation (see Discussion below).

## *Fatal Incidents*

HS staff reviewed all 79 reported fatal incidents to identify the hazard patterns and the causes of death associated with infant support cushions. HS considered all available source documents from Injury or Potential Injury Incident (IPII) reports or from In-Depth Investigations (IDI), where available, including death scene investigations, police department incident reports, medical examiner (ME) reports, narratives from caregivers and witnesses, and death certificates. The official cause of death in all the fatal incidents was reported as asphyxia/probable asphyxia (49 incidents, 62%), sudden unexpected infant death (SUID) events (13 incidents, 17%), undetermined (12 incidents, 15%), or the official cause of death was not available at the time of writing this memorandum (5 incidents, 6%).

Determining an exact cause of death is difficult and sometimes not possible with the available information because of the nature of unwitnessed infant deaths. Autopsy findings in cases of asphyxia are commonly minimal and nonspecific. Other causes of death (natural and unnatural) must be excluded. Thus, in the absence of decisive findings, the pathological diagnosis of a medical examiner can include the medical history of the victim and the circumstances of the death, including the death scene investigation, in addition to a physical examination and/or autopsy (Polson and Gee, 1973; Spitz, 2006). Sudden unexpected infant death (SUID) is a term used to describe any sudden and unexpected death, whether explained or unexplained, occurring during the first 12 months of life. After case determination, the ME may rule that an unexpected infant death was caused by a specific natural cause, such as a preexisting condition, or accidental cause, such as positional asphyxia.

Positional asphyxia is a type of asphyxia associated with abnormal body position, where the position of the subject compromises adequate breathing (Chmieliauskas et al., 2018; Gordon and Shapiro, 1982; Gordon, 1975). Death is caused by body position that prevents adequate gas exchange or causes direct obstruction of the airways (e.g., smothering by an object) and by the failure or inability to move to another position. Unexpected infant deaths that cannot be explained and for which the cause cannot be determined are referred to as either sudden unexplained infant death (SUID), sudden infant death syndrome (SIDS), or undetermined/unknown. Because of the lack of diagnostic features/markers at autopsy, SIDS remains a diagnosis by exclusion and SUID is an umbrella term that may capture many different types of infant deaths. Considering the changes in definitions and guidelines, it is not surprising to find differences in the cause of death reporting by medical examiners (MEs) and coroners, a well-documented observance (Task Force on Infant Positioning and SIDS, 1996). Because there is no standardized method for the classification of asphyxia deaths among MEs/coroners, the terms “asphyxia” and “positional” can also be used differently by ME and Coroners.

Based on a review of incident data, HS staff identified positional asphyxia/suffocation as a fatal risk factor associated with infant support cushions. HS staff identified four major types of positional hazards associated with the use of infant support cushions (see below).<sup>2</sup> The victims ranged in age from 7 days old to 11 months old, with an average age of 2.5 months. Infants under 12 months old are at risk for positional asphyxia and sudden infant death syndrome (SIDS), with peak risk occurring when an infant is 2-6 months old. The victim was 6 months or younger in 74 fatal incidents (94%) and 3 months or younger in 64 fatal incidents (81%), a particularly vulnerable age bracket.

---

<sup>2</sup> In a subset of cases (14 cases, 18%), no hazard pattern was established due to unclear or unavailable reporting.

Infant support cushions involved in fatal incidents included loungers (63 incidents, 80%), large stuffed animal- shaped infant pillows (4 incidents, 5%), sleep positioners (10 incidents, 13%), a wedge (1 incident, 1%) and a small infant pillow (1 incident, 1%). In most incidents, the victim was placed on the infant pillow for extended, unsupervised sleep. This included both daytime naps and nighttime sleep. According to the narratives, infant support cushions were placed in infant sleep settings that included bassinets and bassinet portions of play yards (13 incidents, 16%), cribs (11 incidents, 14%), and play yards and non-full-sized cribs (8 incidents, 10%). Incident narratives also describe infant support cushions placed in non-infant sleep settings, including adult beds (34 incidents, 43%), couches or futons (3 incidents, 4%), an air mattress (1 incident, 1%), and a toddler bed (1 incident, 1%). The infant pillow was placed on the floor in 4 incidents (5%) and the placement was not known in 4 incidents (5%). Some incidents involved victims that were sharing the sleep setting with caregivers and/or siblings, a situation where the possibility of overlay or suffocation due to extraneous adult soft bedding can be a significant risk. Finally, the narratives describe scenarios of infants being placed to sleep on one or more items of soft, extraneous, bedding which poses an additional risk factor that may have contributed to the suffocation of the infant in some incidents.

### *Hazard patterns*

- 1) *Use as an in-bed sleeper/bassinet to facilitate bedsharing.* HS staff identified 27 fatal incidents (34%) where the victims were sharing the sleep setting (an adult bed, a couch, or an air mattress) with caregivers and/or siblings. With or without the presence of an infant pillow, bedsharing with an infant exposes the infant to a potentially fatal asphyxia hazard by overlay or suffocation due to extraneous adult soft bedding (Fleming et.al., 2015; Nakamura, et.al., 1999; Tappin 2005). However, HS staff notes that many narratives specifically describe scenarios where the infant pillow was being used as an in-bed sleeper/bassinet to facilitate bed sharing (IDIs 211201HCC1442, 200917CCC3888, 200825HCC1839, as examples). As described above, because of the lack of pathological markers of asphyxia deaths at autopsy, determining an exact cause of death is difficult and sometimes not possible. Overlay deaths are frequently ruled as SUID associated with co-sleeping and unsafe sleeping conditions, or as SUID/Undetermined but noting that positional asphyxia due to overlay could not be ruled out. In fact, because of the complexity of overlay scenarios, infants were found in various positions including both prone (IDI 210831HCC1877, 210702HCC3238, 210916HCC1110, 210409CAA2585) and supine (IDI 220516HCC1623, 201026HCC1077, 200109CFE0001, 200917CCC2884) on the infant support cushions, partially off the infant pillow (IDI 211215HCC1519), entirely off the infant pillow (IDI 210428HCC3929, 200825HCC3806, 200917CCC3890, 200917CCC3888), and in some incidents, the found position of the infant was not described. In two incidents, the victims were found wedged. In IDI 201201HCC2106, the victim was found wedged between a wall and the mattress of an adult bed, and in IDI 210916HCC1096, the victim was found wedged between the side of an adult bed and a play yard. In incidents where the infant is wedged, depending on the circumstances of entrapment or wedging, the inversion of the upper body (in whole or part) interferes with normal respiration and circulation by compressing or flexing the torso to make breathing less effective; increases intrathoracic pressure and compression of the vena cava and carotid sinus (which changes blood distribution and reduces cardiac performance); and/or restricts the posture of the neck (hyperflexion or hyperextension) which can impede respiratory movements and lead to airway obstruction (Byard et al., 1994; Fleming et al., 1993; Gioia et al., 2020). Sustained pressure on the neck by the weight of the

mattress can lead to asphyxia by strangulation (Alston et al., 2021; Matshes et al., 2017).

- 2) *Neck Hyperextension.* HS staff identified 2 fatal incidents (3%) where the victim's neck was hyperextended. In one incident, the victim was found to have moved further up the infant pillow, with the victim's head off the pillow and now on a comforter and the victim's body remaining on the pillow (IDI 201016HCC1043). In the second incident, the victim partially rolled off the infant pillow and was found hyperextended, with his head over the back of the pillow (IDI 211215HCC1519). Neck hyperextension can result if an infant's unsupported head is tilted backwards over the top of the product. Sustained neck hyperextension restricts the posture of the neck and, where the head is below level of the infant's heart, impedes respiratory movements and can lead to oxygen desaturation and death (Byard et al., 1994; Fleming et al., 1993; Gioia et al., 2020).
  
- 3) *Rolling off product into hazardous setting.* Excluding the bedsharing incidents in which infants were found to have rolled or been otherwise moved as a result of overlay from the infant pillow, HS staff identified 14 fatal incidents (18%) where an infant rolled from the infant pillow into a hazardous setting. In 3 incidents, victims rolled from infant support cushions that had been placed on adult beds and became wedged. In one incident (IDI 10712HCC3276), the victim was found wedged between an adult bed and the wall. In a second incident, (IDI 200527HCC3540), the victim was found wedged between the footboard and mattress of the bed. In the third incident, (IDI 201103CCC2070), the victim's head was entrapped in a prone position between the edge of the bed and the wall in a 3-inch gap. When infant support cushions are placed in infant sleep settings, victims have been found entrapped between an infant pillow and the side of a crib with soft bedding contributing to entrapment (IDI 100810HWE2299), entrapped between infant support cushions and the side walls of bassinets (ID 110822CCC1939 and 200917CCC2883), and entrapped between infant support cushions and the side wall of a play yard (IDI 140827CCC3866). In other incidents, the victims rolled from infant support cushions and were found prone on other soft bedding in sleep settings (200825HCC2807 and 220926HCC1616, as examples). In 2 incidents, the victims slid down off the infant support cushions and remained supine but asphyxiated with their noses and mouths against adult pillows (IDI 200917CCC3891, 20926HCC1621). Clutter and extra bedding were visible in scene photographs from most of the incidents or described in the IDI narratives. If an infant is placed on an infant pillow and rolls off onto a surface where extraneous bedding or other soft items are located, this can lead to increased risk of suffocation through occlusion of the mouth and nose by the soft items. Occlusion of the nose and mouth by a pillow or other bedding can lead to suffocation.
  
- 4) *Remaining on product with nose and mouth occluded.* Excluding the bedsharing incidents where the infant was found to have remained on the infant pillow, HS staff identified at least 23 fatal incidents (29%) where the victim was found still on the infant pillow, with their nose and mouth occluded. According to the narratives, infants were typically placed supine or on their right or left side, an unstable infant position. The victims were found prone on the infant support cushions with their noses and mouths occluded by the infant pillow itself or by the infant pillow and/or other soft bedding present in the sleep setting (such as blankets) (IDI 101027CAA2082, 140903CBB1914, 200924CAA2899, 160310HFE0002, as examples. Infants can unexpectedly roll into a prone position on the infant pillow and be unable to reverse

action and extract themselves from a hazardous situation because either the soft infant pillow prevents it, or the infant was physically incapable of rolling back. If the nose and mouth are occluded in any scenario either against the soft infant pillow itself or other soft bedding in the sleep setting, it may lead to asphyxia. An infant can suffocate/asphyxiate against any object that partially or fully obstructs the nose and mouth and prevents breathing (Wanna-Nakamura, 2010). Obstruction of the airway can lead to unconsciousness in 30-180 seconds, and death as a result of asphyxia can occur in as little as 3 minutes.

### *Pathophysiology of Positional Asphyxia and Injury Mechanism Analysis*

Infants differ greatly in their developmental skills in their first year of life. Unlike healthy adults, the limited physical and developmental capabilities of infants render them susceptible to asphyxiation in certain sleep settings. The American Academy of Pediatrics (AAP) recommends that infants be placed to sleep in a supine position and that soft bedding be avoided in the sleep setting (Moon et al., 2022). While all infants younger than 12 months of age are considered at risk of positional asphyxia, infants 2-6 months of age, premature infants, and infants who are born as a set of multiples are particularly vulnerable and are at the highest risk primarily due to physical inability and an immature physiological system that regulates breathing and arousal in the first few months of life. Physiological abnormalities and delays in the development of vital systems can further hamper an infant's ability to react to a hazardous sleep setting, such as arousing when air supply to the lungs is compromised. This age group is at risk for suffocation and sudden infant death syndrome (SIDS), which is thought to occur when an infant with an underlying biological vulnerability, who is at a critical development age, is exposed to an external trigger, such as an unsafe sleep setting (Dwyer et al., 1995; Byard et al., 1994; Fleming et al., 1993; Hauck et al., 2003; Ponsonby et al., 1993; Smialek et al., 1977).

Once an infant's airflow is compromised, decreased levels of oxygen in the blood can further impair the ability of the infant to respond to the situation. If an infant cannot respond, a feedback loop of decreased heart and respiration rate develops that can eventually lead to cessation of breathing and may become fatal if uninterrupted. Once an infant becomes hypoxic (a state of low levels of oxygen in body tissues) due to smothering, the prognosis depends primarily on the extent of oxygen deprivation, the duration of unconsciousness, and the speed of resuscitation. Rapid reversal of the infant's hypoxic state is essential to prevent or limit the development of pulmonary and cerebral edema, and the rapidity of this reversal ultimately predicts the patient's clinical prognosis (Dzikienė et al, 2021; Jongewaard et al, 1992; Medalia et al., 1991; van Handel et al., 2007). Thus, victims who are oxygen deprived for short durations or quickly receive cardiopulmonary resuscitation to reestablish air flow have the most favorable clinical outcomes. Because these types of wedging incidents and asphyxiations due to soft bedding often happen while an infant has been left alone to sleep on infant support cushions, while not under immediate supervision of a caregiver, the likelihood of the caregiver becoming aware of the event and rescuing the child is often low.

## **III. Conclusions**

HS staff reviewed data on infant support cushion-related deaths, injuries, and potential injuries, including fatal and nonfatal incidents, the mechanism and severity of injury associated with the incidents, the hazard patterns associated with the use of infant support cushions, and the most current medical literature pertaining to the pathophysiology of positional asphyxia. HS staff identified positional asphyxia/suffocation as a health hazard associated with infant support cushions. A primary contributing factor to infant fatality appears to be when infant support

cushions are used for extended, unsupervised rest or sleep on an adult bed or in an infant sleep setting such as a crib, bassinet, or play yard. Other contributing factors staff noted from the narratives included an infant's prematurity, being a twin or other multiple, small size for age of infant, recent respiratory illnesses, the presence of extraneous soft bedding (which can create additional suffocation hazards that are contributory), cluttered sleep settings, bedsharing (risk of overlay), and infant positioning other than supine. Infants should be placed to sleep in a supine position on a firm, flat, level surface without soft bedding in the sleep setting according to the AAP. While all infants under 12 months of age are at high risk from positional asphyxia, infants two to six months of age are at particular risk because they may be developmentally capable of moving around in the sleep environment and moving into a vulnerable situation that can put them at risk of suffocation but not yet have the physical capability to extricate themselves from a hazardous situation.

## IV. References

Alston, M. L., et al. (2021). J Pub Health Issue Pract, 5(2): 186  
<https://doi.org/10.33790/jphip1100186>

Byard RW, Beal S and Bourne AJ. Potentially dangerous sleeping environment and accidental asphyxia in infancy and early childhood. Arch Dis Child 1994; 71: 497-500.

Chmieliauskas S, Mundinas E, Fomin D, Andriuskeviciute G, Laima S, Jurolaie E, Stasiuniene J, Jasulaitis A. Sudden deaths from positional asphyxia: A case report. Medicine (Baltimore). 2018 Jun;97(24): e11041. doi: 10.1097/MD.00000000000011041. PMID: 29901602; PMCID: PMC6023692.

Dwyer T, Ponsonby A-L, Blizzard L, Newman NM, Cochane JA. The contribution of changes in prevalence of prone sleeping position to the decline in sudden infant death syndrome in Tasmania. JAMA. 1995; 273:783-789

Dzikienė R, Lukoševičius S, Laurynaitienė J, Marmienė V, Nedzelskienė I, Tamelienė R, Rimdeikienė I, Kudrevičienė A. Long-Term Outcomes of Perinatal Hypoxia and Asphyxia at an Early School Age. Medicina (Kaunas). 2021 Sep 18;57(9):988. doi: 10.3390/medicina57090988. PMID: 34577911; PMCID: PMC8466311.

Gioia S, Franceschetto L, Carlini L, Suadoni F, Lancia M. A case of a head-down position death in a six-months old baby with concurrent pneumonia. Forensic Science International: Reports, Volume 2, 2020, 100045, ISSN 2665-9107, <https://doi.org/10.1016/j.fsir.2019.100045>.

Gordon I, Shapiro HA. Deaths usually initiated by hypoxia or anoxic anoxia. In: Gordon I, Shapiro HA, editors. Forensic medicine: 2nd ed. Edinburgh, UK: Churchill Livingstone, 1982; 95–129

Gordon I. The medicolegal aspects of rapid deaths initiated by hypoxia and anoxia. Leg Med Annu. 1975:29-47. PMID: 768671.

Fleming PJ, Blair PS, Bacon C, et al. Environment of infants during sleep and risk of the sudden infant death syndrome: results of 1993-5 case-control study for confidential inquiry into stillbirths and deaths in infancy. BMJ. 1996; 313:191-195

Hauck FR, Herman SM, Donovan M, et al. "Sleep Environment and the Risk of Sudden Infant Death Syndrome in an Urban Population: The Chicago Infant Mortality Study." *Pediatrics* 2003; (111): 1207-1214

Jongewaard WR, Cogbill TH, Landercasper J. Neurologic consequences of traumatic asphyxia. *J Trauma*. 1992 Jan;32(1):28-31. doi: 10.1097/00005373-199201000-00006. PMID: 1732570.

Matshes EW, Lew EO. An Approach to the Classification of Apparent Asphyxial Infant Deaths. *Acad Forensic Pathol*. 2017 Jun;7(2):200-211. doi: 10.23907/2017.021. Epub 2017 Jun 1. PMID: 31239974; PMCID: PMC6474537.

Medalia AA, Merriam AE, Ehrenreich JH. The neuropsychological sequelae of attempted hanging. *J Neurol Neurosurg Psychiatry*. 1991; 54:546–8.

Moon RY, Carlin RF, Hand I. The Task Force on Sudden Infant Death Syndrome and the Committee on Fetus and Newborn; Evidence Base for 2022 Updated Recommendations for a Safe Infant Sleeping Environment to Reduce the Risk of Sleep-Related Infant Deaths. *Pediatrics* July 2022; 150 (1): e2022057991. 10.1542/peds.2022-057991

Nakamura S, Wind M, Danello MA. Hazards Associated with Children Placed in Adult Beds. *Arch of Pediatric and Adolesc Med*. 1999; 153:1019-1023.

Polson CJ. Hanging In: Polson CJ and Gee DJ (eds.) *Essentials of forensic medicine* Oxford England, 1973 371-404.

Ponsonby AL, Dwyer T, Gibbons LE, Cochrane JA, Wang Y-G. Factors potentiating the risk of sudden infant death syndrome associated with prone position. *N Engl J Med*. 1993; 329:377-382

Smialek, JE, Smialek, PZ and Spitz, WU. Accidental bed deaths in infants due to unsafe sleeping situations. *Clinical Pediatrics* 1977; 15 (11):1031-1035

Smith, B. Tab A, Epidemiology Memorandum. Staff's Draft Notice of Proposed Rulemaking for Infant Support cushions under Danny Keysar Child Product Safety Notification Act. Bethesda, MD: Office of Hazard Identification and Reduction, U.S. Consumer Product Safety Commission, 2023.

Spitz WU. Asphyxia. In: Spitz WU, Spitz DJ, editors. *Spitz and Fisher's medico-legal investigation of death: guidelines for the application of pathology to crime investigation*, 4th edn.

Task Force on Infant Positioning and SIDS. Positioning and infant death syndrome (SIDS): update *Arch Pediatr Adolesc Med*. 1996; 150:834-837

Tappin D, Ecob R, Brooke H. Bedsharing, room sharing, and sudden infant death syndrome in Scotland: a case control study. *J Pediatr*. July 2005;147(1):32-37

van Handel, M., Swaab, H., de Vries, L.S. *et al*. Long-term cognitive and behavioral consequences of neonatal encephalopathy following perinatal asphyxia: a review. *Eur J Pediatr* 166, 645–654 (2007). <https://doi.org/10.1007/s00431-007-0437-8>

Wanna-Nakamura S. White Paper – Unsafe Sleep Settings: Hazards associated with the infant sleep environment and unsafe practices used by caregivers: a CPSC staff perspective. 2010.

# **TAB C: Staff Recommended Performance Requirements for the Notice of Proposed Rulemaking for Infant Support Cushions**



# Memorandum

**TO:** Stefanie Marques, Ph.D., Supervisory Scientist  
Division of Pharmacology and Physiology Assessment,  
Directorate for Health Sciences

**THROUGH:** Andrew G. Stadnik, P.E., Associate Executive Director  
Directorate for Laboratory Sciences

Michael Nelson, Director,  
Division of Mechanical Engineering,  
Directorate for Laboratory Sciences

**FROM:** Mark Eilbert, Mechanical Engineer  
Division of Mechanical Engineering,  
Directorate for Laboratory Sciences

**SUBJECT:** Staff Recommended Performance Requirements for the Notice of Proposed Rulemaking  
for Infant Support Cushions

---

## I. Introduction

The U.S. Consumer Product Safety Commission (CPSC) directed staff to prepare a Notice of Proposed Rulemaking (NPR) for infant support cushions, which are defined in the draft proposed rule, under section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA).

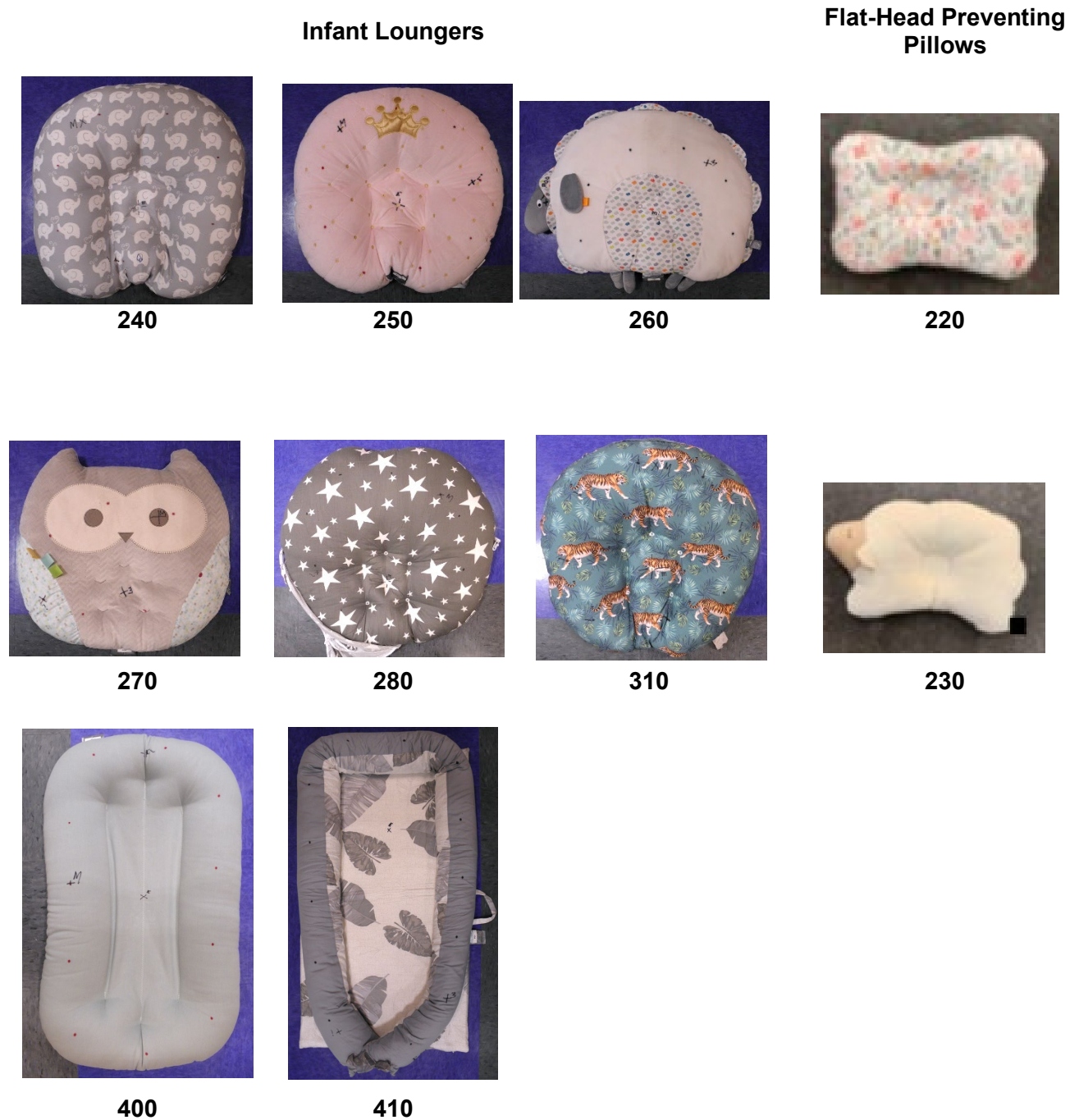
The ASTM F15.21 Infant Loungers Subcommittee (ASTM Loungers Subcommittee) has been developing a voluntary standard for infant loungers<sup>1</sup>. The ASTM Subcommittee, with input from CPSC staff, has drafted firmness requirements for the occupant support surface (OSS), the top of the sidewall, and the intersection of sidewall and OSS, and other requirements in order to reduce the likelihood that an infant could suffocate from the product conforming to the face, staff proposes firmness and dimensional requirements to address suffocation within the product and asphyxia hazards identified in the Directorate for Health Sciences, Division of Pharmacology and Physiology Assessment memorandum (Tab B) and based partially on the ASTM subcommittee draft standard. This memorandum describes the process CPSC staff used in developing general and performance requirements for infant support cushions, including the use of infant loungers and head pillows in sample product testing.

---

<sup>1</sup> Draft Standard for Infant Loungers v2 2023, The most recent update was April 16, 2023.

## II. Background

Figure 1 shows the types of support cushions used for testing and analyses for this NPR.



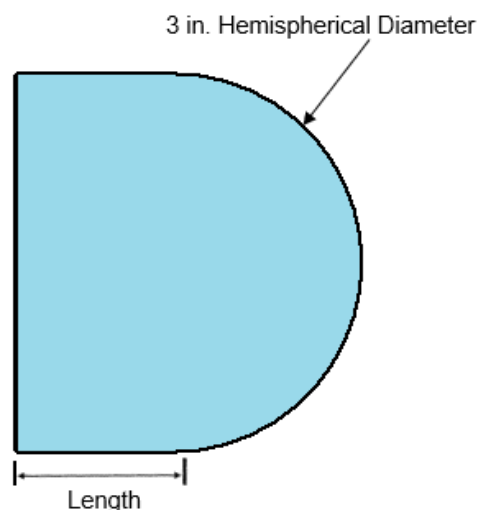
**Figure 1 Test Samples**

At least one manufacturer of infant loungers claims to have tested to the firmness test method in British Standard BS 4578 (1970) Test for Hardness of and for Air Flow Through Infant Pillows.<sup>2</sup> The British standard requires that a pillow shall not deflect more than 25% of the thickness at rest when tested with a probe under a 10 N (2.2 lb) force. Due to this 25% proportionality requirement, the requirement allows thicker pillows more absolute deflection than thinner pillows.

Boise State University (BSU), under contract with CPSC<sup>3</sup>, published a report describing a performance requirement and test method for the firmness of infant support products, including flat-head-preventing pillows and loungers. The test requires that a 3-in (7.6 cm) diameter hemispherical probe (“3-in probe”) must require a force greater than 10 N (2.2 lb) to deflect into the product 1.0 in (2.5 cm). The BSU report describes the probe’s size and shape as based on infant head dimensions and the applied 10 N force as approximately the weight of an infant’s head. Figure 2 shows the BSU 3-in. head probe. BSU did not specify a length for the probe.

In development work, BSU assessed the firmness tests in BS 4578 and in AS/NZS 8811.1<sup>4</sup>. BSU rejected the BS 4578 test method because the flat face of the probe did not represent the suffocation risk of a more realistic three-dimensional probe. Staff, moreover, are aware of fatal incidents due to facial occlusion. Staff therefore assess that the BS 4578 is not adequate to address the facial occlusion hazard for infant support cushions.

BSU established that crib mattresses exhibited a safe level of firmness because they complied with mattress testing in AS/NZS 8811.1. In BSU’s testing, those mattresses also deflected less than 1.0 in (2.5 cm) with the 3-in head probe test. Thus, BSU established a 1.0 in (2.5 cm) deflection as a safe limit for infant lounger and head pillows. Tests on lounger and head pillow products (Figure 2) indicate that some of the test locations on these products complied, but that none fully complied. The BSU recommendation is that “[t]he force required for this 1-in (2.5 cm) displacement should be >10 N (2.2 lb) to pass the firmness test.” The BSU testing was conducted with a vertical test fixture applied to generally horizontal product surfaces. Nevertheless, the test method can be adapted to other test orientations.



**Figure 2. 3-in. Head probe**

<sup>2</sup> The requirements associated with the BS 4578 test method are in BS 1877-8 (1974) Domestic Bedding.

<sup>3</sup> Mannen, E. M., Davis, W., Goldrod, S., Lujan, T., Siddicky, S. F., Whitaker, B., & Carroll, J. (2022). *Pillows Product Characterization and Testing*. Prepared for the U.S. Consumer Product Safety Commission under contract no. 61320620D0002, task order no. 61320621F1015. Available: <https://www.cpsc.gov/content/Pillows-Product-Characterization-and-Testing>.

<sup>4</sup> AS/NZS 8811.1:2013 Methods of testing infant products Method 1: Sleep surfaces—Test for firmness

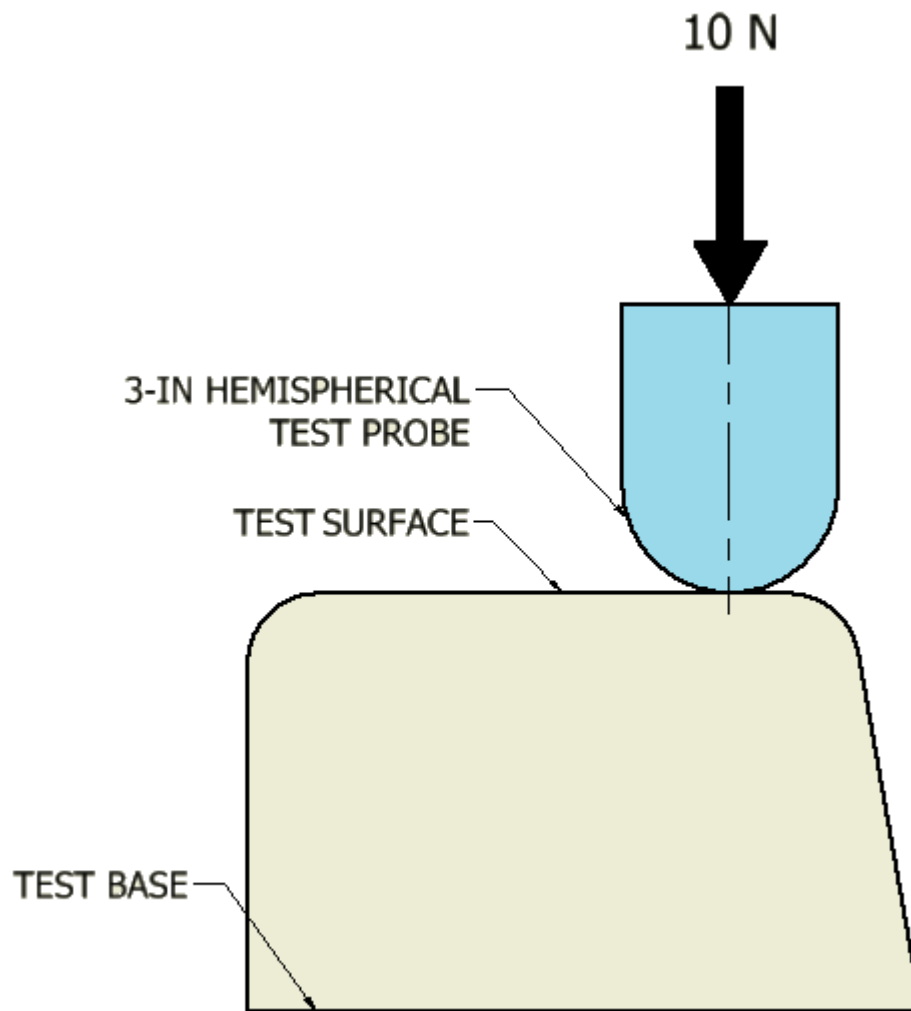
### III. Discussion

For the NPR, CPSC staff recommend using the firmness requirements and test developed by BSU and incorporating language, amended by staff, that ASTM F15.21 Infant Loungers Performance Task Group (“ASTM TG”) drafted for firmness and dimensional requirements and test methods for infant loungers and infant support cushions. These requirements and test methods address the contributions to the suffocation hazards described in the incident review by staff that are attributable to the involved infant lounger and cushion products. CPSC staff discussed firmness and dimensional requirements with the ASTM TG in meetings from August 2022 to January 2023. ASTM drafted requirements to reduce the likelihood that the products could obstruct an infant’s face and cause suffocation. The consensus was to require a minimum firmness for the occupant support surface, the top of sidewalls, and the intersection of sidewall and occupant support surfaces, as well as sidewall height, sidewall angle, and maximum incline angle requirements. An ASTM standard has not yet been balloted for infant loungers. Below, staff discuss requirements and test methods for firmness, sidewall height and angle, and maximum incline angle and provide recommendations for the draft proposed rule.

#### A. Discussions of Staff Proposals for Requirements and Test Methods

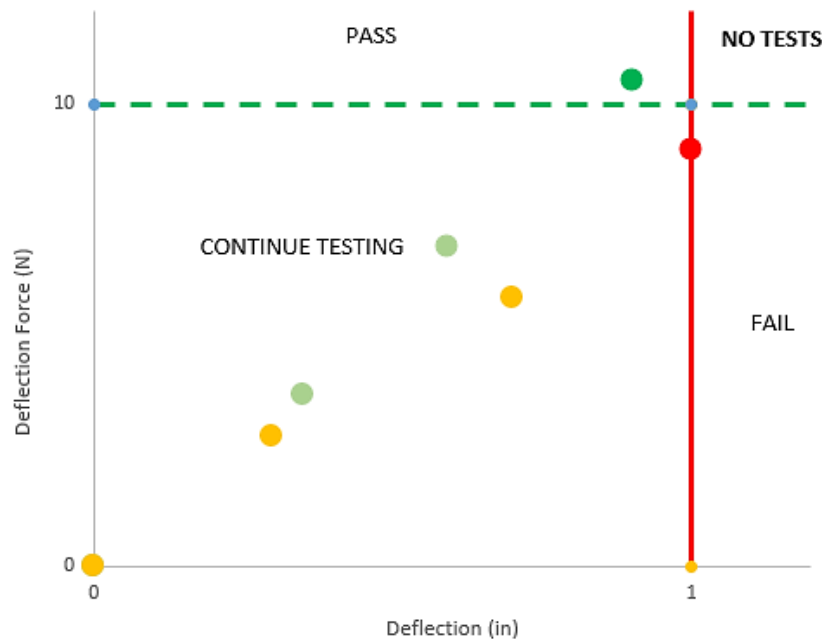
##### i. Firmness

CPSC staff fabricated test fixtures and conducted testing on a sampling of infant cushion products (Figure 1) to evaluate the BSU test method. Staff included adjustable fixturing such that the probe can be orientated perpendicular to the product surface, including the occupant support surface (OSS), the top of sidewalls, and the intersection of OSS and sidewalls. Staff evaluated the BSU test method (Figure 3) in which a 3-in. head probe is lowered vertically down such that a 0 to 10 N force is applied to the test surface of an infant cushion, such that the force can be measured at the point that the deflection equals 1.0 in. If the measured force is 10 N or less at the 1.0 in. deflection, the test location fails the test. If a 1.0 in. deflection won’t be reached due to the firmness of the product, the probe can be advanced further in a similar manner until the force exceeds 10 N and the deflection is less than or equal to 1.0 in., in which case the test location passes the test. Specific firmness tests for the occupant support surface (OSS), the top of sidewalls, and the intersection of OSS and sidewalls will be discussed, including orientations of the 3-in head probe for each test surface.



**Figure 3 BSU Test Configuration for Firmness Tests**

Figure 4 depicts the results of two exemplary tests that show passing and failing the recommended firmness test. Testing begins at a nominally zero deflection and force. Testing continues until either the 1.0 in. deflection is reached before the force exceeds 10 N (red failure), or the 10 N force is exceeded before the 1.0 in. deflection is reached (bright green pass).



**Figure 4. General Firmness Test, Force versus Deflection**

The ASTM firmness requirements and test methods are influenced by the BSU recommended firmness test. In the ASTM sidewall and the intersection of sidewall and OSS firmness tests, the displacement shall not be equal to or greater than 1.0 in when a 10 N force is applied with a 3-in (7.62 cm) hemispherical probe. Tests are conducted at 6 in-intervals around the product. An important difference in the two test methods is that the ASTM requirement has a deflection limit and a test method that applies a fixed force, while the BSU requirement has a force limit and a test method that applies a fixed deflection. A lead screw advances the probe in the BSU test, and the force measurement is taken after at 1 minute time delay. The time delay is included in the BSU test method to allow the material to “relax” to a stable reading. How ASTM applies the force is not stated, however, the deflection is measured when the force is applied, so the force should be applied quickly. Staff assesses that the time delay required by the BSU method increases the repeatability of the test measurements, and that not specifying the method with which force is applied or including a time delay in the ASTM test method can cause issues with repeatability of test results. Staff recommends the BSU test method because it accounts for the downward decay of test forces, and the lead screw enables precise control of deflection.

Staff recommends the BSU firmness test, with modifications that add certain procedural steps to improve the infant cushion firmness test method. In the BSU test method, the force is allowed to stabilize for approximately 1 minute prior to measuring the final force at the 1.0 in. deflection. Through infant lounger testing, staff determined that a 30-s. stabilization period is sufficient to bring changes in the force measurement, which is still slightly decreasing after 30 s., to within an accuracy of 0.05 N (0.01 lb) at the deflection of 1.00 in. (2.54 cm), deflection measured to an accuracy of 0.03 in. (0.08 cm). Staff assesses that these force and deflection accuracies are reasonable goals given the nature of measuring force and distance with a soft product such as the infant cushion. In other procedural steps, staff recommends that the firmness test method

include a rate of approach for the probe of 1 in. per 10 s. and a waiting period between successive tests of 5 minutes if adjacent locations are within 3 in., including successive trials at the same location. The total duration of a test would combine the total time of the rate of approach (10 s.) and the stability period (30 s.), resulting in 40 s. The purpose for the approach rate and stabilization and waiting periods is to improve repeatability and reproducibility. Staff recommends these and additional testing procedures be applied to firmness tests for the occupant support surface (OSS), the top of sidewalls, and the intersection of the OSS and sidewall of infant cushion products.

Staff recommends that these testing procedures be included in the firmness test method:

#### Test sample conditioning.

- Precondition the product to a standard indoor temperature. Staff recommends the product should be conditioned for 48 hours at 23 °C +/- 2 °C (73.4 °F +/- 3.6 °F) and a relative humidity of 50 % +/- 5 %<sup>5</sup> and those conditions be maintained throughout testing. The time duration is reasonable for the typically thick infant cushion products to acclimate prior to firmness testing.
- Perform tests with products as received and after laundering and drying according to the manufacturer's instructions. Washing and drying can change the properties of products, including the firmness at specific locations following the removal and installation of a fitted cover.

#### Test locations on product.

- Perform tests in all intended or feasible product configurations and orientations. An example of a product orientation that is intended is a top occupant support surface identified by the manufacturer. A feasible orientation can be the opposite side from the intended when the two sides can be considered to have equal firmness. Product configurations include those that present distinct firmness such as by folding or by layering of component pieces.
- Allow some discretion in selecting testing locations. Experienced test personnel can assess which location(s) may present lower firmness measurements based on judgements on factors such as product design or changes from laundering.

#### Test repeatability and reproducibility.

- Specify the rigidity of the test fixture when secured to a base support to reduce movement that could affect the force or deflection measurement. Staff recommends that a force of 10 N (2.2 lb), the required force in the firmness tests, when applied to the test probe should not cause a measured deflection of greater than 0.01 in. (0.03 cm). This equipment requirement will limit the measurement error due to flexing of the test fixturing to a reasonable 1 % of full scale, that is 0.01 in divided by the 1.00 in. (2.54 cm) test method deflection.

---

<sup>5</sup> Pre-conditioning specified in AS NZS 8811.1 (2013) *Methods of testing infant products Method 1 Sleep surfaces Test for firmness*.

- Specify that the product should be secured to prevent movement that could affect test results. Firmness tests will compress the test surface and measurement of the deflection of that surface should not be affected by shifting or rotation of the product.
- Use a method to advance and hold precise deflection prior to force measurements. Staff recommends that the test probe be advanced by a lead screw or similar devices or fixturing that can adjust and hold position along a single direction.
- Base the zero reference on the product to begin the deflection measurement on a small initial force rather than by visual inspection. Staff recommends that the deflection be zero at an initial force of 0.1 N, which agrees with the BSU method.
- Specify a maximum rate of travel for the probe into the product. As discussed, staff recommends a rate of 0.1 in per second.
- Specify a time delay prior to the force measurement at each location to allow the material changes to stabilize. As discussed, staff recommends a 30 s. delay.

#### Testing Burden.

- Allow fewer test locations in areas in which the thickness is 1.0 in. or less. Staff assesses by inspection that deflection testing to a requirement of 1.0 in. is inconsequential at locations with product thicknesses of 1.0 inch or less. Staff recommends that only one firmness test location should be required if the test surface has a homogeneous 1.0 in. thickness or less.

## ii. Testing Orientations

The ASTM Subcommittee's definition for occupant support surface (OSS) is "the area that holds up and bears the infant or any portion of the infant." The OSS for infant loungers provides both support for the infant's body and head. Some infant support cushions provide head support, while the infant's body rests on some surface outside the product. The OSS is represented as a reference in four ASTM draft test methods. ASTM derived a firmness test method from the firmness method for mattresses in the AS/NZS 8811.1 standard, in which the deflection from the weight of an 8-in (20.3 cm) diameter probe is used to gauge deflection. The ASTM method places the 8-in probe on the OSS and allows it to "level," which assumes the OSS is a horizontal reference. Similarly, in measuring side height, a 6 in by 6 in (15.2 cm by 15.2 cm) aluminum plate is placed on the OSS as reference for a vertical height measurement, which again assumes a horizontal OSS. In the angle measurement between sidewall and OSS and in the angle specified for the firmness test for the intersection of sidewall and OSS, the OSS is assumed to be a flat plane, but not horizontal. In all four of these test methods, the OSS is assumed to be a flat plane and used as a reference.

On inspection of infant lounger/pillow samples (shown in Figure 1), staff considers the OSS of samples 220, 230, and 410 to be approximately horizontal and planar when laid down on a similar surface (e.g., tabletop). In the remaining samples, the OSS is formed into a curved form, such as with button-like stitching (samples 240, 250, 260, 270, 280, 310), or the OSS is a thin, flexible fabric that is stretched between sidewalls (sample 400). The OSS's of the CPSC

samples are, in general, neither planar nor horizontal. Thus, the four test methods described do not completely address these designs.

To simplify and clarify the determination of the OSS orientation for the test methods for loungers and infant support cushions, staff proposes to conduct the recommended OSS firmness and sidewall firmness tests and measurements of loungers/support cushions vertically if the OSS surface is on average equal or less than 5 degrees from horizontal and to conduct tests and measurements perpendicular to the OSS surface if than greater than 5 degrees. The purpose for this 5-degree allowance at test locations is to avoid unnecessary equipment adjustments and variations in test orientations that can affect test repeatability and reproducibility among test laboratories. Staff assesses that the difference between the deflection and force measurements conducted perpendicular to a 5-degree surface and vertical to that surface, as recommended, is less than 0.5 percent<sup>6</sup>, which is not a deviation expected to affect results.

### iii. Occupant Support Surface (OSS) Firmness

The firmness of the OSS is most critical at each location where an infant's face may make contact. A test for firmness should be designed to apply to all those locations. In the ASTM requirement for OSS firmness, the feeler arm outside the edge of an 8-in (20.3 cm) diameter "firmometer" probe must not contact the OSS. The 8-in diameter size of the "firmometer" was not intended to represent the form of any part of a child's body. ASTM specifies three test locations in terms of the major axis of the product. Among the infant loungers and support cushion samples tested by CPSC, staff finds that the ASTM firmometer is larger than the area of most OSS's and, for the circular-shaped sample loungers (240, 250, 260, 270, 280), contact with the "feeler arm" is outside the OSS. For those samples, the ASTM OSS firmness test does not give results for the OSS, which is the surface firmness that section of the standard seeks to test. For example, in Figure 5 the feeler gauge on the 8-in probe contacts the sidewall of sample 240, and not the OSS. Additionally, staff assessed through testing that certain OSS features, such as deep dimples created by stitch patterns, that could create suffocation hazards are masked by the size of the 8-in wide probe. The 3-in head probe, however, has a size and shape that more closely approximates an infant's head/face and can reach areas of an OSS the firmometer cannot. Firmness measurements with that probe would also be consistent with those in both the sidewall and the intersection of the sidewall and OSS firmness test methods. Staff recommends that the 3-in head probe firmness requirement and test method be used to measure firmness of the OSS. Figure 6 shows the recommended test: a 10 N load applied to a 3-in. head probe directed at the OSS. In addition, staff recommends modifications to the test locations. To address all areas of the OSS, the number of tests performed should be commensurate with the size of the OSS and, because firmness variations do not align with prescribed test locations, testing should include at least one location most likely to fail. Staff inspected one sample that had an OSS thickness of less than 1 in and concluded that compliance to a 1.0-in (2.54 cm) firmness requirement could be satisfied with a reduced testing requirement. Staff recommends that products with an OSS with all areas less than a 1-in thickness may be tested at a single representative location.

<sup>6</sup>Cosine (5 degree) = 0.996, such that the force and deflection in a vertical direction on a 5-degree surface is mathematically 0.4 % less than that of a perpendicular test to the same surface.



Figure 5. ASTM OSS Test with 8-in Diameter Probe, Sample 240

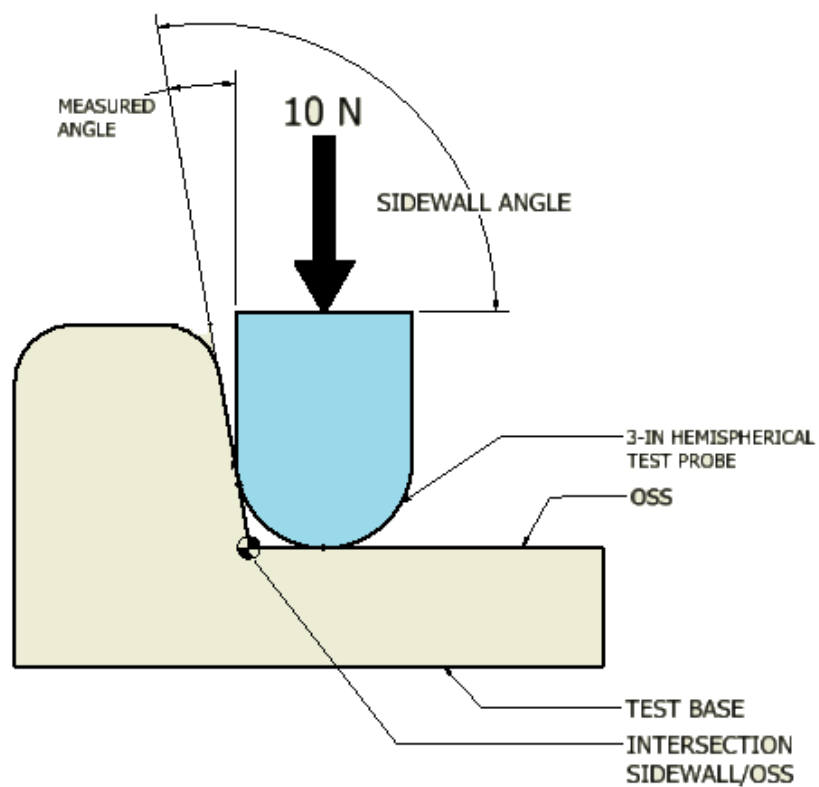


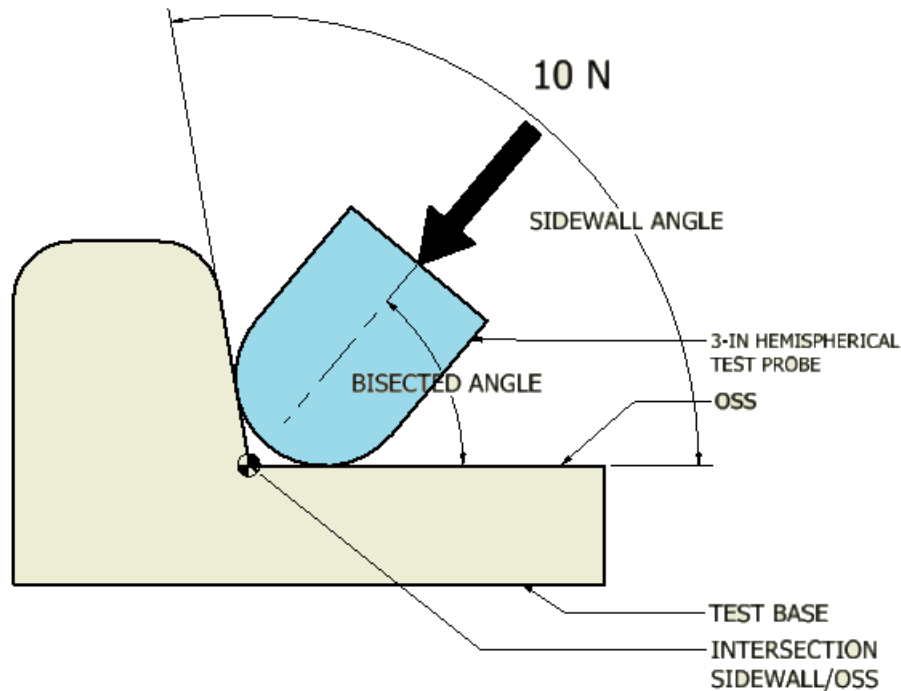
Figure 6. Test Fixture Configuration for Occupant Support Surface Firmness and Sidewall Angle Measurement

#### **iv. Sidewall Firmness**

An infant's head or face may rest on the sidewall of the product. Because the sidewall is distinct from the OSS, a separate sidewall firmness test is necessary to address its dimensions and extents. The ASTM sidewall firmness test requires that the deflection shall not be equal to or greater than 1.0 in when a 10 N force is applied with a 3-in (7.62 cm) hemispherical probe, directed downwards on top of the sidewall, with testing conducted in 6-in increments around the product. Consistent with the General Firmness Test Method, staff recommends a sidewall firmness requirement in which the force required for a 1.0-in (2.54 cm) displacement should be greater than 10 N (2.2 lb). To accommodate smaller head pillows and larger lounger products, staff recommends a minimum of four sidewall firmness tests should be conducted, starting at a test location of maximum sidewall height, and at intervals not to exceed 6 in (15.2 cm). In addition, staff recommends that the test locations include at least one location most likely to fail.

#### **v. Intersection of Sidewall and Occupant Support Surface Firmness**

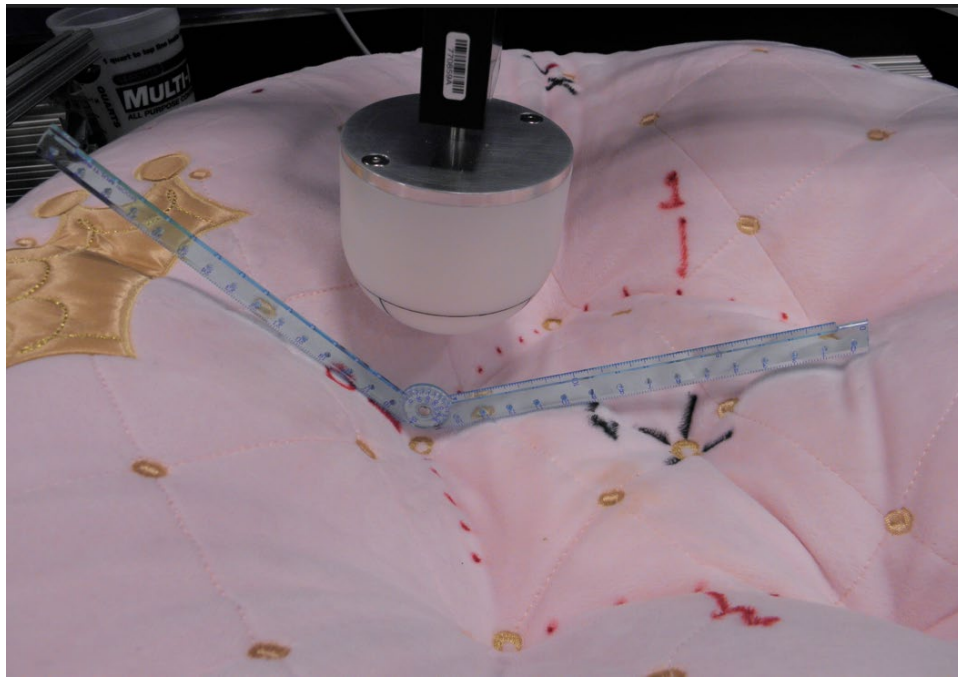
This firmness test is intended to address hazards of suffocation in infant cushion products due to the presence of a sidewall adjacent to an OSS. In the transition from OSS to sidewall, where parts join, sharply transition, or overlay other parts and that can form internal or concave surfaces, the face of the infant can contact multiple surfaces simultaneously. The draft ASTM requirement for deflection at the intersection where a sidewall and OSS meet requires that the deflection must not be equal to or greater than 1.0 in (2.54 cm) when a 10 N (2.2 lb) force is applied through a 3-in (7.62 cm) diameter hemispheric probe directed at an angle to that intersection that bisects the angle between the OSS and the sidewall. Figure 7. Tests are conducted every 6 in (15.2 cm) along the edge where the OSS and the sidewall intersect. For CPSC samples, that intersection for the two rectangular loungers (samples 400, 410) and for the flat head preventing pillows (samples 220, 230) is between a sidewall and OSS that transition with distinctive angle changes. For the remaining loungers (samples 240, 250, 260, 270, 280, 310), that intersection is a curved transition between a thicker outside perimeter and the recess of an occupant support. To reduce the hazard of suffocation between sidewalls and the OSS, staff recommends, consistent with all recommended firmness tests, that the force required for a 1.0-inch displacement should be greater than 10 N (2.2 lb). To accommodate smaller head cushions and larger lounger products, staff recommends a minimum of four sidewall firmness tests should be conducted, starting at a test location of maximum sidewall height, and at intervals not to exceed 6 in (15.2 cm). In addition, staff recommends that the test locations include at least one location most likely to fail.



**Figure 7. Test Configuration for Intersection of Sidewall and Occupant Support Surface Firmness**

The locations ASTM determined for several tests and measurements reference the edge or intersection of the OSS and sidewall. ASTM locates the measurement for sidewall height “next to the sidewall,” and the sidewall angle measurement and a firmness test at the “intersection of the sidewall and the occupant support surface.” On inspection of CPSC samples, staff finds that the transition from an inner infant support surface to an outer raised surface (e.g., sidewall) has various defining features. The rectangular loungers (400, 410) have continuously sewn perimeters at the intersection between the much thinner OSS and the raised sidewall. Flathead preventing pillows (220, 230), have a center depression to provide head support and have a distinct intersection of sidewall and OSS. In the remaining CPSC samples (240, 250, 260, 270, 280, 310), which are circular in basic shape, the OSS is a depression bordered by a series of button-like stitches. The “buttons” clearly mark the OSS border, but the fabric between the buttons is continuous with no true intersection of OSS and sidewall. Locating the intersection or transition from sidewall to OSS will be a challenge in some products. Figure 8 shows the firmness probe aligned approximately to the intersection (dashed red lines) between the raised side (i.e., sidewall) and the OSS in sample 250. Because this transition varies among products, staff does not have a recommendation for a method to determine the exact intersection of the sidewall to OSS. For some CPSC samples, the OSS intersection was obviously at a stitching, but for others it was an inexact, virtual intersection. However, because staff also recommends firmness requirements for sidewalls and occupant support surfaces, which are adjacent to this firmness test for the intersection of sidewall and occupant support surfaces (OSS), the three firmness tests (sidewall, intersection, and OSS) will adequately cover the firmness of the product in representative locations, including products with variable transitions between the sidewall and OSS. Staff therefore recommends that “intersection” adequately describes the transition

between the sidewall and OSS and the exact test locations should be left to the judgement of the testing laboratory



**Figure 8 Firmness Probe at Intersection of Sidewall and OSS, Sample 250**

#### **vi. Maximum Incline Angle**

Positional asphyxia and hazardous positioning of an infant's head and neck that can be caused by inclined sleep, are discussed in the Directorate for Health Sciences, Division of Pharmacology and Physiology Assessment memorandum. The Infant Sleep Products Rule (ISP Rule) has a requirement, Maximum Seat Back/Sleep Surface Angle, for infants up to 5 months of age, that provides for infant sleep products, "The angle of the seat back/sleep surface intended for sleep along the occupant's head to toe axis relative to the horizontal shall not exceed 10 degrees tested in accordance with 7.11.2". The referenced test method requires:

- If applicable, place the product in the manufacturer's recommended highest seat back/sleep surface angle position intended for sleep.
- Place the hinged weight gauge-infant<sup>7</sup> in the product and position the gauge with the hinge centered over the seat bight line and the upper plate of the gauge on the seat back/sleep surface. Place a digital protractor on the upper torso/head area lengthwise.

The draft ASTM performance requirements includes a similar section entitled "Maximum Seat back Angle", which requires that the angle of the seat back along the head-to-toe axis relative to the horizontal shall not exceed 10 degrees when tested with the infant hinged weight gauge. The

<sup>7</sup> A two-part, hinged, metal gauge to represent the approximate form and weight of an infant when lying prostate or supine. This gauge is used in several ASTM infant safety standards.

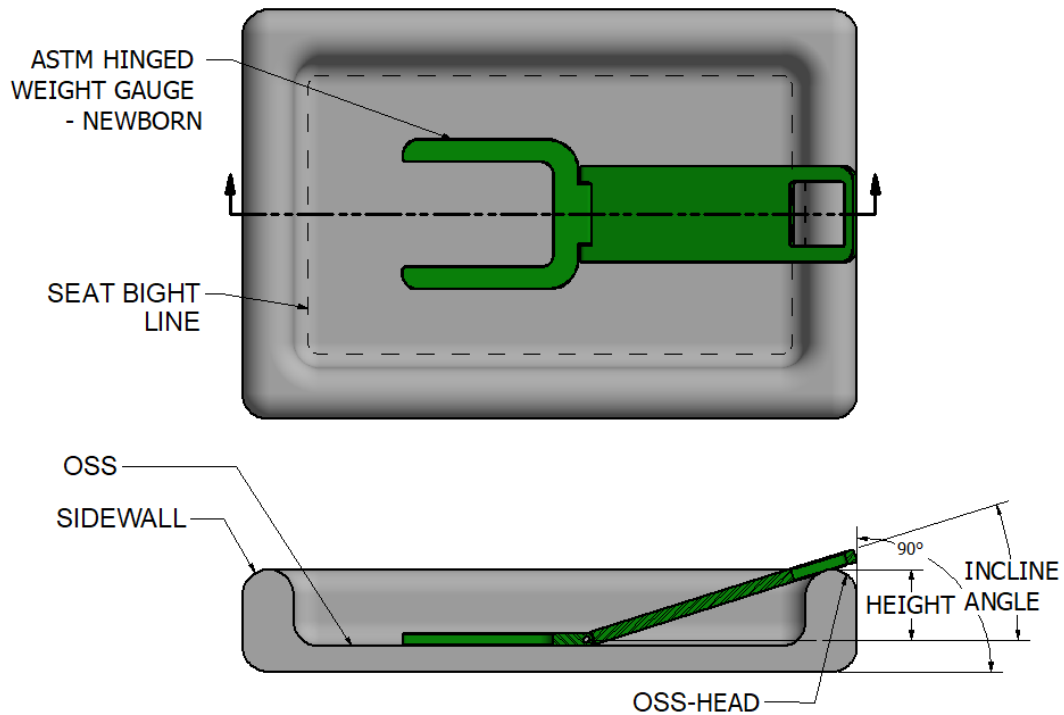
product is placed into the highest of the manufacturer's recommended seat back angle position that is intended for lounging. The infant hinged weight gauge is positioned with the hinge aligned over the seat bight line<sup>8</sup> and with the upper torso/head plate of the gauge on the seat back. The angle is measured with a digital protractor resting on the upper gauge area. The draft ASTM "Maximum Seat back Angle" is intended for lounging while the ISP "Maximum Seat Back/Sleep Surface Angle" is intended for sleep. As discussed in the Directorate for Engineering Sciences, Division of Human Factors memorandum, based on the scope pertaining to infant sleep, as defined in the draft proposed rule, staff recommends that loungers and infant support cushions should have a maximum incline angle that shall not exceed 10 degrees. However, staff recommends modifications to the requirement and test method for a maximum incline angle test to address more potential infant positions relative to the infant cushion product and improve test consistency across all infant support cushion products (Refer to Figure 9):

- Unlike inclined sleep products, infant support cushions do not typically have a defined seat and back. Staff recommends that a maximum 10-degree seat back angle requirement should apply to the foreseeable use in infant support cushions of the sides or a sidewall to support the head for reclining. The maximum incline angle requirement should apply to all manufacturer's recommended use positions, and also to all other infant cushion surfaces that can feasibly support an infant's head (OSS-head), including the angle from the sidewall (if present) to the OSS or from the OSS-head to the floor when no elevated sidewall is present or from sidewall to floor when an elevated sidewall is present.
- A second modification is to use the newborn hinged weight gauge ("newborn gauge") instead of the infant hinged weight gauge. The newborn gauge is lighter than the infant counterpart and presents a worse-case scenario because the lighter newborn gauge would cause the pillow to deflect less, creating a more inclined seat back angle.
- The third modification is a reasoned change to the placement of the newborn gauge. Staff proposes that the torso/head portion of the newborn gauge be positioned so that it rests against the top surface of the product, with the top edge of the torso/head portion positioned according to the use position of the product, and the hinge of the gauge to be supported on an OSS or test base, as appropriate, even if this positioning causes the hinge of the gauge to not align with the bight line or the lower portion of the gauge to rest on surfaces other than the OSS. The top edge of the upper portion of the newborn gauge should be aligned to the product according to whether the use position is inside or outside the product. For lounger products with an OSS and sidewalls, the top edge should be aligned plumb to the outside of the product as shown in Figure 9. For use positions in which the newborn gauge will rest on the test surface, such as for head cushions, the newborn gauge should be adjusted to the greatest incline angle in which the top edge of the gauge maintains contact with the top surface of the product.

The number of test locations should include the manufacturer's recommend use position(s), and a suitable number of locations that represent the feasible uses of the infant support cushion for inclined support. For example, in Figure 8 the newborn hinged weight gauge can represent the feasible locations for an infant resting with an inclined support if the gauge were placed on all four sidewalls, whether or not the manufacturer intends those placements.

---

<sup>8</sup> Seat bight: The intersection between the seat or occupant support surface and seatback or sidewall.



**Figure 9 Test Fixture Configuration to Measure Incline Angle on an Infant Lounger-type Product**

Based on staff's testing and analysis, these recommendations for positioning and using the newborn hinged weight gauge and the resulting maximum incline angle measurement better represent the positioning on the product for the youngest occupant. These recommended modifications of the maximum seat back angle requirement would also limit the heights of OSS-head surfaces for infant support cushion products, as discussed in Sidewall Height Measurement.

### **vii. Sidewall Height Measurement**

The draft ASTM requirement states that the height of the sidewall must be less than 4 in (10.2 cm), however CPSC staff is concerned, as discussed in the Division of Human Factors, Directorate for Engineering Sciences memorandum, that caregivers may judge that a product with 4 in. high sidewalls can safely contain an infant without supervision and may be used on an adult bed or in a crib despite instructional or product warnings. Staff also has concerns with the position of the infant's head and neck on or against the sides of products. Hazardous neck positioning, as described in the Directorate for Health Sciences, Division of Pharmacology and Physiology Assessment memorandum, is due to an infant's head resting on the sidewall with the body positioned either inside or, in the case of head cushions, outside of the product. Accordingly, CPSC staff recommends that side height requirement that addresses hazardous neck positioning and inclined sleep resulting from an infant's head being on the raised sidewall or side of a product.

For lounge-type products, the sidewall height is taken from the OSS-body of the product. For head cushions, the sidewall height is taken from the test base. The maximum sidewall height will depend on the type of product and firmness of the sidewall. In testing of products without side walls such as head cushions, the maximum "sidewall" heights were measured to be up to 3 in. (7.6 cm)<sup>9</sup>. Based on geometry of the newborn hinged weight gauge, staff calculated that the height for very firm products should be limited to approximately 1.9 in (4.8 cm)<sup>10</sup>.

Addressing the neck positioning hazards in this manner will also address the hazard that a side height of up to 4 inches may give caregivers the mistaken impression that the product can safely contain a child without supervision, because this will result in lower sidewall heights as explained above. Staff invite comments on an appropriate sidewall height to address the positional asphyxia hazard.

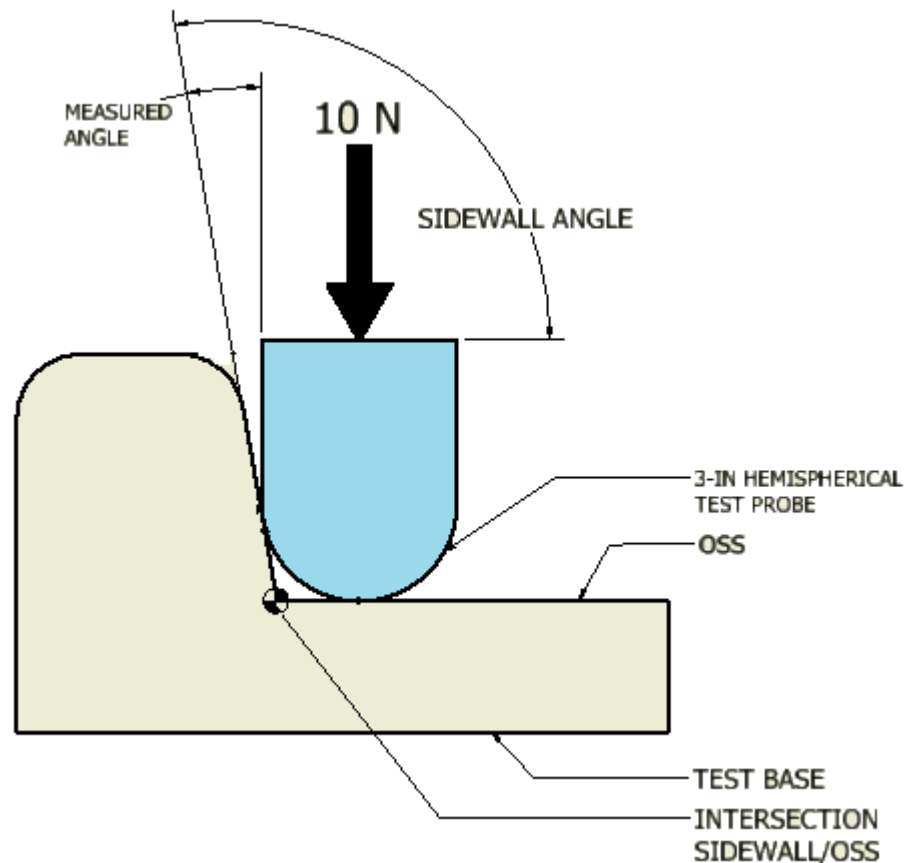
CPSC staff also considered an alternate test method for sidewall height. Further discussion of the alternate test method that was considered but is not recommended is in the Appendix.

### **viii. Sidewall Angle Measurement**

In lounge and head cushion products, the transition from the OSS to the sidewall varies from a small change in elevation (for example, samples 220 and 280 in Figure 1) to the abrupt rise of a sidewall (samples 400.410). Staff recommends a firmness requirement for this area, as described in Intersection of Sidewall and Occupant Support Surface Firmness. However, an additional concern that is not addressed through a firmness requirement alone is the suffocation hazard that a sidewall poses if it overhangs the OSS and encompasses part of the infant's face. In a draft ASTM requirement, the angle between the sidewall and the occupant support surface (OSS) must be greater than 90 degrees. The ASTM draft standard measures the angle with a protractor, or similar tool, every 4 in (10 cm) along the inside perimeter of the product. Staff agrees that the ASTM's 90-degree requirement for sidewall angle will address a suffocation hazard. However, staff proposes to modify the test method, so that (1) consistency of measurement is less affected by the typically irregular surfaces of the products, (2) angles are measured while the OSS has force applied to it that represents the infant's head weight, and (3) the angular assessment is accomplished using the 90-degree angle probe, such that sidewalls that lean away from the infant that is resting on the OSS are safer than sidewalls that lean in and over the infant. Staff's recommended test method is depicted in Figure 10, in which the 90-degree angle requirement for the sidewall is assessed using a 90-degree probe, specifically the cylindrical side of the 3-in probe, applied with a 10 N (2.2 lb) force and placed with the probe side tangent to the intersection of sidewall and OSS. Contact with the probe side by the product sidewall will constitute an angle equal to or less than 90 degrees and no contact will signify an angle greater than 90 degrees.

<sup>9</sup> For infant head cushions, that have no sidewall, the height of the product is measured.

<sup>10</sup> The minimum passing sidewall height would occur when the sidewall has no deflection under the weight of the newborn gauge in the incline angle test: trigonometrical, it is 11-inch times  $\sin(10 \text{ degrees}) = 1.91 \text{ in.}$ , or the vertical rise of the 11 -in. upper segment length of the newborn gauge at a 10-degree incline angle. The maximum sidewall height depends on the sidewall construction. No sample passed both proposed maximum incline angle and sidewall firmness tests. However, samples 220 and 230 (head cushions) are instructive as they had maximum incline angles near 10 degrees (220: 10.6 degrees; 230: 11.2 degrees), and their sidewall heights were 2.72 in. (sample 220) and 2.66 in. (sample 230), measured from the top of the sidewall to the test base.



**Figure 10 Test Fixture Configuration for Sidewall Angle Measurement**

#### **ix. Infant Restraints**

The draft ASTM performance requirements include a section entitled “Restraint” that prohibits “a restraint system Staff agrees that loungers and support cushions should not include restraint systems for infants because staff is aware of incidents in which infants have become entrapped in the restraints of similar products.

#### **x. Seam Strength**

Infant support cushions, as discussed in the Directorate for Economic Analysis memorandum, may be in use for several years, with multiple infants. Support for the product is intended to be on the floor. The seams of the infant support cushions secure the filling material that, if released, can be swallowed by the infant. Staff is aware of incidents involving seams opening and incidents in which infants accessed, and in some cases choked on, filling materials. The federal regulation, 16 CFR part 1250 has requirements that seams withstand a tension force of 10 lb (45 N) for an age category for intended infants of 0-18 months old and 15 lb (67 N) for 18–36-month-old infants. Because infant support cushions are durable infant products, the required force for testing the strength of seams should be at least as great or greater than that for toy products. Staff recommends that infant support cushions seams be tested with a tension force of 15 lb (67

N) applied with ¾ in. diameter clamping fixtures, based on the 16 CFR part 1250 tension test force for 18-month-old infants and using the specified clamping fixture.

#### **xi. Removal of Components**

Components include elements that provide a function to the product, such as zipper pulls and buttons, or provide protection to the infant from hazards. Removal of components can expose the infant to sharp points or edges or to choking hazards, including from the component itself. The draft ASTM voluntary standard's general requirements include a section entitled "Protective Components" that requires protective components may not be removed when subject to a "Removal of Protective Components Test." Staff assesses that, in addition to protective components, components on infant support cushions can include other possibly detachable parts, such as zipper tabs and buttons. If detached these parts can expose the infant to hazards such as choking, sharp points, and sharp edges. Staff recommends that infant support cushions have requirements for removal of components that are graspable by an infant and that present hazards if removed.

#### **xii. Bounded Openings**

Any completely bounded opening that is above the OSS or the floor may be a potential head entrapment hazard. These openings can include those created when attaching accessories products. An opening may present an entrapment hazard if the space between any interior opposing surfaces allows an infant's head to enter, but those same or other involved surfaces do not allow the head to be withdrawn. Head entrapment requirements are common in infant products. ASTM F406-22 *Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards* requires that if a small head probe can enter an opening in an accessory, a large head probe must also enter through the opening. The small head probe leads into an opening, while the large head probe represents the worst-case entrapment potential in the opening. Staff recommends that infant support cushions have entrapment requirements for bounded openings.

### **B. CPSC Staff's Recommended Test Methods**

Staff recommends the basic firmness requirement and test method developed by BSU, as modified by staff, the ASTM firmness test methods for occupant support surfaces, sidewalls, and intersection of OSS and sidewalls, and the sidewall height and angle and maximum incline angle requirements and test methods, as modified by staff, the ASTM infant restraint requirement, and other requirements. Staff's recommended general and performance requirements and test methods for infant support cushions appear in Tab F, Recommended Regulatory Text for the Draft Proposed Rule

## **IV. Testing**

Staff tested sample infant support cushions to assist in development of the test methods. Below we discuss the test results that support staff's recommendations for the draft NPR.

### A. Maximum Incline Angle and ASTM Sidewall Height Measurements

Table 2 contains staff's test results from testing to the draft ASTM sidewall height and CPSC maximum incline angle requirements for the CPSC samples. Maximum ASTM sidewall heights are required to be less than 4 in (10.2 cm). The CPSC maximum incline angle measurements are required to be less than 10 degrees. Passing tests are in green highlight. Results show that the draft ASTM Sidewall Height test method resulted in passing nine of ten samples. Two of ten samples (260, 270) passed the Maximum Incline Angle requirement. (An ASTM test method for maximum incline angles is more narrowly defined than the CPSC staff test method and applies to none of the CPSC samples). The CPSC limit to Maximum Sidewall Height results were not determined because none of the samples passed both the sidewall firmness and the maximum incline angle requirements, both of which affect sidewall height. These results indicate that the Maximum Incline Angle requirement, which is affected by the sidewall height and firmness is a more stringent requirement than the ASTM Sidewall Height requirement alone.

**Table 2. Sample Maximum Incline Angle Measurements and ASTM-CPSC Sidewall Heights Comparisons**

Sample	ASTM Max. Sidewall, Height (in)	CPSC, Limit to Max. Sidewall Height* (in)	CPSC Max. Incline Angle (degrees)	Comment
220	2.72	n/a	10.6	Gauge on top of side
230	2.66	n/a	11.2	Gauge on top of side
240	3.91	n/a	42.2	Hinge at bight line
250	3.23	n/a	28.2	Gauge at edge
260	1.66	n/a	1.6	Gauge at edge
270	1.86	n/a	4.6	Gauge at edge
280	3.39	n/a	22.8	Gauge at edge
310	3.93	n/a	42.5	Hinge at bight line
400	3.17	n/a	21.4	Gauge at edge
410	4.13	n/a	13.5	Gauge at edge

\*The CPSC sidewall height limit pertains to samples that pass both the sidewall firmness and maximum incline angle requirements. No samples passed both requirements.

### B. Sidewall Angle Measurements

Table 3 shows test results for the sidewall angles of the samples. Staff assessed sidewall angles by adding the measured angle from the vertical side of the cylindrical 3-in probe to the sidewall according to the staff recommended method, and as depicted in Figure 10. Staff's recommendation is that the sidewall angle be greater than 90 degrees to address the suffocation hazard of the envelopment of the infant's face into a sidewall overhang. Results show that two of ten samples failed to comply with the sidewall angle requirement. A failure means that an infant could suffocate because the face can become enveloped into the space between the sidewall and OSS, even if not forced into that area, as addressed in the Intersection of Sidewall and OSS firmness requirement.

**Table 3. Sample Maximum Sidewall Angle Measurements**

Sample	Sidewall Angle (degree)	Compliance	Angle Bisect	Comment
220	130	Pass	65	
230	140	Pass	70	
240	120	Pass	60	
250	120	Pass	60	
260	150	Pass	75	
270	130	Pass	65	
280	120	Pass	60	
310	130	Pass	65	
400	=/< 90	Fail	45	90° is failure
410	=/< 90	Fail	45	90° is failure

### C. Firmness Test Results, Occupant Support Surface

Table 4 displays results of the OSS firmness test. Staff measured Occupant Support Surface firmness as the force to deflect the surface 1.0 in (2.54 cm) using the 3-in hemispherical probe oriented vertically, according to the staff recommended method, and as depicted in Figure 6. Staff recommends a force greater than 10 N (2.2 lb) to address the suffocation hazard due to soft surfaces. Results show that nine of the ten samples failed to comply with all the firmness requirements. Sample 410 passed the test because the thickness of the OSS was less than 1.00 in (2.54 cm). The failures mean that an infant could suffocate in those OSS surfaces.

**Table 4. Sample Firmness Results Occupant Support Surface**

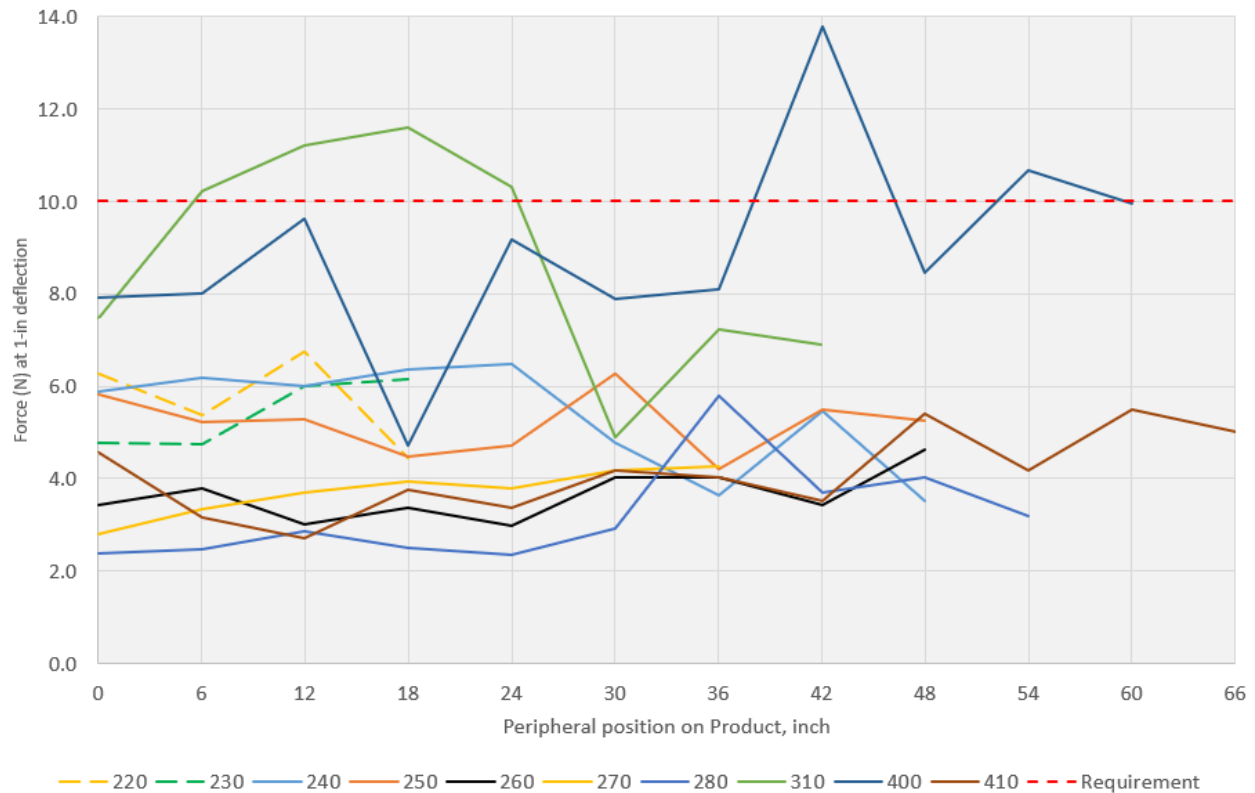
Sample	Maximum Force (N)	Minimum Force (N)	Deflection Set to (in)	All Locations Compliance	Comment
		10.0	1.00		Requirement: > 10 N at 1.0 in deflection
220	6.92	6.92	1.00	Fail	
230	8.15	8.15	1.00	Fail	
240	5.11	3.65	1.00	Fail	
250	5.90	3.09	1.00	Fail	
260	5.32	3.63	1.00	Fail	
270	4.96	2.70	1.00	Fail	
280	6.47	4.02	1.00	Fail	
310	7.57	6.21	1.00	Fail	
400	4.00	3.34	1.00	Fail	
410	16.02	10.63	0.5	Pass	Force > 10 N at < 1.0 in deflection

### D. Firmness Test Results, Sidewall

Table 5 displays the sidewall firmness test results. Staff measured sidewall firmness as the force to deflect the surface 1.0 in (2.54 cm) using the 3-in hemispherical probe oriented vertically, according to the staff recommended method. Staff recommends a force greater than 10 N (2.2 lb) to address the suffocation hazard due to soft surfaces. Results show that all ten samples failed to comply with all the firmness requirements. Two samples (310, 400), although they failed, were sufficiently firm at some test locations, as shown in Figure 11. The failures mean that an infant could suffocate in those sidewall surfaces.

**Table 5. Sample Firmness Results - Sidewall**

Sample	Maximum Force (N)	Minimum Force (N)	Deflection Set to (in)	All Locations Compliance	Comment
		10.0	1.00		Requirement: > 10 N at 1.0 in deflection
220	6.75	4.45	1.00	Fail	
230	6.15	4.75	1.00	Fail	
240	6.47	3.52	1.00	Fail	
250	6.27	4.20	1.00	Fail	
260	4.64	2.98	1.00	Fail	
270	4.27	2.79	1.00	Fail	
280	5.78	2.35	1.00	Fail	
310	11.6	4.91	1.00	Fail	Mixed result
400	13.7	4.71	1.00	Fail	Mixed result
410	5.49	2.72	1.00	Fail	



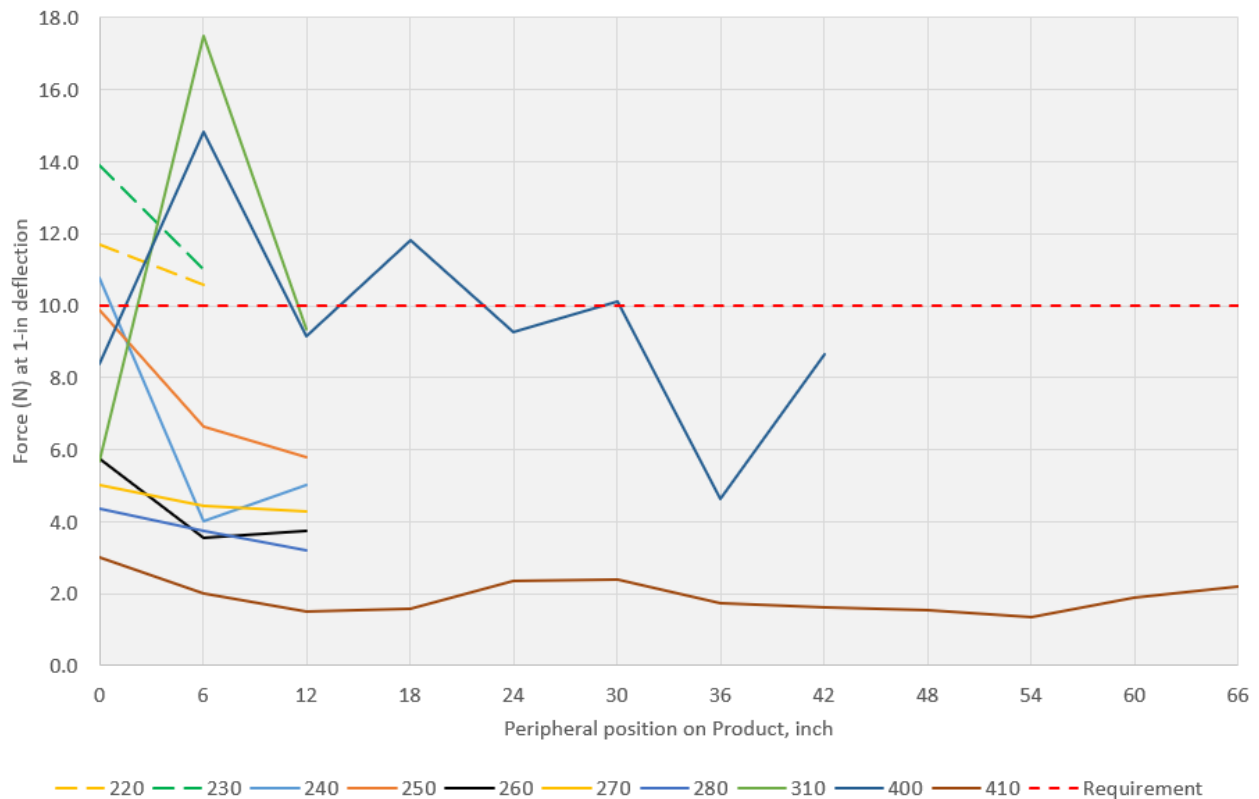
**Figure 11 Sidewall Firmness Results**

### **E. Firmness Test Results, Intersection of Sidewall and Occupant Support Surface (OSS)**

Table 6 displays the intersection of sidewall and OSS firmness test results. Staff measured firmness at the intersection of sidewall and OSS as the force to deflect the surface 1.0 in (2.54 cm) using the 3-in hemispherical probe oriented at an angle, determined according to the staff recommended method, and as depicted in Figure 7. Staff recommends a force greater than 10.0 N (2.24 lb) to address the suffocation hazard due to soft surfaces. The probe orientation was set to the bisecting angle from horizontal, which was determined as one half the angle measured in the Maximum Sidewall Angle measurement, shown in Table 3. Results show that eight of the ten sample intersections failed to comply with all the firmness requirements. Samples 220 (10.6 N, 4.7 lb) and 230 (11.0 N, 4.9 lb) are head support cushions that complied with the firmness requirements. Three samples (240, 310, 400), although they failed, were sufficiently firm at some test locations, as shown in Figure 12. The failures mean that an infant could suffocate when the face is forced into the intersection of the sidewall and the OSS.

**Table 6. Sample Firmness Results, Intersection of Sidewall and OSS**

Sample	Maximum Force (N)	Minimum Force (N)	Deflection Set to (in)	All Locations Compliance	Comment
		10.0	1.00		Requirement: > 10 N at 1.0 in deflection
220	11.7	10.6	1.00	Pass	Head Cushion
230	13.9	11.0	1.00	Pass	Head cushion
240	10.76	4.01	1.00	Fail	Mixed result
250	9.90	5.79	1.00	Fail	
260	5.75	3.55	1.00	Fail	
270	5.02	4.29	1.00	Fail	
280	4.35	3.20	1.00	Fail	
310	17.49	5.66	1.00	Fail	Mixed result
400	14.82	4.62	1.00	Fail	Mixed result
410	3.00	1.35	1.00	Fail	

**Figure 12 Intersection of Sidewall and OSS Firmness Results**

## V. Conclusion

LSM staff recommends for the draft NPR general and performance requirements for infant support cushions and infant loungers that are based on draft requirements developed by the ASTM F 15.21 Infant Loungers Performance Subcommittee and CPSC staff, and on the information and analysis in the published contract report by Boise State University that studied infant suffocation in infant loungers and support cushions. Staff concludes that the firmness and associated requirements and test methods, as set forth in the BSU report reduce the suffocation and other hazards associated with the use of loungers and infant support cushions. Staff recommends a set of firmness requirements for product surfaces that an infant may contact while on the product, and general requirements for the dimensions of that contact.

## Appendix

### Alternative Sidewall Height Method

To develop a safer sidewall requirement, while maintaining ASTM's 4-in height requirement, staff considered that the method to measure the side height could be improved to produce a more realistic height to which the infant is exposed. The BSU anthropometric 3-in hemispherical probe, which is already used for the draft ASTM firmness tests, could be used in measuring side height and replace the 0.25 in thick by 6 in by 6 in plate in the ASTM method. More importantly, the hemispherical probe can apply a relevant force through an anthropometric shape. Applying a force to the OSS would increase the measured sidewall height. Staff applied the 10 N (2.24 lb) force from the OSS firmness test method. Comparing the results of testing using the ASTM height testing method and testing using CPSC staff's height testing method shows that the CPSC staff method results in higher measured sidewall heights. This is because the additional deflection distance of the OSS by the 10 N force on the 3-in probe yields a higher total height measurement using the CPSC test method. Accordingly, for a certain sidewall on a product that has a height near the 4-in height limit, the height measured by the ASTM method can be less than 4 in and pass the requirement, as compared to the height measured by the more realistic CPSC staff method, which can be more than 4 in and fail the requirement. These products would therefore need to be redesigned with lower sidewalls to comply with the 4-in requirement, which would result in products with less perceived utility for unattended sleeping and therefore safer for infants.

In the alternate CPSC method, the side of the 3-in probe is vertical and tangent to the intersection of sidewall and OSS, and a 10 N (2.2 lb) force is applied. The measured height is taken from the base of the hemisphere to the top of the sidewall. Because the draft ASTM test method does not specify testing locations, staff chose a minimum of four sidewall height measurements that should be taken at intervals not to exceed 6 in (15.2 cm).

Test results for Maximum Incline Angles are included in this discussion to show the similar levels of compliance of the samples to the alternate CPSC sidewall height requirement. The height requirement can be another distance. The 4.0 in requirement is used to assess the ASTM and this alternate CPSC test methods. Staff seeks comments on whether and what appropriate sidewall height would sufficiently address the hazard of positional asphyxia for a potential alternative sidewall or OSS height requirement.

### Requirement

The sidewall height shall not exceed 4.0 in (10 cm) when tested to Sidewall Height Measurement.

### Sidewall Height Test Method

a. Orient the 3-in (7.62 cm) diameter hemispherical head probe (Figure A1) vertically and place the probe over the occupant support surface with the cylindrical surface of the probe tangent to the intersection of the sidewall and the OSS. Advance the probe onto the product and set the

deflection to 0.0 in when a force of 0.1 N (0.02 lb) force is reached. Apply a 10 N (2.2 lb) downward force.

b. After 30 s, measure the sidewall height as the vertical distance from bottom of the probe to the top of the adjacent side wall. Measure a minimum of four sidewall heights at intervals not to exceed 6 in (15.2 cm) along the intersection of the sidewall and the OSS.

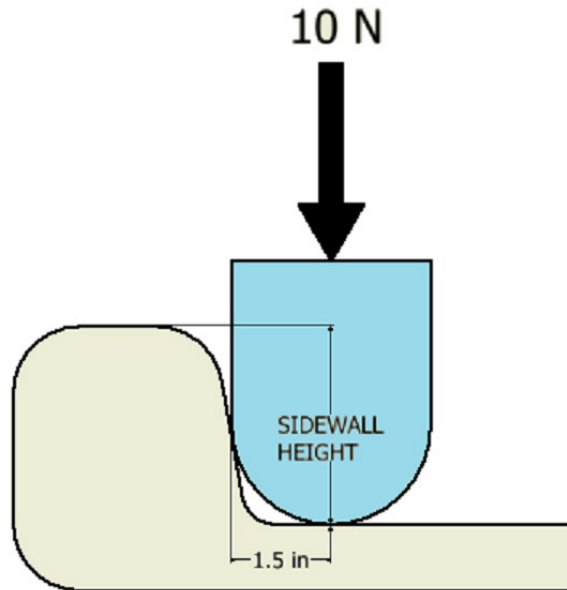


Figure A1 Alternate Sidewall Height Measurement

Test results of maximum sidewall heights and maximum incline angles for the CPSC samples are shown in Table A1. Maximum sidewall height measured by either the ASTM Sidewall Height method or this alternative CPSC sidewall height method is required to be less than 4 in (10.2 cm). Maximum incline angles measured by the recommended Maximum Incline Angle test method are required to be less than 10 degrees. Passing tests are in green highlight. Testing shows that the draft ASTM test method resulted in lower side height measurements and that seven of eight samples passed compared to the two samples that passed the CPSC staff's alternative test method. That is, most of the samples would not pass according to the CPSC test, but most would pass according to the ASTM test. The testing also shows that the maximum side height measurements that passed the CPSC requirement (samples 260 and 270) correspond to the same two samples that passed the CPSC staff's requirement for maximum incline angle. For the later reason, the Maximum Incline Angle test achieves similar results and therefor supersedes this alternative CPSC Sidewall Height test method.

**Table A1 Sample Sidewall Height and Maximum Incline Angle Measurements**

Sample	CPSC Method, Max. Height (in)	ASTM Method, Max. Height (in)	CPSC minus ASTM (in)	CPSC Max. Incline Angle (degrees)	Comment
410	4.46	4.13	0.33	13.5	Gauge at edge
310	4.90	3.93	0.97	42.5	Hinge at bight line
240	5.29	3.91	1.38	42.2	Hinge at bight line
280	4.93	3.39	1.54	22.8	Gauge at edge
250	4.64	3.23	1.41	28.2	Gauge at edge
400	4.65	3.17	1.48	21.4	Gauge at edge
270	3.43	1.86	1.57	4.6	Gauge at edge
260	3.24	1.66	1.58	1.6	Gauge at edge

# **TAB D: Human Factors Review of Incident Data and Recommended Requirements for Infant Support Cushions**



## Memorandum

**TO:** Stefanie Marques, Ph.D., Project Manager Infant Pillow NPR  
Directorate for Health Sciences

**DATE:** November 8,  
2023

**THROUGH:** Mark E. Kumagai, Associate Executive Director,  
Directorate for Engineering Sciences

Rana Balci-Sinha, Ph.D., Director,  
Division of Human Factors, Directorate for Engineering Sciences

**FROM:** Celestine T. Kish, Senior Engineering Psychologist  
Division of Human Factors, Directorate for Engineering Sciences

Timothy P. Smith, Senior Human Factors Engineer,  
Division of Human Factors, Directorate for Engineering Sciences

**SUBJECT:** Human Factors Review of Incident Data and Recommended Requirements for  
Infant Support Cushions

---

### I. Introduction

In June 2022, ASTM International (ASTM) began the process of developing a voluntary standard for “Infant Loungers,” which will contain requirements for various pillow-like infant products intended for infants during awake time, specifically not for sleep. Although ASTM has not yet published the voluntary standard, the draft voluntary standard includes performance requirements for these products, as well as product and packaging marking requirements, which include requirements for warnings that must appear on loungers covered by the standard. The draft voluntary standard also includes requirements for instructional literature to accompany products covered by the standard.

The Consumer Product Safety Commission (CPSC or Commission) staff is preparing for Commission consideration a draft proposed rule on infant support cushions under section 104 of the Consumer Product Safety Act of 2008 (CPSIA) that is based, in part, on the draft voluntary standard for infant loungers.

This memorandum, prepared by staff of CPSC’s Directorate for Engineering Sciences, Division of Human Factors (ESHF), reviews the available incident data involving infant support cushions, including relevant use patterns, discusses human factors issues pertaining to the ASTM draft voluntary standard’s draft performance, warning, and instructional requirements, and provides recommendations for the infant support cushions proposed rule.

## II. Discussion

Infant loungers typically are identified as pillows or mat cushions intended to support an infant while sitting, lying, reclining, or resting. They are also lightweight and portable. While ASTM's draft standard indicates that loungers are intended for use with adult supervision and are not marketed for sleep, numerous "lounger" products available for online purchase specifically state, or show in marketing photographs, that infant loungers and pillows are for use by infants while sleeping. Due to the differences in the scope of the proposed ASTM standard and staff's recommended scope as described in the draft proposed rule, staff invites comments for in-scope and out-of-scope products. In particular, staff is aware that some infant products, such as bouncers, rockers, and swings, are designed with permanently attached infant support pillows. Staff encourages comments on whether these products should also be included in this rule, or just support cushions sold independent of these and other products.

Used infant support cushions are sometimes available from secondary marketplaces such as eBay. For example, at 2:30pm on June 16, 2023, CPSC staff performed a simple search in eBay using phrases "infant head positioner", "infant lounger", "baby lounger", "wedge pillow" infant", "sleep positioner" baby ", "sleep positioner" infant", "infant pillow", and "baby pillow" and filtered the results by selecting "used" as the condition of the product. Staff found that portion of used products ranged from zero percent for "infant head positioner" and "wedge pillow" to 45 percent for the phrase "infant lounger". This suggests that consumers perceive certain infant support cushions as having a future useful life beyond the initial infant user. In addition, consumers who anticipate having multiple children are likely to retain the infant support cushion for future children. Some manufacturers facilitate such reuse by selling replacement outer covers that further extend the useful life of infant support cushions.

In their 2022 Updated Recommendations for a Safe Infant Sleeping Environment, the American Academy of Pediatrics (AAP) states that it is not safe to place soft materials or objects, such as pillows (including semi-circular or other nursing pillows), quilts, comforters, or fur-like materials, even if covered by a sheet, under a sleeping infant (Moon et al., 2022).

Further, the AAP<sup>1</sup>, along with the CPSC<sup>2</sup> and the FDA, warns against the use of positioning products. This is due to the lack of evidence showing these products to be effective against SIDS, suffocation, or gastroesophageal reflux and because of suffocation and entrapment risks. If positioning devices are used in the hospital as part of physical therapy, they should be removed from the infant sleep area well before discharge from the hospital (Moon et al., 2022).

### A. Review of Incident Data

As staff of CPSC's Directorate for Epidemiology, Division of Hazard Analysis (EPHA), discusses in Tab A, staff identified a total of 204 incidents/reports associated with the use of infant support cushions in the CPSC epidemiological databases from January 1, 2010, through December 31, 2022. The data included 79 fatal incidents and 125 non-fatal reports. The dispositions of the 125 non-fatal reports are comprised of 22 emergency department-treated injuries, 3 hospital

<sup>1</sup> [https://publications.aap.org/aapnews/article/31/11/27/23431/Infant-sleep-positioners-pose-suffocation-risk?\\_ga=2.136139320.863140124.1684349484-1986427679.1684349484](https://publications.aap.org/aapnews/article/31/11/27/23431/Infant-sleep-positioners-pose-suffocation-risk?_ga=2.136139320.863140124.1684349484-1986427679.1684349484) (Last accessed September 2023).

<sup>2</sup> Deaths prompt CPSC, FDA warning on infant sleep positioners <https://www.cpsc.gov/Newsroom/News-Releases/2010/Deaths-prompt-CPSC-FDA-warning-on-infant-sleep-positioners> Last accessed September 2023.

admissions, 1 victim leaving before being seen, 1 victim was seen by a medical professional, 46 reports where no injury occurred, and 52 reports with either an unknown or unspecified disposition.

#### Fatal incidents:

Of the reported 79 fatalities, 49 had an official cause of death of asphyxia/probable asphyxia (62% of the total), 13 fatalities were determined to be sudden unexplained infant death (SUID) events (17% of the total), 12 fatalities had either an undetermined or unknown cause of death (15% of the total), and for 5 of the fatalities, the medical examiner report was unavailable (6% of the total). Infants in the 0-3 months age range accounted for 80 percent of all pillow-related fatalities.

Following is scenario-specific information indicating the placement of the decedents:

- 34 decedents were placed on infant pillows in an adult-sized bed;
- 25 decedents were placed on an infant pillow in a crib/bassinet;
- 8 decedents were placed on an infant pillow inside a play yard;
- 3 decedents were placed on an infant pillow on top of a couch/futon;
- 4 decedents were placed on an infant pillow on either a mat or on the floor; and
- 1 decedent was placed on an infant pillow inside a toddler bed.

Decedent placement in 4 fatalities was either undetermined or unknown.

Among the 79 fatalities, staff was able to discern that the subject products were used for sleep in at least 74 incidents. Of the 79 fatalities, 71 were placed on top of a couch or on adult bed, inside a crib/bassinet, play yard or toddler bed. Staff observed bedsharing with caregivers or siblings in at least 27 fatal incidents. As discussed in the Division of Pharmacology and Physiology, Directorate for Health Sciences (HSPP) memorandum (Tab B), HSPP staff identified positional asphyxia/suffocation as a fatal risk factor associated with infant support cushions. Staff notes that many narratives specifically describe scenarios where the infant pillow was being used as an in-bed sleeper/bassinet to facilitate bed sharing.

In 63 of the fatalities, staff categorized the product as a lounger; in five incidents, staff categorized the product as a pillow; in 10 incidents, staff categorized the product as a sleep positioner, and in one incident, the product was a wedge. Given the foreseeability of these products being used for sleep, staff recommends that performance, warning, and labeling requirements be applied to all products within the scope of the proposed rule.

#### Nonfatal incidents:

Among nonfatal incidents, CPSC received 29 reports (23% of the total) of a victim being placed on elevated and soft surfaces including adult beds (9), couches (6), cribs (2), an ottoman (1), and a chair (1), as well as elevated and hard surfaces such as countertops and tables (5) while on top of an infant pillow and falling off, 27 reports of a victim experiencing threatened asphyxia (22% of the total), and 17 reports of a victim receiving a rash from the product (14% of the total). Reports of limb entrapment, mold, choking, near strangulation, and vomiting all had one report

each (1% of the total for each report). CPSC received 47 additional complaints (38% of the total) from consumers regarding infant pillows, however, no incident was clearly indicated.

## **B. ASTM Standard Development and Staff Recommendations for the Proposed Rule**

In January 2022, ASTM formed an Infant Loungers subcommittee. This subcommittee is in the process of developing a voluntary standard for “infant loungers.” However, as of the writing of this memo, a draft voluntary standard for these products has not yet been balloted or published.

### Side Height and Surface Angle Performance Requirements

The ASTM draft voluntary standard currently allows infant loungers to have a maximum side height, relative to the occupant support surface, of under 4 inches. Staff is concerned that a side wall with a height of up to 4 inches may give caregivers the impression that the product can safely contain a child without supervision, regardless of what the product warnings might say. The presence of a distinct, raised perimeter surrounding the occupant support surface, as observed in various products on the market, provides a visual cue to consumers that the infant is safely contained in the product. Infant loungers currently marketed for sale often display images of infants sleeping or resting in such products, and thus convey the appearance of effective containment for purposes of sleep. Despite the fact that most of these infant loungers would fail the requirements in the Safety Standard for Infant Sleep Products (the ISP Rule), 16 C.F.R. part 1236, staff assesses that infant loungers are likely to continue to be used by caregivers for sleeping and napping. For this reason, staff recommends an alternative performance requirement for the angle of the seat back/occupant support surface along the occupant’s head to toe axis, relative to the horizontal, not to exceed 10 degrees; this is the same requirement that appears in the ISP rule.

In addition, because the infant support cushions are designed to support all or part of an infant’s body, it is likely the user’s head will be placed on any side of the product. In this position, with a side height greater than 4 inches an infant could potentially be at a compromised angle that would interfere with breathing. Therefore, staff recommends that the same angle restriction be required from side/sidewall to the occupant support surface as well as from floor to the side/sidewall and from floor to the occupant support surface. Staff invites comments on an appropriate sidewall height to address potential positional asphyxia hazards. As discussed in the Laboratory Sciences Mechanical Engineering memorandum (Tab C), CPSC staff recommends additional requirements such as firmness of the occupant support surface and sidewalls and a sidewall angle measurement to improve the safety of infant support cushions.

### Warning and Instructional Requirements

Safety and warnings literature consistently identify a classic hierarchy of approaches that should be followed to control product-associated hazards. Warning about hazards is viewed universally as less effective at eliminating or reducing exposure to hazards than either designing the hazard out of a product or guarding the consumer from the hazard; therefore, the use of warnings is lower in the hazard-control hierarchy than the other two approaches (Laughery & Wogalter, 2011; Vredenburg & Zackowitz, 2005; Wogalter, 2006; Wogalter & Laughery, 2005). Warnings are less effective than the alternatives because they rely on educating consumers about the

hazard, and then persuading consumers to alter their behavior in some way to avoid the hazard. To be effective, warnings also depend on consumers behaving consistently, regardless of situational or contextual factors that influence precautionary behavior, such as fatigue, stress, or social influences. Thus, one should view warnings as a measure that supplements, rather than replaces, redesign or guarding efforts, unless these higher-level, hazard-control efforts are not feasible.

The current draft of the ASTM voluntary standard for Infant Loungers includes marking and labeling requirements, which include requirements for warnings that must appear on infant lounger products covered by the standard. Figure 1 shows the draft standard's proposed warning statements that must appear on all infant loungers, formatted to be consistent with the design, or format, requirements that also are specified in the draft standard.

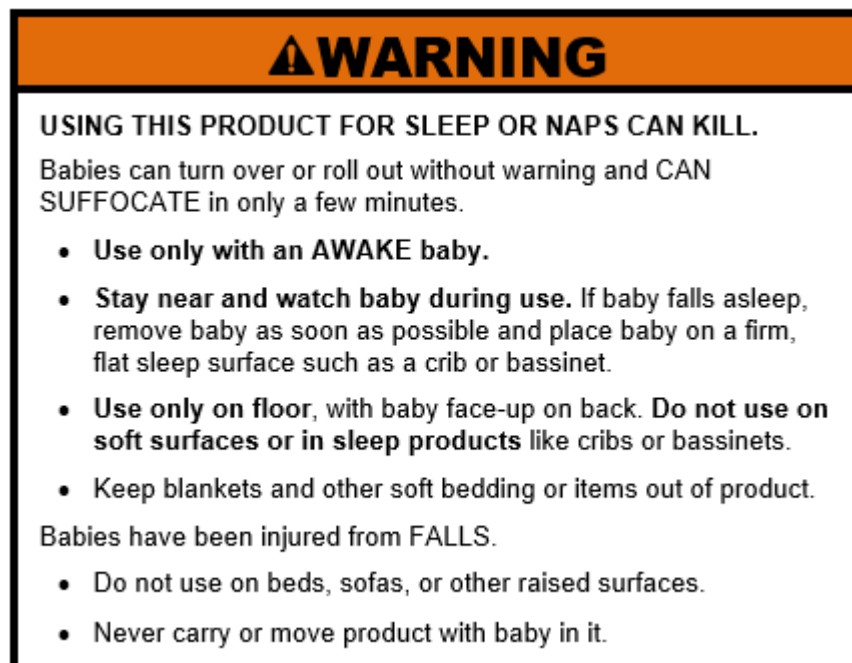


Figure 1 Draft Infant Lounger Warning Label

The draft voluntary standard also includes requirements for instructional literature to accompany products covered by the standard. These requirements state that the instructional literature that accompanies infant loungers must include the warnings on the product, as well as the following additional warnings:

- Read all instructions before using this product.
- Keep instructions for future use.
- Do not use this product if it is damaged or broken.

The instructions also must indicate the manufacturer's recommended maximum weight, height, age, developmental level, or combination thereof, of the infant. If the product is not intended for use by a child for a specific reason, the instructions must state this limitation.

### On-Product Warning Requirements

CPSC staff worked with the ASTM Infant Loungers subcommittee to develop the on-product marking requirements in the draft standard and support the use of the warning content and format requirements for products within the scope of the draft voluntary standard. However, manufacturers of infant support cushions, as defined for the NPR, should not expect to be exempted from this draft proposed rule simply by using a warning label that indicates the product is not for sleep. As noted above, a warning label is the last means of changing a consumer's behavior. If the warning contradicts consumers' experiences, consumers tend to rely on their own knowledge and disregard the warning.

CPSC does not support the use of infant loungers, or other products within the scope of the draft proposed rule, for sleep.<sup>3</sup> Thus, staff recommends the same warning to be present for all infant support cushions.

ESHF staff also recommends that the proposed rule include:

- a requirement for the warning to be conspicuous, and a definition of "conspicuous" that clarifies the required placement of the warning on the product, in terms of when the warning must be visible to the consumer; and
- warning permanence requirements and test methods that are consistent with other ASTM juvenile products standards.

The following subsections describe staff's rationale for the proposed warning requirements.

### Warning Content

The primary U.S. voluntary consensus standard for product safety signs and labels, ANSI Z535.4, *Product Safety Signs and Labels*, and other literature and guidelines on warnings (e.g., Robinson, 2009; Wogalter, 2006; Wogalter, Laughery, & Mayhorn, 2012), consistently recommend that on-product warnings include content that addresses the following three elements:<sup>4</sup>

- a description of the hazard;
- information about the consequences of exposure to the hazard; and
- instructions regarding appropriate hazard-avoidance behaviors.

As mentioned in staff's review of the incident data, the primary hazards associated with the use of infant loungers are asphyxia, or suffocation, and to a lesser extent, falls. Virtually all fatal incidents involved asphyxia or possible asphyxia, as well as consumers placing infants in or on the product for sleep.

Staff's proposed warning content pertaining to the hazard and its consequences directly addresses these issues. Specifically:

---

<sup>3</sup> [Baby Safety Tips | CPSC.gov](https://www.cpsc.gov/Baby-Safety-Tips)

<sup>4</sup> All three elements may not be necessary in some cases, such as if certain information is open and obvious or can be readily inferred by consumers; however, people often overestimate the obviousness of such information to consumers.

- The warning begins with the statement, “USING THIS PRODUCT FOR INFANT SLEEP OR NAPS CAN KILL.” This statement immediately communicates to consumers the potential deadly consequences of using infant support cushions within the scope of the rule for sleep, which is the primary use pattern that has resulted in fatalities with these products. Beginning the warning with an explicit, succinct, and strongly worded description of the usage pattern that often leads to death, printed in all-uppercase lettering, is necessary. The references not only to “sleep” but also to “naps” prevent consumers from concluding that the hazard only applies to cases where the product is used for overnight sleep.
- The warning further explains the hazard and potential consequences with the statement, “Babies can turn over or roll out without warning and CAN SUFFOCATE in only a few minutes.” Staff concludes this statement is needed to clarify how infants are dying (“CAN SUFFOCATE”) and to communicate not only the mechanism by which infants are suffocating, but the unpredictability and speed with which such incidents can occur. Information about the imminence of the suffocation hazard is often lacking in the warnings on existing products and may not be obvious to consumers. The features of staff’s proposed warning should provide consumers with a better understanding of the speed with which suffocation can occur when infants are left unattended in these products and are likely to increase consumers’ motivation to comply with the warning message.<sup>5</sup>
- The warning includes a statement that alerts consumers that “Babies have been injured from FALLS.” Falls are the most common incidents resulting in injury, and staff concludes that warning statements pertaining to this hazard are necessary. Nevertheless, this hazard is less severe and common than the suffocation hazard; thus, staff has positioned the associated warning messages near the bottom of the warning. A description of the additional fall-related warning content appears below.

CPSC staff and members of the ASTM Infant Loungers subcommittee discussed the key actions that consumers should take, or avoid, to prevent suffocation when using an infant lounger. Based on the available incident data, key actions include not using the product for sleep, not leaving the infant unattended in the product, using the product only on the floor and not in sleep products, and keeping soft bedding out of the product. Staff’s proposed warning content addresses these and other issues relevant to infant support cushions within the scope of the rule:

- The warning emphasizes the importance of using infant support cushions within the scope of the rule only with infants who are awake. Warnings for products that are not intended for sleep often tell consumers not to use the product for sleep, and the initial statement of staff’s proposed warning (“USING THIS PRODUCT FOR INFANT SLEEP OR NAPS CAN KILL”) already strongly indicates that consumers should not use the product this way. However, given that this is the primary suffocation avoidance behavior that consumers can take, explicitly addressing this behavior after the hazard description is important. Staff has written this statement in a more positive, or affirmative, form—that is, “Use only with an AWAKE baby”—to further reinforce the message that the infant should be *awake* during use and to remove all doubt about whether consumers could make exceptions for napping, as opposed to overnight sleep. Recognizing that consumers are likely to be presented with scenarios where the infant falls asleep during use, a follow-up sentence reinforces the safe-sleep message that consumers should move the infant to a firm, flat sleep surface if the infant falls asleep after feeding. This

---

<sup>5</sup> For example, the imminence of a hazard tends to increase the perceived threat associated with that hazard (Gass & Seiter, 1999), which is more likely to lead to compliance with the warning.

language is generally consistent with language developed by the ASTM Ad Hoc Language task group<sup>6</sup>

- The warning includes statements that explicitly address leaving the infant unattended in the product. Specifically, the warning tells consumers to stay near and watch the baby during use of the product. As staff noted in its review of the incident data, reported fatalities with infant loungers often involved consumers using the product to prop up the infant within a sleep product, and common sleep products involved in these incidents include cribs, portable playpens or play yards, and bassinets. Thus, the warning includes a statement warning against using infant support cushions in sleep products in general, with cribs and bassinets called out as specific examples. Beds were another common sleep-related product in which infant support cushions were used. Nearly all fatalities involved infant sleep and involved the infant lounger or pillow being used for lounging or sleeping.
- The warning includes a clear and concise statement telling consumers to use the product only on the floor with the baby face-up on its back and to not use on soft surfaces or in sleep products like cribs and bassinets. Staff notes that in 75 of the 79 fatalities where the location of the incident product was known, all were placed in or on another product such as adult bed (34), crib (11), play yard (11), bassinet (9), or other (couch, futon, toddler bed, portable crib) and only four were placed on the floor.
- The warning includes keeping blankets and other soft bedding and other soft items out of the product. At least 58 fatalities involved the lounger or pillow being used on sleep surfaces with bedding, blankets, and other support cushions, which may have contributed to the suffocation hazard.
- Nonfatal injuries from falls most frequently involved placing the infant in the product atop an elevated surface. Thus, the primary hazard-avoidance statement related to falls instructs consumers not to use on beds, sofas, or other raised surfaces. Beds and sofas, or couches, are identified explicitly because they are the most common elevated surfaces involved in these types of falls. The final warning pertaining to falls ends by telling consumers never to carry or move the product while the baby is in the product.

### Warning Format

When assessing the adequacy of a warning, one must consider not only the content of a warning, but also its design or “form” (Laughery & Wogalter, 2006; Madden, 1999; Madden, 2006). The current draft of the ASTM Infant Loungers voluntary standard includes warning format requirements that are consistent with the recommendations of the ASTM Ad Hoc Language Task Group. Since 2016, ASTM juvenile products standards have begun adopting warning format requirements that are consistent with the recommendations of this task group, which ASTM formed to develop standardized language across ASTM juvenile products standards, and which has developed recommendations for a consistent warning format to be applied to these products. One of the authors of this memorandum is a member of the Ad Hoc TG and serves as the CPSC staff representative on the ANSI Z535 Committee on Safety Signs and Colors, which publishes the Z535 series of voluntary standards, including ANSI Z535.4, *Product Safety Signs and*

---

<sup>6</sup> The ASTM Ad Hoc Language Task Group was formed to develop standardized language across ASTM juvenile products standards. This task group is discussed more in the next, *Warning Format*, subsection. The latest version of the Ad Hoc-approved recommended language is published in the “Committee Documents” section of the Committee F15 ASTM website.

*Labels*.<sup>7</sup> ESHF staff collaborated with the other members of the ASTM Ad Hoc Language Task Group to develop recommendations for warning format that are based primarily on the requirements of ANSI Z535.4, *Product Safety Signs and Labels*, while also accounting for the wide range and unique nature of durable nursery products, the concerns raised by industry representatives, and ESHF staff recommendations associated with durable nursery product rulemaking projects over the past several years. These recommendations include requirements for:

- content that is “easy to read and understand,” not contradicted elsewhere on the product, and in English, at a minimum;
- conformance to the following sections of ANSI Z535.4 – 2011, *Product Safety Signs and Labels*:
  - ANSI Z535.4, sections 6.1–6.4, which include requirements related to safety alert symbol use, signal word selection, and warning panel format, arrangement, and shape;
  - ANSI Z535.4, sections 7.2–7.6.3, which include color requirements for each panel; and
  - ANSI Z535.4, section 8.1, which addresses letter style;
- minimum text size and text alignment; and
- the use of bullets, lists, outline, and paragraph form for hazard-avoidance statements.

The Ad Hoc TG recommendations also include recommended text for general labeling issues, such as labeling permanency, and content related to manufacturer contact information and date of manufacture. As staff pointed out earlier, the latest version of the Ad Hoc-approved recommended language is published in the “Committee Documents” section of the Committee F15 ASTM website.<sup>6</sup>

### Warning Placement

The draft ASTM Infant Loungers voluntary standard would require the warning label for in-scope products to be “conspicuous.” Numerous ASTM juvenile products standards specify the placement of product warnings by including a requirement for warnings to be “conspicuous,” which is defined in terms of when the warning must be visible to the consumer.

ANSI Z535.4 provides general guidance on the placement of warnings by stating that warnings must be placed so they are “readily visible to the intended viewer” and will “alert the viewer to the hazard in time to take appropriate action” (section 9.1).<sup>8</sup> This guidance is consistent with the guidance typically offered in human factors and warnings literature. The warning content for infant loungers is directed not to *any* consumer, but to the consumer who would be interacting

<sup>7</sup> ESHF staff consistently uses this standard—the primary U.S. voluntary consensus standard for the design, application, use, and placement of on-product warning labels—when developing or assessing the adequacy of warning labels. Literature on the design and evaluation of on-product warnings frequently cites ANSI Z535.4 as the minimum set of requirements that products containing such labels that are sold in the United States should meet (e.g., Vredenburg & Zackowitz, 2005; Wogalter & Laughery, 2005). Hellier and Edworthy (2006) and Peckham (2006) report that this conclusion has been reaffirmed by the U.S. courts, who have accepted the ANSI Z535 series of standards in general, and the ANSI Z535.4 standard in particular, as the benchmark against which warning labels are evaluated for adequacy, because these standards are seen as the state of the art (also see Laughery & Wogalter, 2006).<sup>7</sup> Furthermore, the scope of ANSI Z535.4 is broad enough to encompass nearly all products, including children’s products and toys (see Kalsher & Wogalter, 2008; Rice, 2012).

<sup>8</sup> However, warnings must not be presented so far ahead that the consumer might forget the message when exposed to the hazard.

with and placing the infant in the product. Thus, ESHF staff recommends the following definition of “conspicuous”:

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

CPSC staff recommended that the ASTM Infant Loungers subcommittee adopt this definition for their pending voluntary standard, and the most recent version of the draft voluntary standard includes a similar definition. The ASTM Infant Loungers Scope and Definitions task group is considering revisions to the draft voluntary standard to bring its definition more in line with staff’s recommendation.

### Warning Permanence

The draft voluntary standard would require warning labels for infant loungers to be “permanent.” The draft standard includes warning label permanence requirements in the *General Requirements* section and specifies that warning labels must be permanent when tested in accordance with specific test methods that appear in the *Test Methods* section. ESHF staff supports these requirements and test methods, which are consistent with the general approach taken across ASTM juvenile products standards. ESHF staff recommends that the draft proposed rule for infant support cushions include all these permanency-related requirements and test methods.

In addition, staff believes that it is important to include an additional warning-permanency requirement that would address so-called “free-hanging” labels; that is, labels that attach to the product at only one end of the label. Warning labels that are attached in this way are more likely to be torn or ripped off, or otherwise altered by the consumer, which would eliminate the potential safety benefit of the warning for future users of the product. Given their importance, the required warnings must be as permanent as possible and discourage easy removal. Thus, staff recommends that the draft proposed rule include the following additional requirement:

x.x.x Warning labels that are attached to the fabric of the product with seams shall remain in contact with the fabric around the entire perimeter of the label, when the product is in all manufacturer-recommended use positions, when tested in accordance with x.x.

A similar requirement appears in the ASTM voluntary standard for infant bedding (F1917 – 20e1), as well as in the CPSC final rule for sling carriers (16 C.F.R. part 1228) to address identical concerns that commenters raised during the NPR public comment period for that proposed rule.

### Instructional Literature Requirements

The draft ASTM Infant Loungers voluntary standard includes requirements for instructional literature to accompany infant loungers. These requirements are based on the ASTM Ad Hoc Language Task Group recommended requirements for instructional literature and for the formatting of warnings in instructional literature, and ESHF staff worked with the ASTM Ad Hoc

Language Task Group to develop these requirements. The requirements generally specify that the accompanying instructions shall

- be easy to read and understand and be in the English language, at a minimum;
- include information regarding specific tasks associated with the product such as assembly, maintenance, cleaning, and use, where applicable;
- address the same warning and safety-related statements that must appear on the product, with similar formatting requirements, but without the need to be in color; and
- not include any instructions that contradict or create confusion about the meaning of the required information, or otherwise mislead the consumer.

The ASTM Infant Loungers subcommittee included the following additional warnings and related statements that must be addressed in the instructional literature that accompanies these products:

- statements about reading all instructions before using the product and keeping the instructions for future use
- a warning to not use the product if it is damaged or broken
- information about the manufacturer's recommended maximum weight, height, age, developmental level, or combination thereof, of the infant intended to be supported by the product, and if the product is not intended for specific children (e.g., related to a specific disability) a description of this limitation

The draft Instructional Literature section also refers the reader to ANSI Z535.6, *Product Safety Information in Product Manuals, Instructions, and Other Collateral Materials*, for additional guidance on the design of warnings for instructional literature.

### C. Use Patterns

Although, CPSC staff and ASTM Subcommittee members have developed requirements for warnings and instructional literature for infant loungers to comply with the most current guidance for wording, design, and format, ESHF staff concludes that infant support cushions/loungers will likely be used for infant sleep despite warnings against such use. Consistent with this, 55 of the 79 fatalities occurred when the lounger was being used in a sleep environment, such as a bed, crib, bassinet, play yard, or toddler bed. In the Caregiver Perceptions and Reactions to Safety Messaging user research study (Fors Marsh Group, 2019), the majority of participants reported adding a comfort item to sleep products for their infant. This ranged from adding a plush mattress to laying down a pillow or blanket to make the sleep experience better for their infant. Grandparents reported adding blankets to their infant's sleep environment more than parents.

Infant loungers are marketed and promoted as comfortable, pillow-like products that snuggle and comfort infants. Manufacturers' use terms such as "baby nest," "soft pillow," "portable bassinet," "womb-like," and "safe, secure" to describe loungers. These products are shown in marketing and advertisements being used with sleeping infants on couches, beds, cribs, bassinets, and play yards. Consumers associate pillows with sleep and therefore, infant loungers that are promoted for resting or lounging, or are either promoted as or have the appearance of pillows, will likely be used for napping and sleeping. Although staff has recommended various performance requirements such as firmness and side height to reduce the likelihood that infant support cushions will be used for sleeping and will be less hazardous when used on the floor,

using the products in environments such as in cribs and bassinets or on a sofa, or on adult beds will create a positional asphyxia/suffocation risk.

### III. Conclusions

ASTM is developing a voluntary standard for "Infant Loungers," which will contain requirements for a very limited set of pillow-like infant products intended for infants to use during awake time, and specifically not for sleep. The draft voluntary standard includes warnings and instructional literature using current, internationally recognized guidance for wording, design, and formatting. Although there may be some existing "infant loungers" that will meet the requirements of the proposed voluntary standard, most infant support cushions/loungers currently available to consumers are marketed and promoted for use by infants while sleeping. Due to the overall design of infant support cushions/loungers, consumer familiarity with pillow products, and the abundance of marketing and promotional materials showing infants sleeping in these products, ESHF staff contends that changing the warnings and instructional literature without also making any physical changes to the product will not dissuade many consumers from using the product for sleep. Products meeting performance requirements will have a firmness similar to a crib mattress, have low sidewalls under 2 inches thick that do not give the impression of containing a child and provide an inclined angle not exceeding 10 degrees, and have warnings against using in a sleep product. Staff assesses that products meeting the proposed requirements may inform and discourage some consumers from using an infant support cushion in a sleep setting, however, many caregivers will continue to use these products for sleep and in sleep environments because they perceive that a support cushion provides a more comfortable sleep environment for a baby. The use of an infant support cushion in a sleep environment will present a suffocation hazard and staff continues to recommend against this practice.

## References

- American National Standards Institute. (2011, reaffirmed 2017). *ANSI Z535.4. American national standard: Product safety signs and labels*. Rosslyn, VA: National Electrical Manufacturers Association.
- American National Standards Institute. (2011, reaffirmed 2017). *ANSI Z535.6. American national standard: Product safety information in product manuals, instructions, and other collateral materials*. Rosslyn, VA: National Electrical Manufacturers Association.
- Fors Marsh Group (2019). Caregiver Perceptions and Reactions to Safety Messaging Final Report. CPSC Contract CPSC-D-16-0002, Task Order: 61320618F1023. Available at [https://www.cpsc.gov/s3fs-public/Consumer%20Product%20Safety%20Commission%20\(CPSC\)-%20Caregiver%20Perceptions%20and%20Reactions%20to%20Safety%20Messaging%20Final%20Report.pdf](https://www.cpsc.gov/s3fs-public/Consumer%20Product%20Safety%20Commission%20(CPSC)-%20Caregiver%20Perceptions%20and%20Reactions%20to%20Safety%20Messaging%20Final%20Report.pdf)
- Gass, R. H., & Seiter, J. S. (1999). *Persuasion, social influence, and compliance gaining*. Boston: Allyn & Bacon.
- Hellier, E., & Edworthy, J. (2006). Signal Words. In M. S. Wogalter (Ed.), *Handbook of Warnings* (pp. 407–417). Mahwah, NJ: Lawrence Erlbaum Associates.
- Kalsher, M. J., & Wogalter, M. S. (2008). Warnings: Hazard Control Methods for Caregivers and Children. In R. Lueder & V. J. B. Rice (Eds.), *Ergonomics for Children: Designing Products and Places for Toddlers to Teens* (pp. 509–539). New York: Taylor & Francis.
- Laughery, Sr., K. R., & Wogalter, M. S. (2006). The Warning Expert in Civil Litigation. In M. S. Wogalter (Ed.), *Handbook of Warnings* (pp. 605–615). Mahwah, NJ: Lawrence Erlbaum Associates.
- Laughery, K. R. & Wogalter, M. S. (2011). Hazard Control Hierarchy and Its Utility in Safety Decisions about Consumer Products. In W. Karwowski, M. M. Soares, & N. A. Stanton (Eds.), *Human Factors and Ergonomics in Consumer Product Design: Uses and Applications* (pp. 33–39). Boca Raton, FL: CRC.
- Madden, M. S. (1999). The Law Relating to Warnings. In M. S. Wogalter, D. M. DeJoy, & K. R. Laughery (Eds.), *Warnings and Risk Communication* (pp. 315–330). Philadelphia: Taylor & Francis.
- Madden, M. S. (2006). The Duty to Warn in Products Liability. In M. S. Wogalter (Ed.), *Handbook of Warnings* (pp. 583–588). Mahwah, NJ: Lawrence Erlbaum Associates.
- Moon, R. Y., Carlin, R. F., Hand, I., & Task Force on Sudden Infant Death Syndrome and the Committee on Fetus and Newborn (2022). Sleep-Related Infant Deaths: Updated 2022 Recommendations for Reducing Infant Deaths in the Sleep Environment. *Pediatrics*, 150(1), e2022057990. <https://doi.org/10.1542/peds.2022-057990>
- Peckham, G. M. (2006). An Overview of the ANSI Z535 Standards for Safety Signs, Labels, and Tags. In M. S. Wogalter (Ed.), *Handbook of Warnings* (pp. 437–443). Mahwah, NJ: Lawrence Erlbaum Associates.

- Rice, V. J. B. (2012). Designing for Children. In G. Salvendy (Ed.), *Handbook of Human Factors and Ergonomics* (4<sup>th</sup> ed.) (pp. 1472 – 1483). Hoboken, NJ: Wiley.
- Robinson, P. A. (2009). *Writing and Designing Manuals and Warnings* (4<sup>th</sup> ed.). Boca Raton, FL: CRC.
- Vredenburg, A. G., & Zackowitz, I. B. (2005). Human Factors Issues to be Considered by Product Liability Experts. In Y. I. Noy & W. Karwowski (Eds.), *Handbook of Human Factors in Litigation* (Chapter 26). Boca Raton, FL: CRC Press.
- Wogalter, M. S. (2006). Purposes and Scope of Warnings. In M. S. Wogalter (Ed.), *Handbook of Warnings* (pp. 3–9). Mahwah, NJ: Lawrence Erlbaum Associates.
- Wogalter, M. S., & Laughery, K. R. (2005). Effectiveness of Consumer Product Warnings: Design and Forensic Considerations. In Y. I. Noy & W. Karwowski (Eds.), *Handbook of Human Factors in Litigation* (Chapter 31). Boca Raton, FL: CRC Press.
- Wogalter, M. S., Laughery, Sr., K. R., & Mayhorn, C. B. (2012). Warnings and Hazard Communications. In G. Salvendy (Ed.), *Handbook of Human Factors and Ergonomics* (4<sup>th</sup> ed.; pp. 868–894). Hoboken, NJ: Wiley.

## **TAB E: Initial Regulatory Flexibility Analysis for the Draft Proposed Rule to Establish a Mandatory Safety Standard for Infant Support Cushions**



# Memorandum

**TO:** Stefanie Marques, Ph.D., Infant Support Cushions Rulemaking  
Project Manager,  
Directorate for Health Sciences

**THROUGH:** Alex Moscoso, Associate Executive Director and  
José Tejeda, Division Director,  
Directorate for Economic Analysis

**FROM:** Susan Proper, Economist  
Directorate for Economic Analysis

**SUBJECT:** Initial Regulatory Flexibility Analysis for the Draft Proposed Rule to  
Establish a Mandatory Safety Standard for Infant Support  
Cushions

---

**DATE:** November 8,  
2023

## I. Introduction

CPSC staff has developed a draft Notice of Proposed Rulemaking (NPR) to establish a mandatory safety standard for infant support cushions, as defined in the draft proposed rule.

Section 603 of the Regulatory Flexibility Act (RFA, 5 U.S.C. §603) requires the Commission to prepare an Initial Regulatory Flexibility Analysis (IRFA) for a proposed rule, describing the impact of the proposed rule on small entities, and identifying efforts by the Commission to reduce those impacts. This memorandum presents the main findings of the IRFA for the infant support cushions' draft proposed rule.

As specified in the RFA, the IRFA must contain:

- (1) a description of the reasons why action by the agency is being considered;
- (2) a succinct statement of the objectives of, and legal basis for, the proposed rule;
- (3) a description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply;
- (4) a description of the projected reporting, recordkeeping and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record;
- (5) an identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap or conflict with the proposed rule.

In summary, staff assesses that this draft proposed rule would have a significant impact on a substantial number of small entities because no existing mandatory or voluntary performance standards exist for infant support cushions, so the requirements are new for all entities. In addition, several thousand small entities are in this market segment, including many very small hand-crafter businesses and small importers.

## II. Reason for Agency Action

CPSC staff identified a total of 204 incidents associated with the use of infant support cushions in CPSC's injury and incident databases<sup>1</sup> from January 1, 2010, through December 31, 2022 (see Tab A). The incidents include 79 fatal injuries and 125 non-fatal incidents, including 22 emergency department treated injuries and 3 hospital admissions. The most common cause of death was asphyxia or probable asphyxia, while the most common cause of non-fatal injuries was a fall, followed by threatened asphyxia. In 2020 alone, the most recent year for which complete data is available, there were 17 fatalities involving infant support cushions, so the existing ban is not addressing the hazards of non-banned infant pillows.

The current ban on "infant pillows" in 16 C.F.R. §1500.18(a)(16) only applies to "infant pillows" that are loosely filled with a granular material, as well as other characteristics. This ban was published in 1992. Most infant support cushions on the market today are filled with some type of foam or fibrous batting, rather than a "granular material," and are therefore not banned.

Despite the significant number of child deaths and injuries discussed above, currently no mandatory safety standard exists for non-banned infant pillows that addresses the hazards of these products being used for infant sleep or propping, sometimes on elevated surfaces, including adult beds, or inside an infant sleep product. Also, no voluntary standard addresses infant support cushions; however, ASTM is developing a voluntary standard for "infant loungers" that has not yet been balloted. The scope of that voluntary standard does not include most types of infant support cushions; for instance, it does not cover sleep positioners, play mats, wedge pillows, or other pillow products marketed for sleep.

Free-standing products marketed or intended to provide sleeping accommodations for infants up to five months of age are in the scope of the mandatory "Safety Standard for Infant Sleep Products" (16 C.F.R. part 1236). However, staff identified incidents associated with infant support cushion products that are not marketed for sleep but have a foreseeable use for sleep and are not covered by another CPSC standard. Staff also identified incidents associated with support cushions that are marketed for sleep, but do not contain an infant (and are thus not "sleeping accommodations"), such as wedge pillows and sleep positioners. Some incidents associated with support cushion products involve children older than 5 months. This rule would establish mandatory safety standards for all infant support cushions intended, marketed or designed for children up to 12 months old that are not covered by another mandatory CPSC standard for durable infant or toddler products as specified in 16 C.F.R. 1130.2(a), except for nursing pillows marketed only for nursing.<sup>2</sup> The scope of this draft proposed rule includes products that support any part of an infant for lounging, rest, or sleep, such as head positioner pillows.

Consequently, because section 104 of the CPSIA requires the Commission to regulate durable infant or toddler products, and because infant support cushions are associated with known hazards that are not addressed by an existing mandatory or voluntary standard, CPSC staff proposes that the Commission publish this draft proposed rule to establish specific performance

<sup>1</sup> Two main databases were used: NEISS and CPSRMS. NEISS (National Electronic Injury Surveillance System) is a collection of consumer product-related injury and incident data from a statistical sample of emergency department at U.S. hospitals; NEISS produces nationwide estimates of product-related injuries. CPSRMS (Consumer Product Safety Risk Management System) is a database of consumer product incident reports.

<sup>2</sup> Nursing pillows are covered by another CPSC draft proposed rule. That draft proposed rule defines nursing pillows as "any product intended, marketed, or designed to position and support an infant close to a caregiver's body while breastfeeding or bottle feeding. These products rest upon, wrap around, or are worn by a caregiver in a seated or reclined position."

standards to address these hazards; and to require a specific warning label, a customer registration card, and instructions; as well as third-party testing to demonstrate compliance.

### **III. Objectives and Legal Basis of the Proposed Rule**

#### **A. Objectives of the Draft Proposed Rule**

The objective of the draft proposed rule is to establish a mandatory safety standard for infant support cushions that addresses known hazards from infant support cushions.

#### **B. Legal Basis of the Draft Proposed Rule**

Section 104(b)(1) of the CPSIA requires the Commission to assess the effectiveness of voluntary standards for durable infant or toddler products, if such standards exist, and to adopt mandatory standards for these products. 15 U.S.C. § 2056a(b)(1). No voluntary standard currently exists for infant support cushions, so staff has drafted a proposed rule to address the hazard presented by these products.

The CPSIA also authorizes the Commission to require manufacturers of durable nursery products to provide consumers with a postage-paid consumer registration form with each such product, and to permanently place the manufacturer name and contact information, model name and number, and the date of manufacture on each durable infant or toddler product. 15 U.S.C. § 2056a(d). This draft proposed rule would add infant support cushions to the list of products for which registration cards are required.

The CPSIA also sets forth the requirements for third-party testing of children's products, and for the accreditation of such testing laboratories. 15 U.S.C. § 2063. This draft proposed rule would add infant support cushions to the list of durable infant products specified in 16 C.F.R. part 1112 "Requirements Pertaining to Third Party Conformity Assessment Bodies."

#### **C. Compliance with Proposed Rule**

The draft proposed rule establishes new performance and labeling requirements. Suppliers would need to conduct third-party testing to demonstrate compliance, provide the specified warning label and instructions, and provide a product registration card.

These are new requirements for these products for all suppliers, large and small. Infant support cushions are currently not required to be third-party tested to any CPSC standard, unless textile content, lead or phthalates content, or small parts requirements apply to a particular item. Most pillows are made of textile materials that are exempt from those testing requirements for lead or phthalates for the textile portion, as specified in 16 CFR §1500.1, although any metal or plastic fasteners may require testing for lead or phthalates content. In any case, the third-party testing requirements in this NPR will be new for all suppliers.

The labelling and instructions requirements are also new for these products. Some pillows currently on the market have warning labels, but not the specific labels or instructions required by this rule. Suppliers would also be required to provide a product registration card, which some companies may already provide.

The labeling and instructions requirements constitute a burden under the Paperwork Reduction Act. CPSC staff will submit an Information Collection Request to the Office of Management and

Budget of the Executive Office of the President (OMB) for approval and obtain an OMB control number for this information collection. Certificates of compliance, called children's product certificates, are already required for all children's products under OMB Control Number 3041-0159. Product Registration cards are exempt from PRA burden analysis under section 104(d)(1) of the CPSIA.

## **IV. Entities to Which This Rule Would Apply**

### **A. The Product**

The draft proposed rule would apply to infant support cushions as described in the draft proposed rule.

Products within the scope of the rule would include, but would not be limited to:

- Head positioner pillows
- Flat baby loungers
- Crib pillows
- Wedge pillows for infants
- Infant sleep positioners, unless regulated by the FDA as medical devices<sup>3</sup>
- 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<sup>4</sup>
- Pads and mats
- Accessory pillows and other padded accessories, often marketed for use with an infant car seat, stroller or bouncer, but not sold with that product and therefore, not included in the mandatory safety testing for those products.

Some of these products are marketed for use inside a crib or other sleep product. Given that newborns normally sleep 16 to 17 hours a day,<sup>5</sup> marketing a support cushion product as "not for sleep" is unlikely to prevent caregivers from foreseeably using the support product during infant sleep. The exception would be products that have a clear purpose for entertaining an awake infant, such as an activity mat with attached toys. However, marketing a product for "tummy time" or "lounging" is unlikely to influence caregiver behavior if the product is a pillow or similar support product (which are typically associated with sleep) and can foreseeably be used for sleep or placed in an infant's sleep environment. CPSC staff considers these types of products to be within scope of this rule.

### **B. Products Out of Scope**

<sup>3</sup> The FDA discourages the use of infant sleep positioners and has never approved a pillow product for preventing sudden infant death syndrome (SIDS). See <https://www.fda.gov/consumers/consumer-updates/do-not-use-infant-sleep-positioners-due-risk-suffocation>

<sup>4</sup> These products are banned in the UK due to suffocation and pneumonia hazards. <https://www.gov.uk/product-safety-alerts-reports-recalls/product-safety-alert-baby-self-feeding-pillows-slash-prop-feeders-psa3>

<sup>5</sup> <https://www.healthychildren.org/English/ages-stages/baby/sleep/Pages/default.aspx>

The following products are out of scope:

- Pillows not marketed or intended for use by infants, including adult bed pillows
- Nursing pillows that are marketed only for feeding and are not marketed, intended, or foreseeably used for lounging, if they meet the requirements of the Commission's proposed nursing pillow rule 88 FR 65865 (Sept. 26, 2023) if that rule is finalized
- Crib and play yard mattresses; that are in scope of the play yard and crib mattress standard in 16 C.F.R. part 1241
- Purely decorative nursery pillows, such as those personalized with the baby's name and birthdate, if they are not intended, designed, or marketed for infant use.
- Stuffed toys (unless they meet the definition of an infant support cushion in this proposed rule)
- Padded seat liners that are sold with a rocker, stroller, car seat, infant carrier, swing, highchair or bouncer that are specifically designed to fit that product
- Sleeping accommodations, which are regulated under the Commission's infant sleep product rule at 16 CFR part 1236

### C. The Market

Staff cannot precisely determine the annual sales volume of new infant support cushions, given the variety of products within the scope of this rule and the large number of suppliers.

Some parents may already own a product that was purchased for an older child, particularly in the case of loungers and sleeping pads that may also be used by toddlers and are marketed for the toddler age range as well as for children under 12 months old. Also, these products are marketed for different uses, for example a head positioner pillow versus a padded sleep mat, so parents may buy more than one product within the scope of this draft proposed rule for their infant or may receive more than one of these items as a gift. However, not every infant support cushion currently in use represents a newly manufactured product. There is a considerable market in used infant support cushions on prominent second-hand online sites. In June 2023, staff found listings on Mercari for used changing pads, large stuffed toys marketed for infant sleep, crib wedge pillows, baby neck pillows, baby sleep positioners, baby loungers, baby sleep mats, baby "pillow chairs", infant "self-feeding" pillows, baby/toddler bean bag chairs, and crib pillows.

Most types of new infant support cushions are sold online, including from general online retailers, online sites for "big box" stores, online baby products sites, and online marketplaces for handcrafted items. A few types of infant support cushions, however, are also available from brick-and-mortar baby specialty stores and general retail stores, particularly crib pillows and baby loungers. Prices for new infant support cushions range from under \$15 for a simple head positioner pillow or crib pillow to more than \$250 for a lounger with a removable cover or a large stuffed toy marketed for sleep, with the average price at roughly \$30. Infant support cushions are supplied by several thousand manufacturers and importers, including hundreds of handcrafters and direct foreign shippers.<sup>6</sup> Staff observes that infant support cushions are widely available used from secondary marketplaces such as Ebay and Mercari, particularly the larger items that may also be marketed for the toddler age range and the more expensive items.

<sup>6</sup> Based on staff analysis of products in scope of this NPR for sale online by major general retail chain stores, department stores, specialty baby stores, a prominent handcrafter site, and the websites of individual companies in the U.S. and other countries.

### **D. Small Entities to Which the Proposed Rule Would Apply**

This draft proposed rule would apply to entities that supply infant support cushions to the U.S. market. These include manufacturers and importers, as well as foreign direct shippers. More than 2,000 suppliers are in this market, the majority of which are small.

The Small Business Administration (SBA) sets size standards for what constitutes a U.S. small business for the purpose of various federal government programs.<sup>7</sup> SBA size standards are based on the number of employees or the annual revenue of the firm, and there is a specific size standard for each 6-digit North American Industry Classification Series (NAICS) category.<sup>8</sup> The U.S. Census Bureau conducts an annual survey of small businesses in the United States, and counts how many large and small businesses are in each NAICS category.<sup>9</sup> The SBA size standard for what constitutes a “small” business is typically 500 to 750 employees for manufacturers and 100 to 150 employees for wholesalers, depending on the industry category. Importers are a type of wholesaler. Manufacturers and importers of infant support cushions could be in a wide variety of such categories, depending on their primary line of business, which often is not support cushions but rather some more general category of children’s products or other consumer goods.

Based on staff’s assessment of prominent online and brick-and-mortar retail sources for infant support cushions in the Spring of 2023, there appear to be more than 2,000 suppliers of infant support cushions to the U.S. market, including many small U.S. crafters, small importers, small manufacturers, and direct foreign shippers.

### **E. Entities to Which the Draft Proposed Rule Would Not Apply**

The draft proposed rule would not have any direct impacts on retailers of any size, except for retailers that have “store brand” infant support cushions and are therefore also manufacturers of infant support cushions. Products manufactured before the effective date of the final rule could still be sold by retailers of any size. There could be an indirect impact on retailers in the longer term, including small retailers, if certain products are removed from the market altogether, so retailers lose the revenue from those future sales.

The draft proposed rule would not have any direct impacts on the many small businesses that make cases or covers for other companies’ infant support cushion products. However, there could be an indirect impact on those firms if they make cases or covers for a specific product, and that product is redesigned or removed from the market by the manufacturer.

## **V. Compliance, Reporting, Paperwork, and Recordkeeping Requirements of the Draft Proposed Rule**

<sup>7</sup> The size standards are in listed in the Code of Federal Regulations. See 13 CFR part 121.

<sup>8</sup> 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.

<sup>9</sup> <https://www.census.gov/programs-surveys/susb/data/tables.html>

Suppliers would be required to comply with the performance requirements of the draft proposed rule, and to provide a warning label, a consumer registration card, and user instructions; as well as conducting third-party testing to demonstrate compliance. This section discusses the reporting and paperwork requirements. The compliance costs are analyzed in detail in section VII.

Manufacturers and importers must demonstrate that they meet the performance requirements of the rule by testing products to the rule and certifying that the products meet the requirements of the rule in a children's product certificate. Also, as specified in 16 C.F.R. part 1109, manufacturers or importers who are not the original manufacturer, such as importers, may rely on testing or a certificate of conformity provided by another firm, as long as the firms meet the requirements in part 1109. Manufacturers and importers must also provide product registration cards. Recordkeeping and compliance documentation do not require specialized expertise. CPSC's public website provides instructions and examples for how to develop the children's product certificate and product registration cards.<sup>10</sup>

While some products currently have labels, all products would have to meet the specific labeling requirements and instructions specified in the draft proposed rule, which provides the text and graphics for the required labels and instructions. Therefore, specialized graphics design expertise would not be required to develop the warnings and instructions. The ongoing cost of the new labels and instruction manuals is estimated at less than \$1 per item for materials. The initial cost for labor of developing the labels and instruction manuals is included in the cost of redesigning models to comply with this draft proposed rule, which is discussed in more detail in section VII of this memo. As noted earlier, the labeling and instructions requirements constitute a burden under the Paperwork Reduction Act. CPSC staff will submit an Information Collection Request to OMB for approval and obtain an OMB control number for this information collection.

CPSC's Office of the Small Business Ombudsman provides additional online resources for small businesses to assist with the recordkeeping requirements.<sup>11</sup>

## **VI. Federal and State Rules that May Overlap with this Draft Proposed Rule**

CPSC staff has not identified any other Federal rules that duplicate, overlap, or conflict with the proposed rule. As noted earlier, CPSC has an existing ban on certain types of infant pillows that have granular filling. Because those products are banned, there should not be any on the market that are in the scope of this draft proposed rule. Multiple states have bans on certain flame retardants in children's products, including pillows, but this draft proposed rule does not set requirements on the use of flame retardants, so there is no overlap or conflict. CPSC has an NPR for nursing pillows in development that covers pillows that are marketed and designed for nursing and bottle-feeding. To the extent these nursing pillow products are also marketed and designed for lounging or resting, they must comply with both the CPSC's draft nursing pillow rule and this draft proposed rule. Some infant support cushions may be in scope of the Commission's ISP rule and/or the Safe Sleep for Babies Act's ban on inclined sleepers for infants if they provide sleeping accommodations.

<sup>10</sup> See for example: <https://www.cpsc.gov/Testing-Certification/Childrens-Product-Certificate-CPC>; and <https://www.cpsc.gov/Business--Manufacturing/Business-Education/Durable-Infant-or-Toddler-Products/FAQs-Durable-Infant-or-Toddler-Product-Consumer-Registration>

<sup>11</sup> See: <https://www.cpsc.gov/Business--Manufacturing/Small-Business-Resources>

## VII. Potential Impact on Small Entities

This draft proposed rule would likely have a significant impact on a substantial number of small entities, based on the estimated costs of modifying the product to achieve compliance, and the ongoing cost of testing to demonstrate compliance. Staff considers one percent of annual revenue to be a “significant” economic impact on a company, consistent with regulatory impact analyses by other federal government agencies. Nearly all the U.S. suppliers of infant support cushions are small entities, and there are more than 2,000 of them.

### A. Cost of Modifying Product

Most infant support cushion products on the market would require redesign to meet the requirements in the NPR, and no products on the market currently have all the specific labels, customer registration forms, and warnings required by the draft proposed rule. A few products on the market may already meet the performance requirements in the draft proposed rule, such as a thin, very firm pillow or nap pad with no straps. However, all products would require third-party testing to demonstrate compliance. Testing costs are covered in part B of this section.

The effort required for a one-time redesign is estimated by CPSC subject matter experts to be 200 hours of professional staff time per model, including in-house testing of the prototypes and development of labels, customer registration forms, and instruction materials.<sup>12</sup> Using current (December 2022) Bureau of Labor Statistics (BLS) Employer Costs of Employee Compensation,<sup>13</sup> the estimated cost per model is \$12,530, at a current cost for professional labor of \$62.65 per hour, rounded for the purpose of analysis to \$12,500 per model. Materials costs for prototyping are estimated to be minimal, likely under \$1,000, given that pillows are typically made of fabric and stuffing materials. The total cost of redesign is approximately \$13,500 per model (\$12,500 for labor and \$1,000 for materials). The cost per company would depend on how many different models each company manufactures.

For small crafters and other non-employee businesses, the cost of labor reflects the economic “opportunity cost” – while such a small business might not hire an engineer for redesign at \$62.65 an hour, they would still need to spend approximately 200 hours redesigning their product, which is 200 hours they would not have for other activities to support their business. Some engineering expertise would likely be required for the redesign, to ensure that in particular the firmness requirement and other requirements are met, using a force gauge and other equipment as specified in the NPR regulatory text. For small crafters, their “opportunity cost” (the value of their time spent on redesign that cannot be spent on other activities) might be worth less than \$62.65 an hour to them. Online prices of handcrafted items vary widely, but the lower end of the handcrafter market does demonstrate that some crafters value their own time at less than \$62.65 an hour. For example, if a hand-crafted item is priced under \$50, and the item appears to require more than one hour to construct and ship, it is likely that crafter valued their own time at less than \$50 an hour. Small crafters may also be able to reduce their redesign costs by observing and learning from how larger companies generally achieve compliance with this rule, such as through certain fabrics, threads, or types of stuffing.

<sup>12</sup> Staff estimate of labor effort reflects that it may require multiple prototypes and design iterations to develop a product that is compliant with the requirements in this NPR. The firmness requirement particularly may require several attempts to meet the requirement.

<sup>13</sup> [https://www.bls.gov/news.release/archives/ecec\\_03172023.pdf](https://www.bls.gov/news.release/archives/ecec_03172023.pdf). These costs reflect the employers’ cost for salaries, wages, and benefits for civilian workers.

Many U.S. manufacturers have outsourced production to foreign countries but design their products in North America. Therefore, this estimate reflects U.S. labor and materials costs for prototype designs. While importers would not directly pay for the cost of redesign by foreign suppliers, the cost of redesign would almost certainly be reflected in the wholesale price.

As noted earlier, staff considers one percent of annual revenue to be a "significant" economic impact on a company, consistent with regulatory flexibility analyses conducted by other federal government agencies. The estimated \$13,500 cost to redesign would be one percent of revenue for a firm with \$1.35 million in revenue. The cost is likely to be significant for a substantial number of small U.S. firms that have less than \$1.35 million in revenue, including small manufacturers and small importers. Small home crafters are a subset of small manufacturers; they would likely be significantly impacted by this rule.

With an estimated 2,000 models that need to be redesigned, at \$13,500 per model, the total cost for the industry as a whole is estimated at up to \$27 million for redesign in the first year after the rule is published, assuming that all suppliers decide to remain in the market. The cost could be less, depending upon the cost for individual firms. It is possible many small volume home crafters will exit the market rather than redesign, and that some of the foreign suppliers to small importers would also exit the market rather than redesign, at least temporarily. If firms choose to exit the market, the impact of lost sales could be significant for those firms. However, because the performance requirements could be met by replacing the stuffing with a firmer type and changing the shape of the product's sides, which does not necessarily require specialized engineering expertise or tools, it is possible that many of the small volume crafters and other small manufacturers would bear the expense of redesign and stay in the market. For small crafters, their "opportunity cost" (the value of their time spent on redesign that cannot be spent on other activities) might be worth less than \$62.65 an hour to them, in which case their cost of redesign could be less than \$13,500. Some engineering expertise would likely be required for the redesign, to ensure that in particular the firmness requirement and other requirements are met, using a force gauge and other equipment as specified in the NPR regulatory text. Small crafters may also be able to reduce their engineering costs by observing and learning from how larger companies generally achieve compliance with this rule, such as through certain fabrics, threads, or types of stuffing. However, that approach will require them to wait until the larger companies introduce compliant products onto the market, and they must also not violate any patented or trademarked designs by larger companies.

Firms may be able to reduce the impact of design costs by raising the retail or wholesale price of infant support cushions to cover the cost of redesign, in which case the impact might not be significant, even for small suppliers. The retail price increase to cover redesign costs could be relatively minor, even for relatively small volume suppliers. For example, a firm supplying 5,000 infant support cushions per year could cover the entire cost of redesign by raising the price by \$2.70. (\$13,500 for redesign, with the cost divided by the 5,000 units, equals a cost of \$2.70 per unit.) Small manufacturers and small importers with several employees might have this level of sales volume, although most small crafters and single person importer businesses would not. However, small crafters and single person importers could cover at least some of their redesign costs by raising price by a few dollars per unit. Given that all suppliers would be redesigning products to comply with this draft proposed rule, small businesses may not necessarily be less competitive if nearly all firms, regardless of size, raise prices to cover costs. Small crafters may also be able to collaboratively share solutions to achieve compliance with other small crafters, thus reducing the engineering costs for redesign by any one firm.

## B. Third-Party Testing Costs

Manufacturers of infant support cushions would be required to comply with the standards of this draft proposed rule, and to demonstrate this compliance through third-party testing. As specified in 16 C.F.R. part 1109, entities that are not manufacturers of children's products, such as importers, may rely on the testing or certification provided by another firm, as long as they follow the requirements in part 1109. Staff assumes that foreign manufacturers would pass on at least some of the cost of testing for compliance to small U.S. importers.

Third-party testing will be a new cost for all suppliers, because infant support cushions are not currently required to be third-party tested unless required by another CPSC regulation, such as small parts, toys, lead, or phthalates.<sup>14</sup> Estimated third party testing costs for infant support cushions is estimated at \$500 to \$1,000 per model, based on current prices for testing other children's durable nursery products. The cost of testing would depend on where the testing takes place, and whether manufacturers' associations or groups add infant support cushions to their certification programs to receive volume discounts for third-party testing. The annual cost of samples for testing is estimated at around \$100. Costs of testing per model will be similar for all sizes of suppliers, although larger firms are more likely to qualify for testing lab volume discounts.

The cost of testing alone could be significant for some small hand crafters. A cost of \$600, the low end of the testing cost estimate including cost of samples for testing, would represent one percent of annual revenue for a company generating \$60,000 in annual revenue. At an estimated average price of \$30 per pillow, this would represent sales of 2,000 units. Many hand crafters show historical sales of less than 100 units. However, a company selling as few as 200 units could cover the cost of annual testing by raising the price \$3, or 10 percent of the average price, which could reduce the impact of the draft proposed rule on that small business.

Small importers are less likely to find that testing costs (as reflected in increased wholesale costs from foreign suppliers) are a significant burden. For example, baby head sleep positioner pillows are currently available on Alibaba<sup>15</sup> for about \$1 to \$3, with lower prices for larger volume orders. If testing costs added ten percent to the wholesale cost, that would be less than 50 cents per unit, and importers could raise the retail price to cover compliance costs with minimal, if any impact, on consumer demand. However, small importers may not be able to find a compliant supplier, depending on the decisions foreign manufacturers make about whether to redesign and test to the CPSC standard.

## C. Summary of Impacts

Redesign costs would be a potentially significant cost for a substantial number of small firms for the first year that the draft proposed rule is effective. One-time redesign costs, including costs of designing warning labels and instruction manuals, are estimated at \$13,500 per model. The cost for crafters and other very small businesses may be more of an "opportunity cost" if they undertake some of the redesign themselves. Small crafters' cost may also be less if the cost of

<sup>14</sup> Several manufacturers make vague references to third-party testing in their marketing; such references are likely in relation to testing for textile content, lead content of fasteners, or small parts.

<sup>15</sup> Alibaba is a prominent Chinese site for wholesale consumer products.

their own labor is below the BLS average for professional staff (i.e., small business owners take less wages and are instead compensated by equity in their business) or if their engineering costs can be shared with other small crafters. Ongoing annual testing costs are estimated at \$600 to \$1,100 per model, including the cost of the samples for testing. Small companies may be able to reduce the impact of the rule by raising retail prices by 10 percent or less to cover all or a portion of redesign and testing costs.

Staff assesses the impact to be significant for a substantial number of small firms with low volume sales. Many small volume hand crafters may stop selling infant support cushions. Small volume hand crafters may not have the sales volume to cover the expense of redesign and testing and still generate a profit, even if they raise prices, while small volume importers may not be able to find a compliant supplier. There may be reduced demand for redesigned products.

Remarketing options are limited, as most infant support cushion products are clearly intended for sleep or foreseeably used for sleep. A few possible exceptions are stuffed toys, activity mats with toys, and changing pads, which could be credibly remarketed as not for sleep.

Consumers may not experience a significant loss of consumer utility as small volume sellers exit the market, as there are many different products available from different suppliers, including a large number of online sellers. However, if the redesigned products are less appealing to consumers, there may be a loss in sale volumes of specific products as a result of this draft proposed rule. Small businesses may decide to exit the market if there is not sufficient demand for redesigned product.

The performance requirements in this draft proposed rule require that products meet certain firmness criteria and incline requirements. While any product within the scope of this draft proposed rule could be redesigned to meet its performance requirements, some suppliers may decide to exit the market rather because they anticipate that consumers would not want the redesigned products. For example, a “wedge” pillow could be redesigned to be compliant with this rule, but its incline would need to decrease significantly from its current angle. An infant sleep positioner could be redesigned to be compliant, but it would need to meet the firmness requirements in the draft proposed rule. In terms of small businesses, the impact of removing a product from the market instead of redesigning it could be significant as a result of a potentially large volume of lost sales.

Product redesign may not increase the ongoing cost of producing the product, given that the materials and production methods are likely to remain roughly similar. If companies decide to pass the ongoing cost of testing onto consumers, the price increase could be relatively modest, perhaps under \$3 at retail, or 10 percent of the price of a \$30 item.

## **VII. Efforts to Minimize Impact, Alternatives Considered**

The RFA specifies that the IRFA must contain a

description of any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes, and which minimize any significant economic impact of the proposed rule on small entities. Consistent with the stated objectives of applicable statutes, the analysis shall discuss significant alternatives such as-

(1) the establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities;

- (2) the clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities;
- (3) the use of performance rather than design standards; and
- (4) an exemption from coverage of the rule, or any part thereof, for such small entities.

CPSC staff did not consider either exempting small entities from this draft proposed rule or parts of it or establishing differing requirements for small entities because neither of these options would be consistent with the applicable statutes on durable infant or toddler products. 15 U.S.C. § 2063(d)(4)(C). Staff has also developed simplified compliance and reporting requirements for all entities that render additional simplification for small entities unfeasible. For example, a children's product certificate can be one page, and there are detailed guidelines and examples on the Commission's <sup>16</sup> website. Finally, the standard in this NPR is already a performance standard rather than a design standard.

CPSC staff considered several alternatives to this draft proposed rule, which are discussed in more detail below, including:

- Not establishing a safety standard for infant support cushions
- Delaying the draft proposed rule until a voluntary standard is published
- A shorter effective date

#### Not establishing a safety standard for infant support cushions

Not establishing a safety standard for infant support cushions would result in no regulatory impact on small businesses, but it would also lead to a continuation of the injury and death patterns from the known hazards associated with infant support cushions. Deaths and injuries from the use of infant support cushions<sup>17</sup> would continue to occur, likely at similar rates as those observed by CPSC during the period from January 1, 2010, through December 31, 2022. In 2020, the most recent year for which complete data is available, there were 17 fatalities involving infant support cushions. (see Tab A)

Not implementing the rule would reduce the regulatory burden on small firms, but at high societal cost in terms of deaths and injuries. The rule may provide a temporary competitive advantage to small firms whose products already meet the requirements in this rule.

#### Delaying the Draft Proposed Rule until a Voluntary Standard is published

ASTM has not yet balloted or published a voluntary standard for infant support cushions. ASTM is developing a voluntary standard for infant loungers, which would include a much narrower scope of products than would this draft proposed rule.

Staff does not know, given the predominance of very small companies in this product sector, whether there would be sufficient interest in developing a voluntary standard that covers all types of infant support cushions within the scope of this draft proposed rule. Therefore, delaying the draft proposed rule until a voluntary standard is developed could cause an indefinite delay. Such a delay would reduce the impact on small businesses but would also allow the hazard to

<sup>16</sup> <https://www.cpsc.gov/Testing-Certification/Childrens-Product-Certificate-CPC>

<sup>17</sup> Even though there is a ban on infant pillows, this ban in 16 CFR 1500 does not apply to most infant pillows on the market today. Based on hazard data, the existing ban does not address the hazard of people using infant pillows to prop up sleeping infants on elevated surfaces, and/or inside other sleep products. The existing infant pillow ban in 16 CFR 1500 was published in 1992.

continue for an unspecified time. In addition, any eventual voluntary standard may not be as stringent as this draft proposed rule and may not adequately address deaths and injuries.

#### A different effective date

Staff recommends an effective date of 180 days. In the past, 180 days has generally been sufficient time for suppliers to come into compliance with durable infant or toddler product rules. Additionally, six months from the change in a voluntary standard is the period that JPMA uses for its certification program, so compliant manufacturers are used to this time frame to comply with a modified standard. Testing laboratories should have no difficulty preparing to test to the proposed new mandatory standards within a 180-day period, given that no new complex testing instruments, devices, or procedures are required to test infant support cushions for compliance to this draft proposed rule.

The majority of businesses supplying infant support cushions are small, and that currently there are no existing performance standard or labeling requirements for infant support cushions. A shorter effective date could provide safety benefits more quickly, but it would likely increase the burden on small businesses to quickly redesign and test their products. It could also result in temporary shortages of infant support cushions, because testing labs may need to apply for accreditation, and potentially approximately 2,000 businesses would need to have their products tested for compliance. A longer effective date would reduce the burden on small businesses to redesign their products quickly, and schedule third party testing, but would delay the safety benefits of the rule. Considering the burden on small businesses, the testing lab requirements, and the safety benefits of this rule, staff is recommending 180 days.

## **IX. Impact on Testing Labs**

In accordance with section 14 of the CPSA, all children's products that are subject to a children's product safety rule must be tested by a third-party conformity assessment body that has been accredited by CPSC. These third-party conformity assessment bodies test products for compliance with applicable children's product safety rules. Testing laboratories that want to conduct this testing must meet the Notice of Requirements (NOR) for third-party conformity testing (CPSC has codified NORs in 16 C.F.R. part 1112). This section assesses the impact a proposed amendment would have on small laboratories.

Staff concludes that there should be no significant adverse impact on testing laboratories as a result of this rule. No new complex testing instruments, devices, or procedures are required to test infant support cushions for compliance to this draft proposed rule. The testing devices include a probe, a distance measurement device, a force gauge, a hinged weight gauge, and a frame to hold the product and testing devices in place. Testing laboratories are not required to provide these testing services; only those laboratories that make the business decision that there is sufficient demand for such services would need to procure the testing devices and apply for accreditation.

For the reasons described above, revising the NOR to add infant support cushions to the list of products subject to part 1112 would not have a significant adverse impact on small laboratories. Most laboratories are not small U.S. businesses. Companies in the lab testing industry include companies with hundreds of locations, including labs in Asia and Europe, and thousands of employees. Therefore, the Commission could certify that the NOR for the infant pillow mandatory standard will not have a significant impact on a substantial number of small laboratories.

## X. Conclusion

The NPR would likely have a significant impact on a substantial number of small entities. Using the SBA size standards, nearly all the manufacturers and importers of infant support cushions are small businesses. Most products currently on the market would need to be redesigned, and all products would need new labelling and instructions. The cost of redesign and testing would likely be significant for most small businesses currently in the market. It is possible that many small volume hand crafters and small importers would exit the market<sup>18</sup> because of the relatively large cost of compliance as compared to their annual revenue. Remarketing to be out of scope of the draft proposed rule is not feasible for most in-scope products, with the possible exceptions of some stuffed toys, activity mats with toys, and changing pads, all of which have a credible purpose other than infant sleep.

Consumers may not experience a significant loss of utility due to the exit of small businesses from the market, as the standard adopted in the draft proposed rule is not expected to raise prices of infant support cushions by more than 10 percent (\$3 on a \$30 item), and currently there is a large variety of infant pillow products available in the market. All of the product types identified as within the scope of the draft proposed rule could meet the requirements of this draft proposed rule with redesign and labeling. However, it is also possible that many small suppliers would choose to remove their products from the market rather than redesign them, which will mean that consumers can no longer purchase those products.

---

<sup>18</sup> Note that "exit the market" does not necessarily mean going out of business. Small businesses that sell a variety of products may stay in business, but stop selling infant support cushions, either temporarily or permanently.

## **TAB F: Recommended Regulatory Text for the Draft Proposed Rule**

**TO:** The Infant Support Cushions Rulemaking Project File

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

**FROM:** The Infant Support Cushions Rulemaking Team

**SUBJECT:** Recommended Regulatory Text for the Draft Proposed Rule

**DATE:** November 8,  
2023

---

## Part XXXX-Safety Standard for Infant Support Cushions

### XXXX.1 Scope, Purpose, and Application, and Exemptions

#### XXXX.2 Definitions

#### XXXX.3 General Requirements

#### XXXX.4 Performance requirements

#### XXXX.5 Test Methods

#### XXXX.6 Marking and Labeling

#### XXXX.7 Instructional Literature

### § XXXX.1 Scope, Purpose, Application, and Exemptions

- (a) *Scope and Purpose.* This consumer product safety standard prescribes requirements to reduce the risk of death and injury from hazards associated with *infant support cushions*, as defined in XXXX.2. This includes but is not limited to *infant positioners*, nursing products with a dual use for lounging, *infant loungers*, and infant props or cushions used to support an infant. All *infant support cushions* must be tested according to the requirements of XXXX.5 and comply with all requirements of this part.
- (b) *Application.* All infant support cushions that are manufactured after [effective date], are subject to the requirements of this part XXXX.
- (c) *Exemptions.* Products subject to another standard listed in 16 CFR 1130.2(a) are exempt from this part XXXX. Nursing pillows that also meet the definition of *infant lounger*, however, are not exempt from this part XXXX.

### § XXXX.2 Definitions

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

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

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

*Infant support cushion* – an infant product that is filled with or comprised of resilient material such as foam, fibrous batting, or granular material, or with a gel, liquid, or gas, and which is marketed, designed, or intended to support an infant's weight or any portion

of an infant while reclining or in a supine, prone, or recumbent position.

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

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

### § XXXX.3 General Requirements

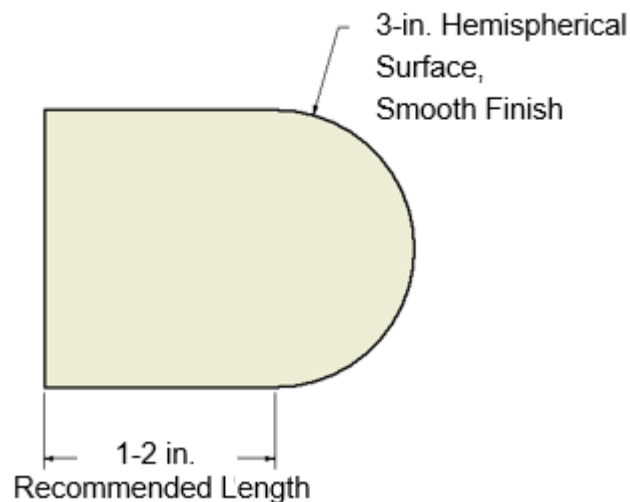
- (a) *Hazardous Sharp Edges or Points*—There shall be no hazardous sharp points or edges as defined in 16 CFR 1500.48 and 16 CFR 1500.49 before or after the product has been tested.
- (b) *Small Parts*—There shall be no small parts as defined in 16 CFR 1501 before testing or presented as a result of testing.
- (c) *Lead in Paints*—All paint and surface coatings on the product shall comply with the requirements of 16 CFR 1303.
- (d) *Toys*—Toy accessories attached to, removable from, or sold with an infant pillow, as well as their means of attachment, shall comply with the applicable requirements of Consumer Safety Specification for Toy Safety 16 CFR part 1250.
- (e) *Side Height*—The maximum side height for the product, measured from the OSS-body or test base, as appropriate, to the top of the sidewall, shall not exceed the maximum of the side heights determined in § XXXX.5(d)(8).
- (f) *Removal of Components*. When tested in accordance with § XXXX.5(g), any removal of components that are accessible to an infant while in the product or from any position around the product shall not present a small part, sharp point, or sharp edge as required in § XXXX.3(a) and § XXXX.3(b)
- (g) *Permanency of Labeling and Warnings*
  - (1) Warning labels, whether paper or non-paper, shall be permanent when tested in accordance with XXXX.5(b)(1)-(3)
  - (2) Warning statements applied directly onto the surface of the product by hot stamping, heat transfer, printing, wood burning, etc. shall be permanent when tested in accordance with XXX.5(b)(4)i-iii.
  - (3) Non-paper labels shall not liberate small parts when tested in accordance with XXXX.5(b)(5).
  - (4) Warning labels that are attached to the fabric of the product with seams shall remain in contact with the fabric around the entire perimeter of the label, when the product is in all manufacturer-recommended use positions, when tested in accordance with XXXX.5(b)(3).
- (h) If the infant support cushion can be converted into another product for which a consumer product safety standard exists, the product also shall comply with the applicable requirements of that standard.

### § XXXX.4 Performance Requirements

- (a) *Restraint*— The product shall not include a restraint system.
- (b) *Seam Strength* – When tested in accordance with § XXXX.5(j), fabric/mesh seams and points of attachment shall not fail such that a small part, sharp point, or sharp edge is

presented, as required in § XXXX.3(a) and § XXXX.3(b).

- (c) *Bounded Openings*— When tested to XXXX.5(c), all completely bounded openings that exist at the front, sides, or back of the occupant lounging area, or that are created when an accessory is attached to the product, shall not allow complete passage of the small head probe unless it allows the complete passage of the large head probe.
- (d) *Maximum Incline Angle*—The maximum incline angle shall not exceed 10 degrees when tested in accordance with XXXX.5(d).
- (e) *Firmness*
  - (1) *Occupant support surface firmness*—When the 3-in diameter (Figure 1) hemispherical head probe is applied according to the test method for occupant support surface firmness XXXX.5(f), the force required for a 1-inch displacement shall be greater than 10N.
  - (2) *Sidewall firmness*— When the 3-in diameter hemispherical head probe is applied according to test method sidewall firmness XXXX.5(g), the force required for a 1-inch displacement shall be greater than 10N.
  - (3) *Firmness at intersection of sidewall and occupant support surface*—When the 3-in diameter hemispherical head probe is applied according to test method for Firmness at intersection of sidewall and occupant support surface XXXX.5(h), the force required for a 1-inch displacement shall be greater than 10N.
- (f) *Side Wall Angle*—Sidewall angle shall be greater than 90 degrees when determined according to the Sidewall Angle Determination XXXX.5(i).



**Figure 1. 3-in Head Probe**

## § XXXX.5 Test Methods

- (a) *Test Conditions.*
  - (1) Condition the product for 48 hours at 23 °C +/- 2 °C (73.4 °F +/- 3.6 °F) and a relative humidity of 50 % +/- 5 %.
- (b) *Permanence of Labels and Warnings:*
  - (1) A paper label (excluding labels attached by a seam) shall be considered

- permanent if, during an attempt to remove it without the aid of tools or solvents, it cannot be removed, it tears into pieces upon removal or such action damages the surface to which it is attached.
- (2) A non-paper label (excluding labels attached by a seam) shall be considered permanent if, during an attempt to remove it without the aid of tools or solvents, it cannot be removed or such action damages the surface to which it is attached.
  - (3) A warning label attached by a seam shall be considered permanent if it does not detach when subjected to a 15-lbf (67-N) pull force applied in any direction using a 3/4-in. diameter clamp surface.
  - (4) Adhesion test for warnings applied directly onto the surface of the product.
    - i. Apply the tape test defined in Test Method B, Cross-Cut Tape Test of ASTM Test Methods D3359, eliminating parallel cuts.
    - ii. Perform this test once in each different location where warnings are applied.
    - iii. The warning statements will be considered permanent if the printing in the area tested is still legible and attached after being subjected to this test.
  - (5) A non-paper label, during an attempt to remove it without the aid of tools or solvents, shall not be removed or shall not fit entirely within the small parts cylinder defined in 16 CFR 1501 if it can be removed.
- (c) *Head Entrapment Test*— For all applicable openings, rotate the small head probe (Figure 2) to the orientation most likely to fail and gradually apply an outward force from the occupant lounging area of 25 lb (111 N). Apply the force to the probe in the direction most likely to fail within a period of 5 s and maintain it for an additional 10 s. If the small head probe can pass entirely through the opening in any orientation, determine if the large head probe (Figure 3) can be freely inserted through the opening.

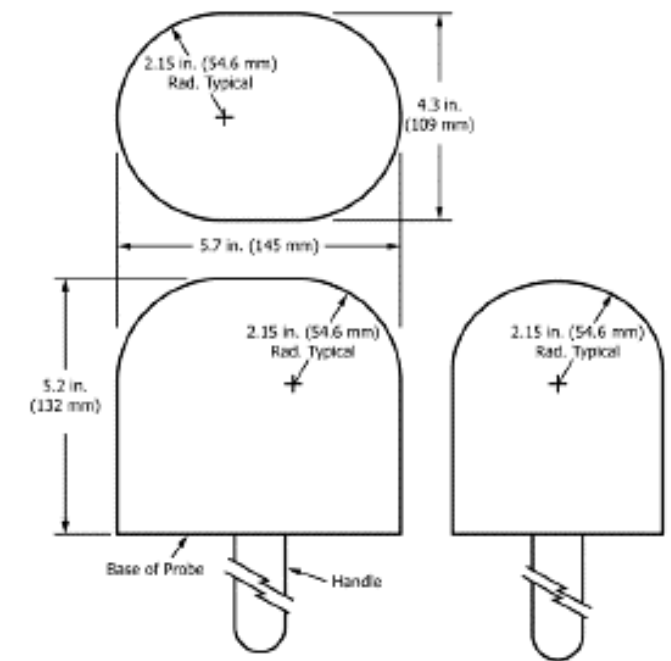


Figure 2. Small Head Probe

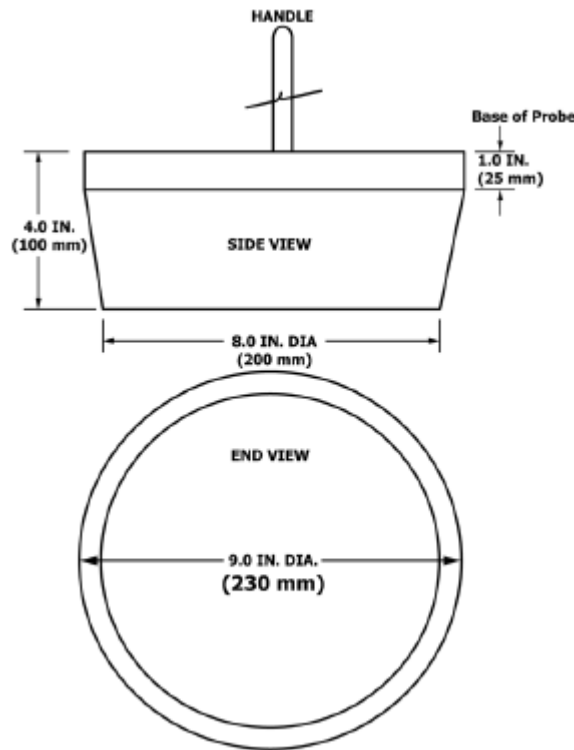


Figure 3. Large Head Probe

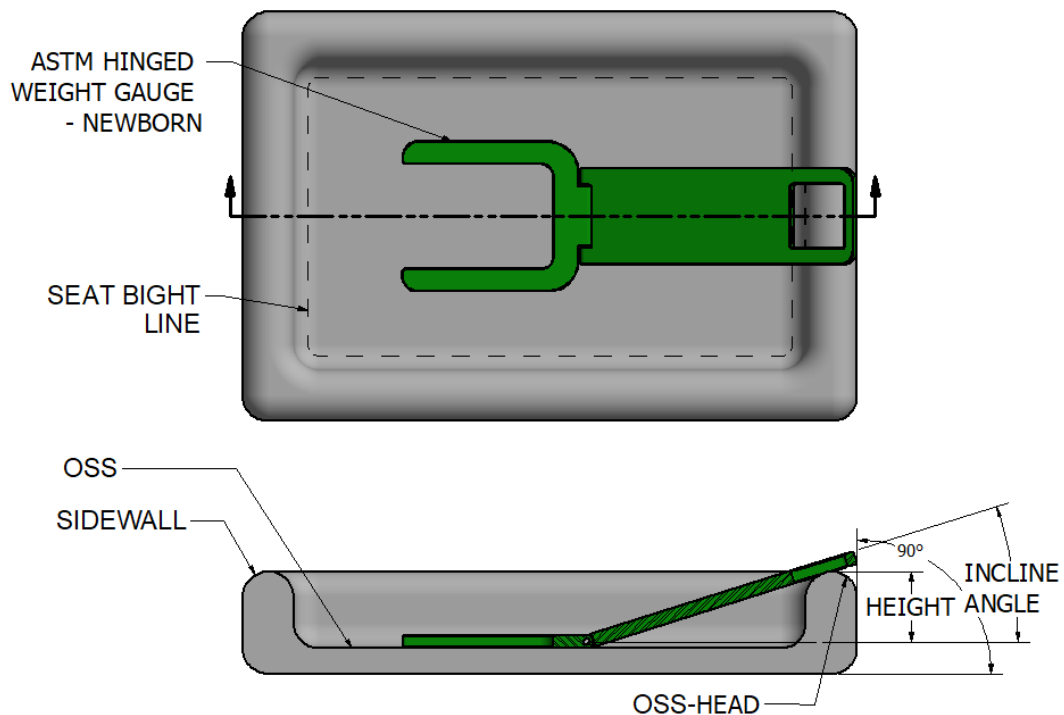
(d) *Maximum Incline Test:*

## (1) Equipment:

- i. Digital Protractor with accuracy +/- 1 degree
- ii. Hinged Weight Gauge–Newborn, Figures 10 and 11.
- iii. A test base that is horizontal, flat, firm, and smooth.

- (2) If applicable, place the product in the manufacturer's recommended highest seat back angle position intended for lounging.
- (3) If applicable, place the hinged weight gauge–newborn in the product and position the gauge with the hinge centered over the seat bight line and the upper plate of the gauge on the seat back. Place a digital protractor on the upper torso/head area lengthwise and measure the incline angle.
- (4) Place the head/torso portion of the newborn hinged weight gauge on the product according to the manufacturer's recommended use position with the seat portion of the gauge, depending on the product design, allowed to lay freely on the product or on the test base (Figure 4).
- (5) Move and rotate the newborn hinged weight gauge the minimum amount necessary such that the head/torso portion rests on an OSS that could foreseeably support an infant's head and place the head/torso portion of the gauge according to all situations that apply:
  - a. In tests on products with an OSS for the infant's body, align the top edge of the head/torso portion of the gauge to coincide with a plumb line to the outermost edge of the OSS-head.
  - b. In all tests, place the seat portion of the gauge on the test base, adjust the newborn gauge to the greatest incline angle in which the top edge of the gauge maintains contact with the top surface of the product.
- (6) If a product's seating bight area prevents reasonable positioning of the head/torso portion to the outermost edge, then position the seat portion of the newborn hinged

- weight gauge as far forward as possible towards the outermost edge and allow the head/torso portion of the gauge to rest on the product.
- (7) Place a digital protractor lengthwise on the head/torso portion of the gauge and measure the incline angle.
  - (8) Remove the newborn gauge and determine the side height at the incline angle location, measured from the OSS-body or test base, as appropriate, to the top of the OSS-head.
  - (9) Measure the incline angle at the manufacturer's recommended use location(s), at feasible locations such as perpendicular to the recommended use location(s), and at least one location likely to fail in which the newborn gauge seat is supported on the test surface.
  - (10) Determine the maximum incline angle from the incline angle measurements.



**Figure 4. Test Fixture Configuration to Measure Incline Angle on an Infant Support Cushion Product**

**(e) Firmness Test Setup**

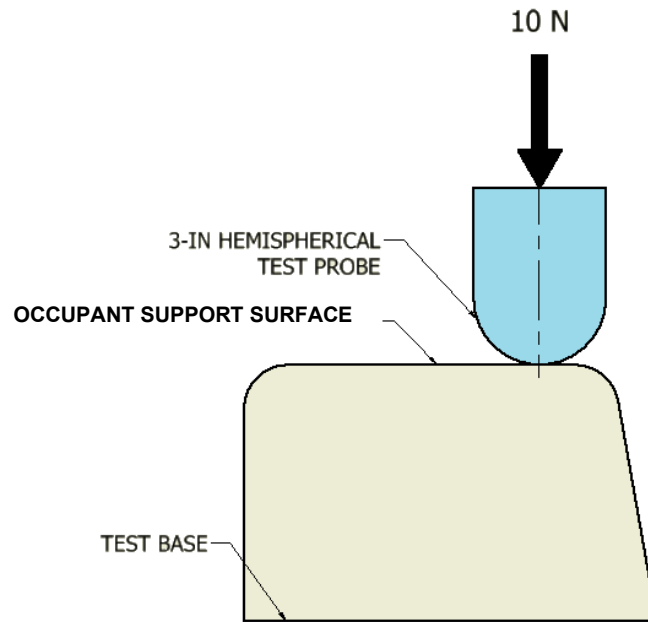
**(1) Equipment.**

- (i) Force gauge with accuracy  $\pm 0.05$  N (0.01 lb).
  - (ii) Distance gauge with accuracy  $\pm 0.01$  in. (0.03 cm).
- (2) Align the axis of the 3-in head probe (Figure 1) with a force gauge and parallel to a distance measurement device or gauge.
  - (3) Use a lead screw or similar device to control movement along a single direction.

- (4) Support the firmness fixture to a test base such that the head probe does not deflect more than 0.01 in. (0.025 cm) under a 10 N (2.2 lb) load applied in each orientation required in the test methods.

(f) *Occupant Support Surface Firmness Test Method.* Perform the following steps to determine the occupant support surface firmness of the product as received from the manufacturer. Figure 5.

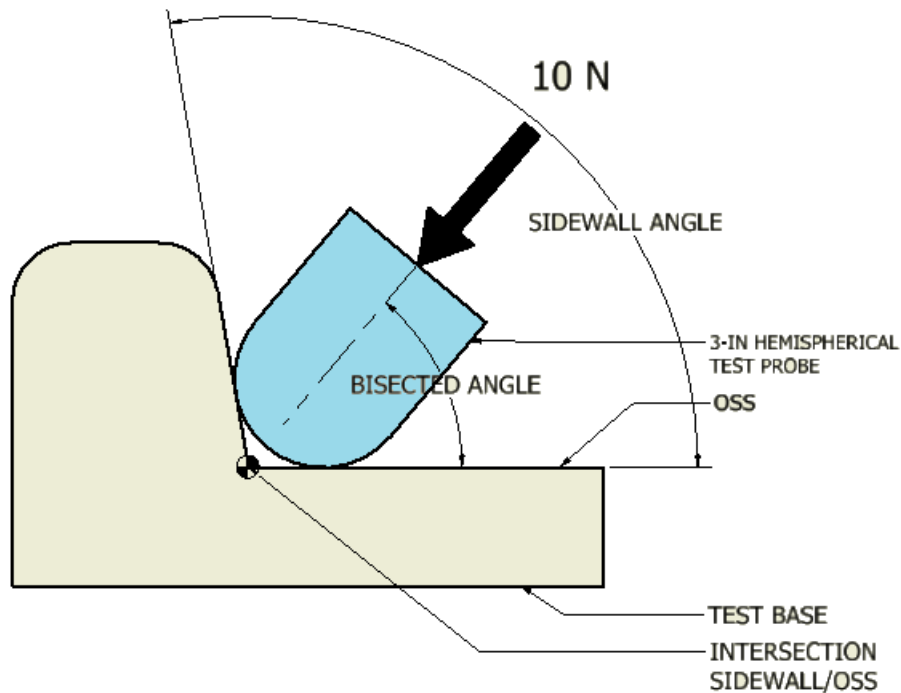
- (1) Orient the axis of the 3-in. head probe perpendicular to the surface of the product at each test location that is oriented greater than 5 degrees relative to the test base or align the axis of the probe perpendicular to the test base (vertically) at each test location that is oriented equal to or less than 5 degrees to the test base.
- (2) The first test location shall be at the location of maximum thickness of the surface being tested, perpendicular to the test base.
- (3) Lay the product, with the occupant support surface facing up, on a test base that is horizontal, flat, firm, and smooth.
- (4) Prevent movement of the product in a manner that does not affect the force or deflection measurement of the product surface under test. Provide no additional support beneath the product.
- (5) Advance the probe into the product and set the deflection to 0.0 in. when a force of 0.1 N (0.02 lb) force is reached.
- (6) Continue to advance the head probe into the product at a rate not to exceed 0.1 inch per second and pause when the force exceeds 10.0 N (2.24 lb), or the deflection is equal to 1.00 in. (2.54 cm).
- (7) Wait 30 seconds. If the deflection is less than 1.00 in. and the force is 10.0 N or less, repeat steps § XXXX.5(f)(6) and § XXXX.5(f)(7)).
- (8) Record the final force and deflection when the deflection has reached 1.00 in. or when the force has exceeded 10.0 N.
- (9) If the maximum thickness of the OSS is greater than 1.0 in (2.54 cm), perform additional tests, space permitting, at the geometric center of the OSS, at four locations along the product's longitudinal and lateral axes therefrom, 1.5 in (3.8 cm) towards center from the intersection of the sidewall and OSS, and at one location most likely to fail.
- (10) Repeat the occupant support surface firmness tests on any other occupant support surface and in all intended and feasible configurations that could affect an occupant support surface, such as the folding or layering of parts of the product.



**Figure 5. Test Configuration for Occupant Support Surface Firmness Test**

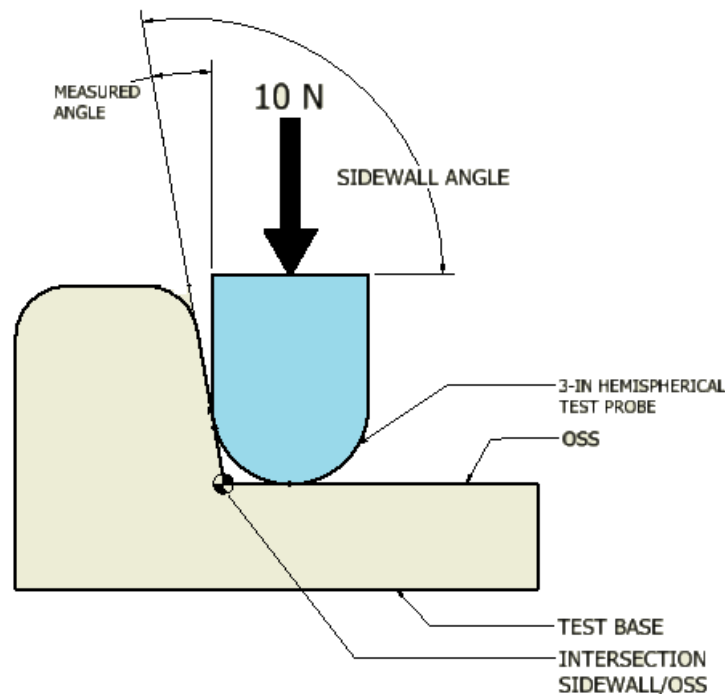
- (g) Sidewall Firmness Test Method. For sidewalls, perform the steps in § XXXX.5(f)(1) through § XXXX.5(f)(8) to determine the sidewall firmness of the product as received from the manufacturer and then perform the following,
- (1) Perform a minimum of four additional tests, located at intervals not to exceed 6 in. along the entire top perimeter of the sidewall, starting from the maximum side height location, and at one additional location most likely to fail.
  - (2) Repeat the sidewall firmness test in all the intended or feasible configurations that could affect the sidewall firmness, such as the folding or layering of parts of the product.
- (h) Intersection of Sidewall and Occupant Support Surface Firmness. Perform the following steps to determine the intersection firmness of the product as received from the manufacturer (Figure 6),
- (1) Orient the axis of the 3-in head probe perpendicular to the sidewall perimeter at an angle from horizontal that bisects the angle determined in Sidewall Angle with the axis directed at the intersection of the occupant support surface and the sidewall (Figure 4).
  - (2) The first test location shall be at the location of maximum product thickness parallel to the test base.
  - (3) Perform the steps in § XXXX.5(f)(3) through § XXXX.5(f)(8).
  - (4) Perform a minimum of four additional tests, located at intervals not to exceed 6 in. along the entire inside perimeter of the intersection of the sidewall and OSS, and at one additional location most likely to fail.
  - (5) Repeat the intersection of sidewall and occupant support surface firmness test in all

the intended or feasible configurations that could affect the intersection firmness, such as the folding or layering of parts of the product.



**Figure 6. Test Configuration for Intersection of Sidewall and Occupant Support Surface Firmness**

- (i) *Sidewall Angle Determination.* Perform the following steps to determine if the angle between the sidewall and OSS is 90 degrees or less, or to measure the angle above 90 degrees. Figure 7.
  - (1) Orient the 3-in (7.62 cm) diameter hemispherical head probe vertically and place over the OSS with the cylindrical surface of the probe tangent to the intersection of the sidewall and the OSS. Advance the probe into the product until a downward force of 10 N (2.2 lb) force is reached. Figure 5.
  - (2) After 30 s, determine whether the sidewall is in contact with the cylindrical side of the 3-in head probe. If the sidewall contacts the cylindrical part of the probe, the sidewall angle is equal to or less than 90 degrees.
  - (3) For sidewall angles greater than 90 degrees, calculate the sidewall angle as 90 degrees plus the measured angle between the cylindrical side of the 3-in head probe and the sidewall.
  - (4) Determine a minimum of four sidewall angles at locations not to exceed 6 in (15.2 cm) intervals along the intersection of the sidewall and OSS.
  - (5) Measure the angle with a protractor or gauge placed to the depth of and in contact with the cylindrical side of the three-inch probe side and the sidewall.



**Figure 7. Test Fixture Configuration for Sidewall Angle Measurement**

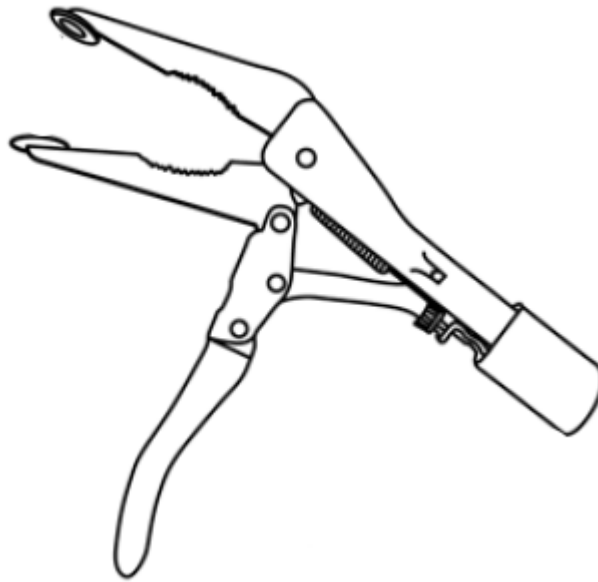
(j) *Seam Strength Test Method.*

- (1) *Equipment.* Clamps with 0.75 in. (1.9 cm) diameter clamping surfaces capable of holding fabric and with a means to attach a force gauge. Figure 8, or equivalent. A force gauge, accuracy  $\pm 0.5$  lb (1.1 N).
- (2) Clamp the fabric of the infant support cushion on each side of the seam under test with the 0.75 in. clamping surfaces placed not less than 0.5 in. (1.2 cm) from the seam.
- (3) Apply a tension of 15 lb (67 N) evenly over 5 s. and maintain for an additional 10 s.
- (4) Repeat the test on every distinct seam and every 12 in. (15 cm) along each seam.

(k) *Removal of Components Test Method.*

- (1) For torque and tension tests, any suitable device may be used to grasp the component that does not interfere with the attachment elements that are stressed during the tests.
- (2) *Torque Test.* Gradually apply a 4 lb-in. (0.4 N-m) torque over 5 s. in a clockwise rotation to 180 degrees or until 4 lb-in. has been reached. Maintain for 10 s. Release and allow component to return to relaxed state. Repeat the torque test in a counterclockwise rotation.
- (3) *Tension Test.* For components that can reasonably be grasped between thumb and forefinger, or teeth, apply a 15 lb (67 N) force over 5 s., in a direction to remove the component. Maintain for 10 s. A clamp such as shown in Figure 9 may be used if the gap between the back of the component and the base

material is 0.04 in. (0.1 cm) or more.



**Figure 8. Seam Clamp**



**Figure 9. Tension Test Adapter Clamp**

## § XXXX.6 Marking and Labeling

- (a) Each product and its retail package shall be marked or labeled clearly and legibly to indicate the following:
  - (1) The name, place of business (city, state, and mailing address, including zip code), and telephone number of the manufacturer, distributor, or seller.
  - (2) A code mark or other means that identifies the date (month and year as a minimum) of manufacture.
  - (3) The marking or labeling in XXXX.6(a)(1) and (2) are not required on the retail package if they are on the product and are visible in their entirety through the retail package. When no retail packaging is used to enclose the product, the information provided on the product shall be used for determining compliance with XXXX.6(a)(1) and (2). Cartons and other materials used exclusively for shipping the product are not considered retail packaging.
- (b) The marking and labeling on the product shall be permanent.
- (c) Any upholstery labeling required by law shall not be used to meet the requirements of this section.
- (d) Warning Design for Product:
  - (1) The warnings shall be easy to read and understand and be in the English language at a minimum.
  - (2) Any marking or labeling provided in addition to those required by this section shall not contradict or confuse the meaning of the required information or be otherwise misleading to the consumer.
  - (3) The warnings shall be conspicuous and permanent.
  - (4) The warnings shall conform to ANSI Z535.4–2011, American National Standard for Product Safety Signs and Labels, sections 6.1–6.4, 7.2–7.6.3, and 8.1, with the following changes.
    - i. In sections 6.2.2, 7.3, 7.5, and 8.1.2, replace “should” with “shall.”
    - ii. In section 7.6.3, replace “should (when feasible)” with “shall.”
    - iii. Strike the word “safety” when used immediately before a color (for example, replace “safety white” with “white”).

NOTE — For reference, ANSI Z535.1, American National Standard for Safety Colors, provides a system for specifying safety colors
  - (5) The safety alert symbol and the signal word “WARNING” shall be at least 0.2 in. (5 mm) high. The remainder of the text shall be in characters whose upper case shall be at least 0.1 in. (2.5 mm), except where otherwise specified.

NOTE — For improved warning readability, typefaces with large height-to-width ratios, which are commonly identified as “condensed,” “compressed,” “narrow,” or similar should be avoided.

- (6) Message Panel Text Layout:
  - i. The text shall be left-aligned, ragged-right for all but one-line text messages, which can be left-aligned or centered.

NOTE — Left-aligned means that the text is aligned along the left margin, and in the case of multiple columns of text, along the left side of each individual column.

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

paragraph formatting is used.

(7) An example warning in the format described in this section is shown in Figure 12.

(e) Warning Statements — Each product shall have warning statements to address the following at a minimum.

NOTE — “Address” means that verbiage other than what is shown can be used as long as the meaning is the same or information that is product-specific is presented.

**USING THIS PRODUCT FOR SLEEP OR NAPS CAN KILL.**

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

- **Use only with an AWAKE baby.**
- **Stay near and watch baby during use.** If baby falls asleep, remove baby as soon as possible and place baby on a firm, flat surface such as a crib or bassinet.
- **Use only on floor,** with baby face-up on back. Do not use on soft surfaces or in sleep products like cribs and bassinets.
- Keep blankets and other soft bedding or items out of product.

Babies have been injured from FALLS.

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

## 5) § XXXX.7 Instructional Literature

(a) Instructions shall be provided with the product and shall be easy to read and understand and shall be in the English language at a minimum. These instructions shall include information on assembly, maintenance, cleaning, and use, where applicable.

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

- (1) Read all instructions before using this product.
- (2) Keep instructions for future use.
- (3) Do not use this this product if it is damaged or broken.
- (4) Instructions shall indicate the manufacturers recommended maximum weight, height, age, developmental level, or combination thereof, of the occupant for which the infant support is intended. If this product is not intended for use by a child for a specific reason, the instructions shall so state this limitation.

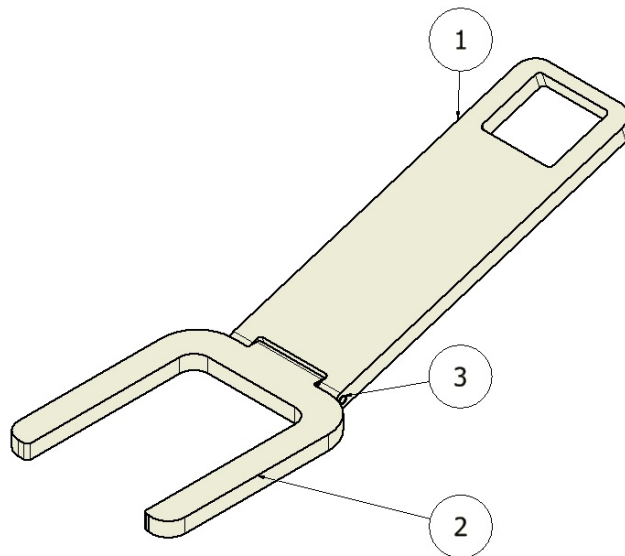
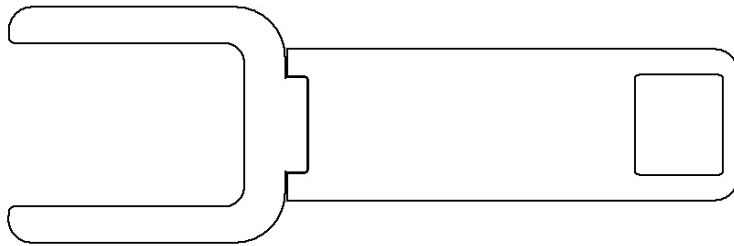
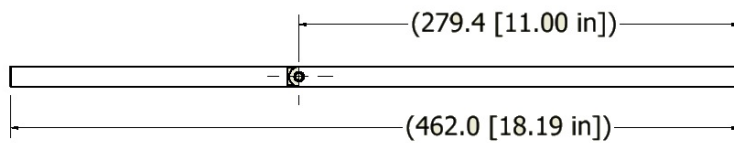
(c) The cautions and warnings in the instructions shall meet the requirements specified in XXXX.6(d)(4), XXXX.6(d)(5), and XXXX.6(d)(6), except those sections 6.4 and 7.2–7.6.3 of ANSI Z535.4 – 2011, American National Standard for Product Safety Signs and Labels, need not be applied. However, the signal word and safety alert symbol shall contrast with the background of the signal word panel, and the cautions and warnings shall contrast with the background of the instructional literature.

*NOTE Y1 —For example, the signal word, safety alert symbol, and the warnings may be black letters on a white background, white letters on a black background, navy blue letters on an off-white background, or some other high-contrast combination.*

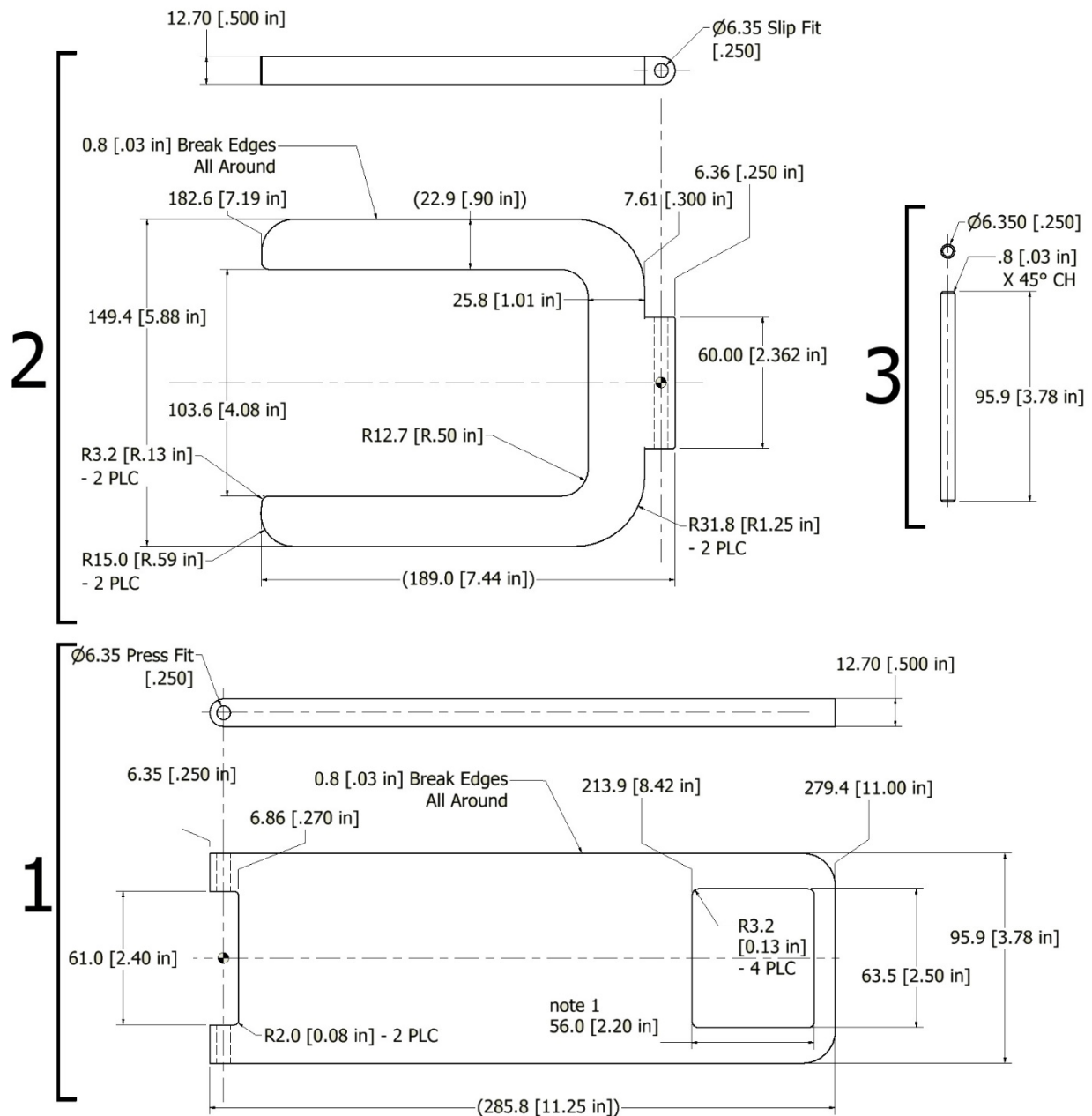
(d) Any instructions provided in addition to those required by this section shall not contradict or confuse the meaning of the required information or be otherwise misleading to the consumer.

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

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



**Figure 10. Hinged Weight Gauge–Newborn Assembly Drawings and Parts List**



**Figure 11. Hinged Weight Gauge–Newborn Part Drawings**



Figure 12. Example of Warning