UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
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This document has been electronically approved and signed.

DATE: September 4, 2019

BALLOT VOTE SHEET

TO: The Commission
Alberta E. Mills, Secretary

THROUGH: Patricia M. Hanz, General Counsel
Mary T. Boyle, Executive Director

FROM: Patricia M. Pollitzer, Assistant General Counsel
Barbara E. Little, Attorney, OGC

SUBJECT: Proposed Rule: Safety Standard for Crib Bumpers/Liners under the Danny Keysar Child Product Safety Notification Act

BALLOT VOTE DUE Tuesday, September 10, 2019

Staff is forwarding to the Commission a briefing package recommending that the Commission issue a proposed rule under section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA) to incorporate by reference the voluntary standard, ASTM F1917-12, *Standard Consumer Safety Performance Specification for Infant Bedding and Related Accessories*, with modifications, as a mandatory federal safety standard for crib bumpers/liners. The Office of the General Counsel is providing the attached draft proposed rule for Commission consideration.

Please indicate your vote on the following options:

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

_____ _____
(Signature) (Date)

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

_____

_____

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_____

_____ _____

(Signature) (Date)

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

_____ _____

(Signature) (Date)

IV. Take other action specified below.

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_____ _____

(Signature) (Date)

Attachment: Draft *Federal Register* Notice: Proposed Rule to Establish a Safety Standard for Bumpers/Liners.

Billing Code 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1112, 1130, and 1240

[CPSC Docket No. 2019-XXXX]

Safety Standard for Crib Bumpers/Liners

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Danny Keysar Child Product Safety Notification Act, *i.e.*, section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), requires the United States Consumer Product Safety Commission (CPSC) to promulgate consumer product safety standards for durable infant or toddler products. These standards are to be "substantially the same as" applicable voluntary standards, or more stringent than the voluntary standard if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product. The Commission is proposing a safety standard for crib bumpers/liners, and it is also proposing to identify crib bumpers/liners as durable infant or toddler products subject to CPSC's consumer registration requirements. In addition, the Commission is proposing an amendment to include crib bumpers in the list of notice of requirements (NORs) issued by the Commission.

DATES: Submit comments by [INSERT DATE 75 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 mandatory standard for crib bumpers/liners should be directed to the Office of Information and Regulatory Affairs, the Office

of Management and Budget, Attn: CPSC Desk Officer, FAX: 202-395-6974, or e-mailed to oira_submission@omb.eop.gov.

Other comments, identified by Docket No. CPSC-2019-XXXX, may be submitted electronically or in writing:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: http://www.regulations.gov. Follow the instructions for submitting comments. The Commission does not accept comments submitted by electronic mail (e-mail), except through www.regulations.gov. The Commission encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

Written Submissions: Submit written submissions by mail/hand delivery/courier to: Office of the Secretary, Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7923.

Instructions: All submissions received must include the agency name and docket number for this proposed rulemaking. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to: http://www.regulations.gov. Do not submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If furnished at all, such information should be submitted in writing.

Docket: For access to the docket to read background documents or comments received, go to: http://www.regulations.gov, and insert the docket number, CPSC-2019-XXXX, into the "Search" box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Timothy P. Smith, Project Manager, Directorate for Engineering Sciences, U.S. Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone: (301) 987-2557; email: *tsmith@cpsc.gov*.

SUPPLEMENTARY INFORMATION: The CPSC proposes to issue a standard for crib bumpers/liners under section 104 of the CPSIA, amend the consumer registration rule to include crib bumpers/liners, and add crib bumpers/liners to the NOR list in 16 CFR part 1112.[1]

I. Background and Statutory Authority

Section 104(b) of the CPSIA, part of the Danny Keysar Child Product Safety Notification Act, 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 or toddler products. Standards issued under section 104 are to be "substantially the same as" the applicable voluntary standards, or more stringent than the voluntary standard if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product.

Section 104(f)(1) 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." The statute also specifies 12 categories of products that fall within the definition. Crib bumpers are not listed among the products in section 104(f); however, on October 19, 2016, the Commission voted to amend the agency's fiscal year 2017 (FY 2017) Operating Plan, directing staff to initiate rulemaking under section 104 of the CPSIA to

[1] [Add information about Commission vote].

promulgate a mandatory consumer product safety standard to address the risk of injury associated with the use of padded crib bumpers. [2] The FY 2017 Operating Plan also directed staff to propose to amend the definition of "durable infant or toddler product" in the consumer registration rule to include "crib bumpers."

Pursuant to section 104(b)(1)(A) of the CPSIA, CPSC staff consulted with manufacturers, retailers, trade organizations, laboratories, consumer advocacy groups, consultants, and members of the public in the development of this notice of proposed rulemaking (NPR), largely through the ASTM process. ASTM subcommittee members represent producers, users, consumers, government, and academia.[3] Staff began the consultation process for this rulemaking in December 2016 in a letter to ASTM requesting that the ASTM F15.19 Subcommittee on Infant Bedding form task groups related to (1) firmness requirements, (2) airflow requirements, and (3) warning and instructional requirements, to initiate activities to update ASTM F1917, *Standard Consumer Safety Performance Specification for Infant Bedding and Related Accessories*, with more stringent requirements that will further reduce the risk of injury associated with crib bumpers. Since then, CPSC staff has been actively participating in the ASTM subcommittee activities to address these issues.

This NPR incorporates by reference the most recent voluntary standard developed by ASTM International, ASTM F1917-12, *Standard Consumer Safety Performance Specification for Infant Bedding and Related Accessories*, with substantial modifications that would further reduce the risk of injury or death from crib bumpers/liners. If finalized, the ASTM standard

[2] The final, approved FY 2017 Operating Plan can be found here: https://www.cpsc.gov/s3fs-public/CPSCFY2017OpPlan.pdf. The Commission reaffirmed this decision in the FY18 Operating Plan, which can be found here: https://www.cpsc.gov/s3fs-public/FY_2018_Operating_Plan_August302017.pdf.

[3] ASTM International website: www.astm.org, About ASTM International.

incorporated by reference, as modified, would be a mandatory safety rule under the Consumer Product Safety Act (CPSA).

The testing and certification requirements of section 14(a) of the CPSA apply to the standards promulgated under section 104 of the CPSIA. Section 14(a)(3) of the 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 for crib bumpers/liners, if issued as a final rule, would be a children's product safety rule that requires the issuance of an NOR. To meet the requirement that the Commission issue an NOR for the crib bumpers/liners standard, this NPR also proposes to amend 16 CFR part 1112 to include 16 CFR part 1240, the CFR section where the crib bumpers standard will be codified, if the standard becomes final.

II. Product Description

Traditionally, crib bumpers are infant bedding accessories that attach to the interior perimeter of a crib and function as a barrier between the infant and the sides of the crib. However, the design of these products can vary. The most common type of crib bumper consists of one or more rectangular fabric panels, constructed of cotton or polyester, with filling material for padding and with fasteners to attach to a crib. The fasteners are often ties that are secured to the crib corner posts, crib slats or spindles, or both. However, other fastening methods exist. These products commonly are marketed as preventing injury to infants from impacts against the sides of a crib and preventing limb entrapments between crib slats. Bumpers also are used to decorate the infant's sleep environment and might be promoted as making a crib more comfortable.

Less common designs of crib bumpers include "vertical" bumpers or liners, which essentially are a series of small bumpers that individually enshroud each vertical crib slat or spindle. These products generally claim to offer benefits that are comparable to traditional bumpers while allowing airflow through the sides of a crib. More recent crib bumper variants are braided bumpers, which consist of two or more fabric sleeves, containing filling material, and that are braided together. Other bumper variants exist that look similar to traditional bumpers but are marketed with claims of being "breathable." Mesh crib liners are similar in their marketing claims that the products are breathable, but these products tend to be thinner than traditional bumpers, with minimal padding, if any, because they are not intended to prevent impact injuries.

All of these products, like traditional crib bumpers, line the interior sides of a crib and functionally limit or prevent access to the crib sides, so, in principle, all of these products might present similar hazards and benefits to infants. Thus, this proposed rule includes all of these products within its scope. Throughout this Federal Register notice, the term "crib bumpers" or "bumpers" includes these other products, unless specifically excluded.[4]

III. Incident Data

CPSC has identified 113 fatal incidents associated with crib bumpers (*i.e.*, cases in which a crib bumper was present in the sleep environment) reported to have occurred from January 1, 1990 through March 31, 2019.[5] CPSC has identified 113 nonfatal incidents and concerns that involved crib bumpers and were reported to CPSC from January 1, 2008, through March 31,

[4] As discussed herein, ASTM F1917-12 does not contain a definition of "crib bumpers."

[5] Although this nearly 30-year timeframe is considerably longer than the 10-year timeframe that CPSC commonly employs in other section 104 rulemaking activities, CPSC staff's 2016 briefing package concluded that all the reported fatalities that staff examined and considered most likely to be addressable occurred before 2008. (https://www.cpsc.gov/s3fs-public/StaffResponsetotheRecordofCommissionActiononCribBumper.pdf.) Thus, to be as inclusive as possible, CPSC has chosen to retain reported fatalities as far back as 1990.

2019. Because reporting is ongoing, the number of reported fatalities and nonfatal incidents and concerns may change in the future. Specifically, data for years 2017 through 2019 are not complete.

A. Fatalities

CPSC has reports of 113 fatalities associated with bumpers, which were reported to have occurred between January 1, 1990 and March 31, 2019. To CPSC's knowledge, all bumpers involved in these incidents were traditional bumpers, and all but eight involved the bumper inside a crib.[6]

CPSC classified 30 of the 113 crib bumper-related fatalities as "incidental." In three of these cases, the cause of death was known to have been exclusively medical in nature, and therefore unrelated to the bumper. In 27 of these 30 cases, although a bumper was present, there was no evidence of bumper contact with the infant.

Of the remaining 83 reported fatalities, 75 (90 percent) involved infants younger than 12 months and 51 (61 percent) involved infants 4 months old or younger. Only three of the 83 reported fatalities involved children 2 years old or older; one of these children had health issues, one was developmentally delayed, and the third went into cardiac arrest about a year after the bumper-related incident, when the child was likely an infant.

B. Nonfatal Incidents and Concerns

CPSC has reports of 113 bumper-related nonfatal incidents and concerns that were related to crib bumpers and were reported to CPSC from January 1, 2008, through March 31, 2019. Of these 113 nonfatal reports, 60 resulted in injury, 50 did not result in injury, and the disposition of 3 is unknown. Fifteen (13 percent) of the 113 nonfatal incidents and concerns

[6] Three incidents occurred in a toddler bed, three in a bassinet, one in a playpen, and one on a mattress on the floor.

reportedly involved a breathable bumper or mesh liner. Thirty-five cases did not report the child's age. Of the remaining 78 nonfatal incidents and concerns, 47 (60 percent) involved infants younger than 12 months.

C. Product Recalls

CPSC staff reviewed recalls involving crib bumpers that occurred from July 9, 1990 through April 17, 2019. Staff identified five consumer-level recalls during that period to mitigate against risks of entanglement, entrapment, suffocation, and choking from loose threads (e.g., unraveling ties, breaking threads and seams) and from bumper ties that either detached from the product or were too long.

IV. Hazard Pattern Identification

A. Fatal Incidents

Generally, the cause of death in the fatal incidents was reported as asphyxia, suffocation, or Sudden Infant Death Syndrome (SIDS). A number of reports indicated that in addition to a crib bumper being present, the sleeping environment contained multiple additional items, such as pillows, blankets, and stuffed dolls. In many of these incidents, it is unclear what role, if any, the crib bumper played in the death of the child. CPSC staff, through group consensus, categorized the fatalities into hazard scenarios based on the best available account information about the position of the child when found and the cause of death ruled by the medical examiner.

As mentioned previously, 30 of the 113 reported fatalities were incidental. Table 1 shows the distribution of the remaining 83 non-incidental reported fatalities by hazard scenarios.

Table 1: Reported Fatalities by Hazard Scenario
January 1, 1990 - March 31, 2019

Hazard	Reported Fatalities	Percent[7]
Entrapment/Wedging	**44**	**53**
Against Object in Crib	*25*	*30*
In Perimeter of Crib	*13*	*16*
Other	*6*	*7*
Contact Without Entrapment/Wedging	**27**	**33**
Contact With Possible Entrapment/Wedging	**7**	**8**
Contact Outside Crib	**5**	**6**
Total	**83**	**100**

Source: CPSRMS and NEISS databases
Reporting is ongoing for these databases, especially for 2017-2019.

1. Entrapment/Wedging: In 53 percent (44 out of 83 fatalities) of the reported fatalities, the child was found wedged or entrapped against the bumper. This category was divided into three scenarios in which the child was found wedged or entrapped.

a. *Against Object in Crib*: In 30 percent (25 out of 83 fatalities) of the reported fatalities, the child was entrapped or wedged between a crib bumper and another object in the crib, such as a bed pillow, an infant recliner, or a cushion.

b. *In Perimeter of Crib*: In 16 percent (13 out of 83 fatalities) of the reported fatalities the child was found entrapped between the mattress and the side of the crib, on which a crib bumper was installed. Nine of these cases involved a crib that was structurally compromised, with features such as detached crib side rails, or missing or detached crib slats.

c. *Other*: Seven percent (6 out of 83 fatalities) of the reported fatalities involved entrapment against a crib bumper in some scenario not covered by the two prior Entrapment/Wedging hazard patterns, such as a child being found wedged under the crib bumper.

[7] Percentages may not sum to 100 due to rounding.

2. Contact Without Entrapment/Wedging: In 33 percent (27 out of 83 fatalities) of the reported fatalities, the child was reportedly in contact with, but not entrapped or wedged against, the crib bumper.

3. Contact With Possible Entrapment/Wedging: In eight percent (7 out of 83 fatalities) of the reported fatalities, the child was found to be in contact with the crib bumper, but the incident scenario lacked sufficient details for the staff to determine whether the child was entrapped or wedged against the bumper. These fatalities typically described the child as being found with his or her face between the mattress and the crib bumper. The incident descriptions often used the phrase "wedged between" to describe the position of the child's face when found. However, staff discovered that some incidents without entrapment or wedging used similar language to describe the orientation of the child's face relative to the two surfaces. Thus, incidents in this category did not include sufficient details to enable CPSC staff to conclude whether the child was truly entrapped or wedged against the bumper.

4. Contact Outside Crib: Six percent (5 out of 83 fatalities) of the reported fatalities were cases in which the child was in contact with a crib bumper that was outside a crib. Staff is aware of three other incidents involving a bumper outside a crib, but in those incidents there was no evidence of contact with the crib bumper, and thus, these three fatalities were ruled incidental and not included.

B. Nonfatal Incidents

Table 2 summarizes the hazard patterns for the bumper-related nonfatal incidents. In cases where multiple hazards were mentioned, the hazard that could have caused the most severe injury was used.

Table 2 Reported Nonfatal Incidents or Concerns by Hazard Pattern
January 1, 2008 - March 31, 2019

Hazard	Incidents/Complaints	Percent[8]
Slat Entrapments	38	34
Climbing or Climb-Outs	12	11
Under or Behind Bumper	10	9
Near-Strangulation or Entanglements	8	7
Entrapped Against Object in Crib	7	6
Choking or Ingestion of Small Parts	7	6
Other	14	12
Concerns	17	15
Total	**113**	**100**

Source: CPSRMS and NEISS databases
Reporting is ongoing for these databases, especially for 2017-2019.

1. Slat Entrapments: Thirty-four percent (38 out of 113 non-fatalities) of reported nonfatal incidents involved arm or leg entrapments between the slats of the crib, even though a crib bumper was present. Seven of the 38 slat entrapments reportedly involved a breathable bumper or mesh liner. Of the 38 slat entrapments, 27 incurred injuries.

2. Climbing or Climb-Outs: Eleven percent (12 out of 113 non-fatalities) of reported nonfatal incidents occurred when a child, old enough to stand up, reportedly used the bumper as a step to climb. The child often fell back into the crib or fell out of the crib. The youngest children in these incidents were two 7-month-old children.

3. Under or Behind Bumper: In nine percent (10 out of 113 non-fatalities) of reported nonfatal incidents, the child or some part of the child was found under or behind (*i.e.*, against the crib side) the crib bumper. In seven cases, the child reportedly was trapped under or behind the bumper. In two cases, the bumper covered the child's face, but the child was not entrapped. In one case, the face was under the bumper while the legs were trapped in the slats. Some of these cases reported that the bumper was missing bottom ties.

[8] Percentages may not sum to 100 due to rounding.

4. Near-Strangulation or Entanglements: Seven percent (8 out of 113 non-fatalities) of reported nonfatal incidents involved the tie, threading, or stitched-on components of a crib bumper becoming loose and wrapping around body parts of the child. Half of these incidents specifically mention the head, mouth, or neck being wrapped up by a piece of a crib bumper. However, none of these incidents involved a bumper tie wrapping around a child's neck.

5. Entrapped Against Object in Crib: In six percent (7 out of 113 non-fatalities) of reported nonfatal incidents, the child was entrapped between a crib bumper and another object in the crib, such as a sleep positioner or an infant recliner.

6. Choking or Ingestion of Small Parts: Six percent (7 out of 113 non-fatalities) of reported nonfatal incidents involved choking or ingestions. These incidents generally involved the child putting a piece of the crib bumper, such as decorative stitched-on patterns, the ties, or the stuffing from inside the bumper, into their mouth.

7. Other: Twelve percent (14 out of 113 non-fatalities) of reported nonfatal incidents were other issues involving a child, including: bumper integrity issues such as ties detaching or being pulled off, stitching being pulled out, and paint rubbing off; injuries caused by contact with crib bumpers; needles found in the padding of the bumper; injuries, such as cuts and bruises on the crib rail, that occurred despite the presence of the bumper; portions of the crib (*e.g.*, crib rails or slats, crib side) breaking or separating while bumpers were in use; and an entrapment between a crib toy and the crib mattress while in contact with the bumpers.

8. Concerns: Fifteen percent (17 out of 113 non-fatalities) of reported nonfatal incidents and concerns did not involve an actual incident with a child, but instead, were general crib bumper-related problems observed by the parent or complainant. Common examples of concerns with crib bumpers were: bumper integrity issues such as ties detaching or the bumper coming apart;

concerns about poor bumper fit or bumpers missing the lower ties; and general concerns about bumpers posing a safety hazard.

V. Standards for Crib Bumpers

A. International Standard

CPSC is aware of one international standard that contains performance requirements for crib bumpers/liners: BS EN 16780:2018, *Textile child care articles – Safety requirements and test methods for children's cot bumpers.* (BS EN 16780:2018).[9] BS EN 16780:2018 has requirements to address falls from the crib, suffocation on materials, strangulation on cords, entrapment of fingers/toes, sharp or abrasive edges, choking, internal injuries from magnets, entrapment, strangulation, choking, cuts and abrasions. EN 16780:2018 also includes requirements pertaining to chemical hazards, fire hazards, and hygiene hazards.

EN 16780:2018 requires that the design of the product prevent the crib bumper/liner from falling into the crib, but the design requirement does not have a test method. The standard does not have a requirement for the firmness of crib bumpers/liners. Additionally, although there are specific requirements (prohibitions) for plastic surfaces that could affect breathability, the rationale for that requirement assumes the air flow characteristics of the underlying woven fabric and filling materials are adequate. The standard provides no basis for its rationale and lacks a test method. The contact of an infant's face into a soft crib bumper/liner is not addressed.

[9] The foreword to BS EN 16780:2018 states that the British Standard is the UK implementation of EN 16780:2018, and it partially supersedes BS 1877-10:2011+A1:2012. The foreword also states that "BSI, as a member of CEN, is obliged to publish EN 16780:2018 as a British Standard. However, attention is drawn to the fact that during the development of this European Standard, the UK committee voted against its approval." BS 1877-10:2011+A1:2012 has length and strength requirements for crib bumper ties similar to those in EN 16780:2018, but does not have any thickness or firmness requirements for crib bumpers.

B. State and Local Standards

Some state and local jurisdictions have banned the sale of crib bumpers.

- *Chicago, IL:* The sale or lease of any "crib bumper pad" is illegal in Chicago, IL, effective April 5, 2012.[10] The Chicago code defines a "crib bumper pad" as: "any padding material, including but not limited to a roll of stuffed fabric, which is designed for placement within a crib to cushion one or more of the crib's inner sides adjacent to the crib mattress."
- *Maryland:* Effective June 21, 2013, Maryland's Department of Health and Mental Hygiene (DHMH) published final regulations that declare "baby bumper pads" to be a hazardous material that may not be shipped or sold to a purchaser in Maryland. The Maryland regulation defines "baby bumper pad" as: "a pad or pads of non-mesh material resting directly above the mattress in a crib, running the circumference of the crib or along the length of any of the interior sides of the crib, and intended to be used until the age that an infant pulls to a stand." The regulation also states that a "new" ASTM voluntary standard for these products might replace the ban if the DHMH Secretary determines that products complying with the ASTM standard are not a danger to public health and safety, and that the Secretary may suspend the regulation if the CPSC affirmatively finds that the benefits of certain bumpers exceed the risks. The ban does not apply to mesh crib liners or to vertical bumpers that wrap tightly around each individual crib rail.[11]

[10] Chicago, IL., Mun. Code § 7-36-112.
[11] See https://phpa.health.maryland.gov/mch/Pages/crib-bumpers.aspx.

- *Watchung, NJ:* On December 15, 2016, the borough of Watchung, NJ, amended its police regulations to prohibit the sale or lease of "crib bumper pads,"[12] which are defined as: "any padding material, including but not limited to a roll of stuffed fabric or breathable liner, which is designed for placement within a crib to cushion one or more of the crib's inner sides adjacent to the crib mattress." The ordinance explicitly states that mesh liners are not included in the definition of "crib bumper pad."
- *Ohio:* On April 6, 2017, Ohio banned the manufacture, sale, or delivery of "crib bumper pads,"[13] defined as: "any padding material, including a roll of stuffed fabric, that is designed for placement within a crib to cushion one or more of the crib's inner sides adjacent to the crib mattress." The definition also states that "crib bumper pad" excludes mesh crib liners, regardless of whether CPSC includes mesh liners in its definition of "crib bumper pad." The ban excludes mesh crib liners for no more than 3 years after the effective date, unless such liners comply with consumer product safety standards promulgated by CPSC to ensure sufficient permeability and breathability to prevent infant suffocation.

The states of Missouri, New York, and Vermont are considering similar bans. In addition, in June 2019, a bill to ban the manufacture, importation, and sale of crib bumpers in the United States, the "Safe Cribs Act of 2019" (H. R. 3170 and S. 1816), was introduced in Congress. The bill, as introduced, defined the term "crib bumper" broadly to include not only traditional padded crib bumpers, but also mesh crib liners and vertical bumpers, or crib slat covers. However, on July 10, 2019, the House Committee on Energy and Commerce,

[12] Revised General Ordinances of the Borough of Watchung, Chapter VI § 6-13, Ord. No. 2016-15.
[13] 37 Ohio Rev. Code § 3713.

Subcommittee on Consumer Protection and Commerce, amended the definition of "crib bumper" in H. R. 3170 to exclude mesh liners.

VI. Voluntary Standard–ASTM F1917

A. Background

ASTM F1917, *Standard Consumer Safety Performance Specification for Infant Bedding and Related Accessories*, contains requirements for infant bedding and related accessories, including crib bumpers, in the United States. The current version of the voluntary standard was published in 2012 (ASTM F1917 – 12). This is the third revision since the standard was first published in 1999.

B. Description of the Current Voluntary Standard–ASTM F1917-12

ASTM F1917-12 includes the following key provisions: scope, terminology, general requirements, performance requirements, test methods, and labeling requirements. Tab C of the staff's briefing package provides details about the standard. We summarize key provisions below.

The scope section of ASTM F1917-12 provides that the standard applies to "infant bedding and related accessories." Section 3.1.4 of ASTM F1917-12 defines the term "infant bedding and related accessories" to include the following items intended for use in a nursery: fitted sheets, blankets, dust ruffles, covers and drapes for canopies, pillows, mattress covers, diaper stackers, fabric wall, bumper guards, headboard bumper guards, and comforters. This proposed rule would apply only to crib bumpers. ASTM F1917-12 does not define "crib bumper."

ASTM F1917-12 contains general requirements for the bumper's attachment means (*e.g.*, ties), decorative components, and threads. Section 5 of ASTM F1917-12 requires crib bumpers

to be "capable of being secured at or near all corners and at the midpoints of the long sides of the crib," and specifies that bumpers intended for circular cribs must be capable of being secured at intervals not exceeding 26 inches.

Section 6 of ASTM F1917-12 includes performance requirements and test methods for unsupported vinyls, maximum bumper thickness, and bumper pad tie strength. ASTM F1917-12 defines unsupported vinyl as vinyl that is not integrated to a backing material. The standard requires that unsupported vinyl that is accessible to an infant be 0.012-in (0.3mm) thickness or greater. The maximum bumper thickness requirement in ASTM F1917-12 uses a bumper thickness test fixture to limit the maximum thickness of crib bumpers to about 2 inches. The bumper thickness test applies only to crib bumpers manufactured of fabric and filled with a fibrous material. The bumper pad tie strength requirement in AST MF1917-12 only applies to ties, and no other means of attachment.

Section 8 of ASTM F1917-12 contains warning and instructional requirements for infant bedding and related accessories, and includes warnings that must appear on certain products covered by the standard.

VII. Assessment of the Voluntary Standard ASTM F1917-12

CPSC assessed the adequacy of ASTM F1917-12 on the basis of the incident data and hazard patterns, and on CPSC's review of the current voluntary standard for issues requiring clarification. A more stringent standard than the current ASTM standard is necessary to further reduce the risk of injury associated with crib bumpers. Accordingly, the proposed rule includes substantial changes and additions to the existing voluntary standard requirements.

A. Addition of Crib Bumper Definition

ASTM F1917–12 includes several performance and labeling requirements for crib bumpers. However, the voluntary standard identifies these products inconsistently as: "bumper pad" (section 6.3, 7.4, 7.4.1, Note 2), "bumper guards" (3.1.4, 5.1, 5.4), "headboard bumper guards" (3.1.4, 5.1), "headboard/bumper set" (8.2.1), "bumper" (3.1.1, 6.2, Figure 1 caption, 7.3, 8.2.1), and "crib bumper" (6.2). The voluntary standard does not define any of these terms. The Commission is proposing a broad definition that encompasses traditional crib bumpers as well as mesh crib liners. Products that cover only the top rail of a crib would not be considered crib bumpers. Such top rail covers do not serve the same function as a crib bumper or mesh liner. Taking these factors into account, the Commission proposes to define products that are subject to the rule in the following way:

> *crib bumper/liner, n*—any product intended to be placed against any portion of the interior perimeter of a crib, and that reduces or eliminates an infant's access to the crib sides, slats, spindles, or the spaces between these components.
>
> *Discussion*—Such products are commonly referred to as crib bumpers, crib liners, mesh liners, bumper pads, bumper guards, and headboard panels, but do not include products intended to cover only the top horizontal rail of a crib.

Defining the products that are subject to the rule using consistent terms will further reduce the risk of injury associated with crib bumpers by providing clarity to manufacturers and testing laboratories about which products are subject to the requirements of the proposed rule. The ASTM Infant Bedding subcommittee intends to ballot this definition as part of its revisions to the F1917 standard.

B. Suffocation Hazard

1. Crib Bumper Thickness

Pillows, and other soft, pillow-like objects can pose a suffocation hazard to infants by conforming to the face and blocking the nose and mouth. ASTM F1917-12 addresses the potential suffocation hazard posed by crib bumpers by limiting the maximum thickness of crib bumpers to about 2 inches, thereby eliminating soft, pillow-like crib bumpers from the marketplace. The ASTM standard specifies a bumper thickness test fixture to assess the bumper's thickness, by limiting the maximum thickness of crib bumpers to about 2 inches, thereby eliminating soft, pillow-like crib bumpers from the marketplace.[14,15] However, ASTM F1917–12 only applies this test to bumpers manufactured of fabric and filled with a fibrous material. The Commission proposes to apply this thickness requirement to all crib bumpers/liners, regardless of their construction, because bumpers made from other materials (*e.g.*, filled with foam) still could be soft and pillow-like, and pose the same hazard. Broadening the existing requirement to apply to all crib bumpers/liners would further reduce the risk of suffocation. The ASTM Infant Bedding subcommittee intends to ballot a similar change to the F1917 standard.

CPSC staff's testing of crib bumper samples also identified some bumpers that passed through the bumper test fixture, but at such an extremely slow rate that staff found it difficult to determine whether the bumper passed or failed the test. Thus, the Commission is proposing to include a minimum rate at which the bumper must pass through the fixture to more clearly delineate a pass from a fail. Specifically, the Commission proposes a rate of no less than 0.5

[14] ASTM F1917 – 12, Section X1.1.
[15] Petition CP 12-2, "Petition Requesting a Performance Standard to Distinguish and Regulate Hazardous Pillow-Like Crib Bumpers from Non Hazardous Traditional Crib Bumpers Under Sections 7 and 9 of the Consumer Product Safety Act," from the Juvenile Products Manufacturers Association (JPMA).

inches per second. Because the surface finish of the slot in the bumper thickness test fixture can affect how quickly a bumper can slide through it and can introduce variation among test laboratories and fixtures, the Commission is also proposing a minimum finish requirement for the test fixture. Specifically, the Commission proposes a surface finish of 1.6 Ra (roughness average), which is a common "smooth" specification and is practical to achieve. Both of these additional requirements—the recommended rate and the recommended surface finish—should further reduce the risk of suffocation by improving a test laboratory's ability to identify crib bumpers that would fail the thickness test.

2. Crib Bumper Firmness. The F1917–12 maximum thickness requirement for crib bumpers is intended to address the suffocation hazard by eliminating "soft" pillow-like crib bumpers. However, thickness is not the same as softness, and the ability of a surface to conform around a child's face is an important indicator of suffocation hazards. Currently, one could make a crib bumper that would pass the maximum thickness requirement in ASTM F1917–12, but still would be soft enough to readily conform to an infant's face. In fact, a crib bumper that is especially soft could be thicker than the bumper thickness test fixture and still pass the maximum thickness test because of its very pliable, pillow-like quality. Thus, to further reduce the risk of injury associated with crib bumpers, the Commission proposes to include an additional firmness requirement.

The Commission is proposing a firmness requirement and test method that is based on an Australian/New Zealand standard, AS/NZS 8811.1:2013, *Methods of Testing Infant Products: Part 1: Sleep Surfaces—Test for Firmness*, which is intended to assess the firmness of infant mattresses and other horizontal sleep surfaces for "excessive compression." The test uses 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 device is placed on the product, which compresses under the device's weight. If the compression is enough to cause the feeler arm to touch the surface of the product, the product fails. The test device was developed based on a device that was used in a German study to objectively measure the softness of mattresses and underlay surfaces as part of a case-control study of SIDS.

The test's failure criteria are intended to identify soft surfaces that pose a three-fold increase in the risk of SIDS. CPSC staff tested crib bumper samples to the ASTM F1917–12 thickness requirement and to the proposed firmness requirement. Staff found that many bumpers that passed the thickness requirement would fail the firmness requirement. Although staff tested a limited number of samples, all bumper samples up to 0.8 inches thickness passed the firmness test, while all bumper samples 1.2 inches or greater failed the test; bumpers 1 inch thick had mixed results. Nevertheless, it is possible that some bumpers greater than 1 inch thick could be firm enough to pass the test, and some bumpers less than 1 inch could be soft enough to fail. One of the samples that failed the firmness test yet passed the F1917 maximum thickness test measured 2.5 inches thick, which is a half-inch thicker than the 2-inch slot that is used to test thickness. Its very pliability, or softness, allowed it to pass the thickness test.

CPSC staff has been working with the ASTM Infant Bedding Subcommittee task group on crib bumper firmness. CPSC staff and members of the task group agree that the proposed firmness requirement and test method would address a worst-case scenario in which the crib bumper separates from the crib side or otherwise protrudes into the sleep area and gets underneath an infant. In this scenario, the bumper would present a smothering-type suffocation hazard similar to a quilt or other piece of soft bedding that is able to conform to, and occlude, airway openings. CPSC is aware of nonfatal incidents involving bumpers without lower ties or

with ties detaching from the bumper, either of which would allow for this scenario. Some reported fatalities have limited or conflicting details about the infant's face relative to the crib bumper, and these incidents might have involved this scenario. In addition, CPSC examination of crib bumper samples found that long continuous bumpers could be mistakenly installed on a crib in ways that would result in a loose fit and possible sagging. The proposed firmness requirement would reduce the risk of injury of bumpers in the event that consumers incorrectly install these products and the product enters the sleep area.

The Commission also concludes that its proposed firmness requirement could improve the safety of crib bumpers by offering some protection against other smothering-type suffocation deaths where the victim's face is forcefully pressed against a bumper to fully or partially occlude external airway openings. Scenarios involving infant wedging or entrapment against a bumper, in general, and infant entrapment between the bumper and another object in the crib in particular, are especially common in the reported fatalities. Some of these incidents involve the face being pressed against the bumper, and a firmness requirement would reduce the risk of injury associated with this scenario, provided the applied pressure was not sufficient to compress and close nostril openings.

The ASTM Infant Bedding subcommittee is preparing a ballot that includes the proposed firmness requirement.

C. Suffocation Hazard and Entrapment Hazard—Crib Bumper Attachment

ASTM F1917–12 requires crib bumpers to be "capable of being secured at or near all corners and at the midpoints of the long sides of the crib," and specifies that bumpers intended for circular cribs must be capable of being secured at intervals not exceeding 26 inches (section 5.4). CPSC has the following concerns with this provision:

- How "near" the corners a bumper would need to be to pass the requirement is not clear.
- The intervals specified—from 26 inches for a circular crib to 28 inches corner to corner for the short end of a crib— are large enough to easily allow a bumper to sag or to pull away from the crib side. CPSC is aware of reported fatalities involving bumpers that were sagging, and consumers have reported concerns about poor fit between bumpers and the crib in which they were installed.
- Crib bumpers can meet the requirement when they are not secured or flush at both the top and bottom edges of the bumper. CPSC is aware of reported fatalities and nonfatal incidents in which the victim was entrapped or able to slip beneath the bottom edge of the bumper, and there have been nonfatal incidents involving entrapment behind the bumper (*i.e.*, between the bumper and the crib side). In addition, some consumers have reported concerns about bumpers that did not include ties along the bottom of the bumper.

The Commission is proposing a new performance requirement that would replace the existing F1917 attachment requirements. The proposed requirement would not allow a small head probe to pass between an installed crib bumper and the interior crib side, at any location around the perimeter of the bumper most likely to fail. The small head probe is the same one used in ASTM F963, *Standard Consumer Safety Specification for Toy Safety*, and approximates the 5th percentile head size of an infant 0 to 3 months old.[16] The Commission believes that this alternative attachment requirement and test method will further reduce the risk of injury associated with crib bumpers. Specifically, the proposed requirement could reduce the risks of suffocation and entrapment associated with infants accessing the spaces under and behind installed crib bumpers. The ASTM Infant Bedding subcommittee has formed a Bumper/Liner

[16] This probe, which is used to test for hazardous loops and cords, is based on the 5th percentile head length and breadth dimensions of an infant 0 to 3 months old (ASTM F963 – 03, Section A5.7.13).

Attachment task group, which is developing a similar requirement for the F1917 voluntary standard.

D. Entanglement, Choking, and Suffocation Hazards—Crib Bumper Tie/Attachment Means Strength Requirement

Some nonfatal incidents and reported consumer concerns involved parts of the crib bumper (such as the ties, threads, or stitched-on decorative patterns) wrapped around the neck, limb or digit of the child. In addition to entanglement concerns, some incidents involved a child's ingestion of, or choking on, part of the crib bumper, such as a decorative stitched-on pattern or the bumper's filling material. The attachments means separating from the bumper could also pose a suffocation hazard, because this could allow the bumper to fall or sag into the crib.

1. Attachment Means, Decorative Components, and Seams

ASTM F1917–12 includes a strength requirement for crib bumper ties. The ties must withstand a certain amount of force without detaching from the bumper. This requirement addresses the nonfatal incidents and reported consumer concerns involving crib bumper ties separating from bumpers. However, the standard does not define "ties," but rather, "attachment means." Ties are merely one form of attachment means. Thus, the Commission is proposing to revise the strength requirement for bumper ties to apply to all attachment means, rather than just to ties. The ASTM Infant Bedding subcommittee currently is considering an identical change to the F1917 standard.

2. Decorative Components and Seams Strength Requirements

In addition, the Commission is proposing to include strength requirements for decorative components and bumper seams so that they too must withstand a certain amount of force without

detaching from the bumper. Because decorative components may be subjected to similar stressors as attachment means, the Commission proposes similar strength requirements for both. The proposed seam strength requirement includes a criterion that, after testing, there shall not be an opening that permits insertion of a 0.22-inch diameter rod. This diameter is based on the finger entrapment probe that is employed in many children's product tests.

ASTM F1917–12 specifies certain dimensional limits (*e.g.*, measured lengths or perimeters) for attachment means (section 5.1) and decorative components (5.2). However, the current language would pass crib bumpers that include components that exceed these limits after having been subjected to the strength testing, which could present entanglement and choking hazards. The Commission proposes to require crib bumpers to meet these dimensional limits both before and after strength testing.

E. Suffocation, Entanglement and Fall Hazards—Crib Bumper Warnings and Instructions

ASTM F1917–12 includes marking and labeling requirements—primarily warning requirements—for crib bumpers. However, the Commission concludes that these requirements do not adequately address the risk of injury and death associated with crib bumpers. The current warning content, format, and placement requirements are deficient. Additional requirements, including requirements for warning permanence and instructional literature, would further reduce the risk of injury associated with crib bumpers.

1. Warning Content and Format

The current F1917 warning provides incomplete and insufficient information about steps that consumers can take to reduce the risk of suffocation, and lacks key details about when and why crib bumpers should be removed from the crib. For example, CPSC is aware of reported fatalities involving entrapments between the bumper and another object in the crib, use of the

bumper outside a crib (*e.g.*, in a toddler bed or bassinet), and use of the bumper in a broken crib. The current warning requirement does not address these use patterns. CPSC also is aware of nonfatal incidents involving climbing or climb-outs, which the current warning requirement does not address explicitly.

In addition, the specified labeling and warning-format requirements are not consistent with the recommendations of the ASTM Ad Hoc Language task group. ASTM juvenile products standards have begun adopting these "Ad Hoc" recommendations since 2016 to increase the consistency of on-product warning design among juvenile products, and to address numerous warning format issues related to capturing consumer attention, improving readability, and increasing hazard perception and avoidance behavior.

On the basis of the issues identified above, the Commission proposes to replace the ASTM F1917–12 warning requirements to produce the following warning, in terms of content and general format:

⚠WARNING

To reduce the risk of **SUFFOCATION**:

- **Keep tight against side of crib.** Do not use if product is loose or sags down toward sleeping surface.
- **Never put pillows or anything else in crib** that could trap baby against this product.
- **Only use in a crib without broken parts or missing slats.** This product will not fix a broken crib or prevent baby from falling out. **Never use in a toddler bed or bassinet.**

To help prevent **ENTANGLEMENT** or **STRANGULATION**, position ties to outside of crib and secure tightly.

Remove this product when baby can pull to a stand using crib side (starting about 6 months). Older babies can use product to climb out of crib.

Because crib bumper ties or other attachment means up to 7 inches long do not pose a strangulation hazard, the Commission proposes requiring the warning statement about entanglement and strangulation only for those bumpers with attachment means exceeding 7 inches in length.[17]

a. *Warning Placement*

ASTM F1917–12 requires the warnings for crib bumpers to be "conspicuous," but does not define this term. Numerous ASTM juvenile product standards require warnings to be "conspicuous," and they define this term in a way that enables one to assess conformance, typically by stating when the warning must be visible. Thus, to clarify the required placement of the warning on the product, the proposed rule includes a definition of "conspicuous" that is consistent with the definition used in many other ASTM juvenile product standards.

b. *Warning Permanence*

ASTM F1917–12 requires the warnings for crib bumpers to be "permanent"; however, the standard neither defines "permanent" nor specifies how one would assess conformance to this requirement. Thus, the proposed rule includes requirements for warning permanence that are consistent with similar requirements in other ASTM juvenile products standards. The Commission proposes to require that warnings that are attached to the fabric with seams must remain in contact around the entire perimeter of the warning. This requirement is intended to avoid so called "free-hanging" labels, which can be removed easily.

c. *Additional Crib Bumper Markings*

The proposed rule would require permanent markings on the crib bumper that indicate which portions of the bumper are intended for the long and short sides of the crib, except for

[17] ASTM F1917–12 specifies that bumper ties cannot be longer than 9 inches, and staff recommends that the proposed rule apply this limit to all attachment means.

those crib bumpers intended for circular cribs. This proposed requirement would reduce the likelihood of consumers installing the bumper incorrectly, and thus will reduce the potential for loose or sagging bumpers. CPSC is aware of fatal incidents involving sagging bumpers, and consumers have reported concerns about installation difficulties and poor bumper fit.

d. *Instructional Literature*

ASTM F1917 – 12 does not include requirements for instructional literature to accompany crib bumpers. Numerous ASTM juvenile product standards require manufacturers to provide instructions with the product. Given the importance of proper bumper installation, the Commission concludes that instructional literature regarding installation is essential to adequately address the risk of injury and death associated with bumpers. In addition, the ASTM Ad Hoc Language task group has published recommended requirements for instructional literature and for the formatting of warnings in instructional literature. Thus, the proposed rule includes requirements for instructional literature, largely based on the Ad Hoc Language recommended requirements.

F. Commission Direction Pertaining to Crib Bumpers

In the FY 2017 Operating Plan, the Commission stated that in developing a proposed standard, CPSC staff shall, at a minimum:

- "develop a performance requirement and test method to show that a crib bumper is firm enough not to conform to the face of an infant, based on known anthropometric parameters;"
- "develop a performance requirement and test method based on known infant inhalation and exhalation requirements and anthropometric parameters to demonstrate that a crib

bumper matches or exceeds the airflow characteristics of mesh or mesh-like materials, taking into account the safety of infants with compromised breathing;" and

- "compose warnings and instructions on the product that explain all of the types of cribs on which the product can and cannot be installed, clear advice about how to install the product and at what age of the child to stop using the product."

1. Firmness

CPSC staff performed work to develop an anthropometry-based probe. However, the rigidity of the probe's cone-shaped protrusion does not necessarily represent the highly flexible cartilage in young infants' noses, and therefore, might not account for the potential of the nose to compress and close the nostrils when pressure is applied. In addition, in performing preliminary testing of crib bumper samples using the anthropometry-based probe, staff was unable to establish a clear pass-fall criterion. As a result, staff is uncertain whether the probe would accurately measure or relate to the risk of suffocation. Consequently, staff's recommended firmness is not based on anthropometric parameters. Thus, the Commission is proposing adding a firmness requirement to ASTM's requirements, but the proposed requirement is not based on anthropometric parameters.

2. Airflow

The current ASTM voluntary standard for crib bumpers does not include an airflow-related performance requirement. CPSC staff developed a test method for assessing the airflow of crib bumpers that is based on British standard BS 4578:1970, *Specification for Methods of Test for Hardness of, and for Air Flow Through, Infant Pillows*, and British standard BS 1877-8:1974, *Specification for Domestic bedding -- Part 8: Pillows and bolsters for domestic use (excluding cellular rubber pillows and bolsters)*. Staff modified the test method to use a

"breathing" rate that is physiologically representative of a sleeping 3-month old infant. Although staff's test could be used to distinguish mesh liners from most padded crib bumpers, as discussed more fully in the briefing package, CPSC staff was unable to conclude that the requirement would reduce the risk of injury associated with crib bumpers. Thus, the Commission is not proposing an airflow requirement for crib bumpers.

3. Warnings and Instructions

CPSC staff addressed the Commission's request related to warnings and instructions by recommending the following revisions to ASTM F1917-12 for the proposed rule in the staff briefing package:

- New warning statements about only using crib bumpers in unbroken, full-size cribs, and not using bumpers in toddler beds or bassinets;
- More explicit descriptions of how the bumper should fit when properly installed; and
- More details about when and why consumers should remove crib bumpers from a crib.

As discussed in Section VII.E of this preamble, the proposed rule includes these modifications to ASTM F1917-12.

VIII. Proposed Standard for Crib Bumpers

The Commission proposes to incorporate by reference ASTM F1917-12, *Standard Consumer Safety Performance Specification for Infant Bedding and Related Accessories,* with modifications that would further reduce the risk of injury or death associated with crib bumpers. The proposed modifications are discussed in detail in the Section VII of this preamble and are summarized below:

- Add a "crib bumper/liner" definition.

- Revise the crib bumper thickness requirement to apply to all crib bumpers and liners, and revise the test method by adding a minimum rate at which the bumper must pass through the test fixture and a surface finish requirement of 1.6 Ra for the text fixture.
- Add a crib bumper firmness requirement and test method.
- Replace the existing requirement for crib bumpers to be capable of being secured at certain locations with a new crib bumper attachment requirement and test method.
- Revise the strength requirement for crib bumper ties to apply to all attachment means, and add new strength requirements and test methods for decorative components and seams.
- Revise the crib bumper warning content, format, and placement requirements; add warning permanence requirements and test methods; and add a requirement for additional crib bumper markings.
- Add crib bumper instructional literature requirements.

IX. Proposed Amendment to 16 CFR part 1112 to Include NOR for Bumpers

The CPSA establishes certain requirements for product certification and testing. 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. *Id*. 2063(a)(2). The Commission must publish an NOR for the accreditation of third party conformity assessment bodies to assess conformity with a children's product safety rule to which a children's product is subject. *Id.*

2063(a)(3). Thus, the proposed rule for 16 CFR part 1240, *Safety Standard for Crib Bumpers/Liners,* if issued as a final rule, would be a children's product safety rule that requires the issuance of an NOR.

The Commission published a final rule, *Requirements Pertaining to Third Party Conformity Assessment Bodies*, 78 FR 15836 (March 12, 2013), codified at 16 CFR part 1112 ("part 1112") and effective on June 10, 2013, which establishes requirements for accreditation of third party conformity assessment bodies to test for conformity with a children's product safety rule in accordance with section 14(a)(2) of the CPSA. Part 1112 also codifies all of the NORs the Commission issued previously.

All new NORs for new children's product safety rules, such as the crib bumper/liner standard, require an amendment to part 1112. To meet the requirement that the Commission issue an NOR for the crib bumper/liner standard, as part of this NPR, the Commission proposes to amend the existing rule that codifies the list of all NORs issued by the Commission to add crib bumpers/liners to the list of children's product safety rules for which the CPSC has issued an NOR.

Test laboratories applying for acceptance as a CPSC-accepted third party conformity assessment body to test to the new standard for crib bumpers/liners would be 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 16 CFR part 1240, *Safety Standard for Crib Bumpers/Liners,* included in the laboratory's scope of accreditation of CPSC safety rules listed for the laboratory on the CPSC website at: www.cpsc.gov/labsearch.

X. Proposed Amendment to Definitions in Consumer Registration Rule

The statutory definition of "durable infant or toddler product" in section 104(f) applies to all of section 104 of the CPSIA. In addition to requiring the Commission to issue safety standards for durable infant or toddler products, section 104 of the CPSIA also directs 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 examples of 12 such product categories. The examples do not include crib bumpers.

> (f) DEFINITION OF DURABLE INFANT OR TODDLER PRODUCT. As used in this section, the term "durable infant or toddler product" –
>
> (1) means a durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years; and
>
> (2) includes –
>
> (A) full-size cribs and non-full-size cribs;
>
> (B) toddler beds;
>
> (C) high chairs, booster chairs, and hook-on-chairs;
>
> (D) bath seats;
>
> (E) gates and other enclosures for confining a child;
>
> (F) play yards;
>
> (G) stationary activity centers;
>
> (H) infant carriers;

(I) strollers;

(J) walkers;

(K) swings; and

(L) bassinets and cradles.

Id. 2056a(f).

In 2009, the Commission issued a rule implementing the consumer registration requirement. 16 CFR part 1130. As 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 the Commission issued 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.

16 CFR 1130.2. The Commission stated that the specified statutory categories were not exclusive, but that the Commission should explicitly identify the product categories that are covered. The preamble to the 2009 final consumer registration rule states: "Because the statute has a broad definition of a durable infant or toddler product but also includes 12 specific product

categories, additional items can and should be included in the definition, but should also be specifically listed in the rule." 74 FR 68668, 68669 (Dec. 29, 2009).

On October 19, 2016, the Commission voted to consider crib bumpers to be durable infant or toddler products and directed staff to develop a notice of proposed regulation for crib bumpers under section 104 of the Consumer Product Safety Improvement Act. In this document, the Commission proposes to amend the definition of "durable infant or toddler product" in the consumer registration rule to clarify that crib bumpers fall within the term "durable infant or toddler product" as used in the product registration card rule and section 104 of the CPSIA. Crib bumpers are intended for, and reasonably expected to be used by, children under age 5. They are used with cribs, a product the CPSIA identifies as an example of a durable infant or toddler product. Like the other product categories, crib bumpers are covered by voluntary standard.

XI. Incorporation by Reference

The Commission proposes to incorporate by reference ASTM F1917-12, with modifications to the standard, discussed above. The Office of the Federal Register (OFR) has regulations concerning incorporation by reference. 1 CFR part 51. For a proposed rule, agencies must discuss in the preamble of the NPR ways that the materials the agency proposes to incorporate by reference are reasonably available to interested persons or how the agency worked to make the materials reasonably available. In addition, the preamble of the proposed rule must summarize the material. 1 CFR 51.5(a).

In accordance with the OFR's requirements, section VI of this preamble summarizes the provisions of ASTM F1917-12 that the Commission proposes to incorporate by reference. ASTM F1917-12 is copyrighted. By permission of ASTM, the standard can be viewed as a read-only document during the comment period on this NPR, at: http://www.astm.org/cpsc.htm.

Interested persons may also purchase a copy of ASTM F1917-12 from ASTM International, 100 Bar Harbor Drive, P.O. Box 0700, West Conshohocken, PA 19428; http://www.astm.org/cpsc.htm. One may also inspect a copy at CPSC's Division of the Secretariat, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone 301-504-7923.

XII. 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 to incorporate by reference ASTM F1917-12, with modifications. To allow time for bumper manufacturers to bring their products into compliance after a final rule is issued, the Commission proposes that the rule would take effect 6 months after publication of the final rule in the Federal Register. The rule would apply to products manufactured or imported on or after that date. Barring evidence to the contrary, the Commission generally considers 6 months to be sufficient time for suppliers to come into compliance with a new standard. Six months is also the period that JPMA typically allows for products in its certification program to shift to a new standard once that new standard is published. CPSC invites comments, particularly from small businesses, regarding the amount of time they will need to come into compliance. We also propose a 6-month effective date for the amendments to parts 1112 and 1130.

XIII. Regulatory Flexibility Act

A. Introduction

Under Section 603 of the RFA, if a notice of proposed rulemaking is required, agencies must prepare an initial regulatory flexibility analysis (IRFA) and make it available to the public for comment when the general notice of proposed rulemaking is published, unless the head of the

agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The IRFA must describe the impact of the proposed rule on small entities and identify significant alternatives that could accomplish the statutory objective while minimizing any significant economic impact. Specifically, the IRFA must contain:

- a description of the reasons why action by the agency is being considered;
- a succinct statement of the objectives of, and legal basis for, the proposed rule;
- a description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply;
- a description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities subject to the requirements and the type of professional skills necessary for the preparation of reports or records; and
- an identification, to the extent possible, of all relevant federal rules which may duplicate, overlap, or conflict with the proposed rule.

B. Market Description

Crib bumpers range in price from $12 to $500, and also are sold in bedding sets, which can range in price from $80 to $1,200. Manufacturers typically produce only a few models with differences in color, art design, cover material, and filling material being the primary identifying factors. Those products at the higher end of the price range typically are decorated with detailed paint or woven art.

C. Objectives and Legal Basis for Proposed Rule

The objective of this proposed rule is to reduce the risk of injury and death associated with crib bumpers. CPSC staff identified 113 fatalities from 1990 to March 2019 and 113 nonfatal incidents from 2008 to 2019 associated with crib bumpers.

The legal basis of the proposed rule is Section 104 of the CPSIA, which requires the CPSC to examine and assess the effectiveness of any voluntary consumer product safety standards for durable infant or toddler products, and promulgate 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 requirements would further reduce the risk of injury associated with the products.

D. Crib Bumpers in Use

Based on information from the 2013 CPSC Durable Nursery Products Exposure Survey of U.S. households with children under 6 years old:

- An estimated 9.2 million cribs were in use in households with young children in 2013. This represented about 73 percent of the estimated 12.6 million total cribs owned by households (i.e., about 3.4 million cribs were owned, but not in use).
- Among the 9.2 million cribs in use, an estimated 5.3 million were equipped with bumpers. This represents about 55 percent of the 9.9 million total bumpers owned by households (i.e., about 4.5 million bumpers were owned, but not in use).

In addition to the products in use in households with young children, as estimated from the survey, cribs and bumpers are probably in use in some households without young children (e.g., unsurveyed homes of older adults providing care for grandchildren). Additionally, the survey did not cover child care facilities. One childcare industry group's 2018 directory lists more than

115,000 licensed childcare centers and more than 137,000 home daycare providers, some of which may use cribs and bumpers. Furthermore, the survey did not cover hotels or other commercial lodging establishments. The U.S. Bureau of Labor Statistics (BLS) reports that there are about 70,000 lodging establishments in the accommodation industry sector, North American Industry Classification System (NAICS) code 721. Based on the Commission's contacts with childcare and lodging facilities, bumper usage in such establishments is probably low.

E. Small Entities to Which the Proposed Rule Would Apply

Manufacturers of crib bumpers are typically categorized under the NAICS category 314120 (Curtain and Linen Mills) but may also fall under code 314999 (All Other Miscellaneous Textile Product Mills). Curtain and linen mills are considered small if they have fewer than 750 employees; miscellaneous textile product mills are considered small if they have fewer than 500 employees.[18] Importers of crib bumpers are typically categorized under NAICS code 423220 (Home Furnishing Merchant Wholesalers) and would be considered small if they have fewer than 100 employees.

Aside from small handcrafters selling products on electronic commerce websites, staff identified 46 manufacturers, distributors and importers. A total of 33 of these 46 firms meet the SBA criteria for small businesses.[19,20,21] A majority of the 46 firms have under 25 employees with 8 firms meeting the criteria of a large firm. Most of the firms are domestic manufacturers (28), with domestic importers (7) and domestic distributors (6) accounting for a small minority. The lowest annual revenue among the 46 manufacturers, distributors, and importers was $135,000.

[18] The size guidelines are established by the U.S. Small Business Administration (SBA).
[19] Based on size and revenue data from Reference USA and firm financial reports, websites, and press releases.
[20] The Commission could not determine the status of five firms, but they are most likely small.
[21] Eleven of the forty-six firms identified supply mesh liner or similar mesh type products.

A large number of producers supply crib bumpers to the U.S. market via electronic commerce websites such as Etsy. CPSC staff has identified 174 of these firms of which 86 are importers.[22,23] CPSC staff considered these firms as small manufacturers/importers because many are one-person firms providing handcrafted nursery products with large varieties in materials and designs. These firms would be considered small by SBA size standards. The revenues for 81 of the small importers is most likely below $25,000 based estimates from the Nonemployer Statistics from the U.S. Bureau of the Census. Of the five remaining small importers, one has annual revenue between $25,000 and $250,000 and the revenue of the other four is between $250,000 and $500,000.

F. Requirements of the Proposed Rule

The proposed rule would incorporate by reference ASTM F1917–12 with modifications that CPSC believes may further reduce the risk of injury. The proposed rule would also make some changes to the definitions and terminology used in the standard to better clarify the requirements. If promulgated by the Commission, the proposed rule would, among other things:

- Establish a crib bumper firmness test that is partly adopted from the Australian/New Zealand Standard (AS/NZS 8811.1) for testing infant products. The test involves using a test fixture to measure firmness of the crib bumper at multiple points along its length.
- Establish maximum lengths for the attachments means and decorative components on bumper pads;
- Establish that the requirements for the length of attachment means and decorative components shall apply both before and after testing;

[22] Based on a review of electronic commerce websites that specialize in handmade products.
[23] Approximately 90 percent of these small handcrafters provide traditional crib bumpers with mesh liner handcrafters accounting for only 4.6 percent.

- Prohibit the use of monofilament thread;
- Establish a minimum thickness for accessible, unsupported vinyl material;
- Establish a test for limiting the maximum thickness of all crib bumpers;
- Establish minimum strength requirements for attachment means and decorative components;
- Establish a strength requirement for bumper seams;
- Require crib bumpers to have labels identifying the manufacturer, distributor, or seller;
- Establish requirements for appropriate warning labels on crib bumpers;
- Establish requirements for the permanence of the warning labels;
- Require instructional literature to be provided with crib bumpers detailing the proper installation methods and the hazards associated with the crib bumpers;
- Establish a test to ensure the bumper remains securely attached to the crib side. The test involves inserting a probe between the crib bumper and the crib slat.

In addition to the requirements outlined above, the proposed rule would modify or clarify some of the terms and definitions used in ASTM F1917–12. For example, the proposed rule would consistently refer to "crib bumpers/liners" and not "bumper pads," "bumper guards," and similar terms that are sometimes used in ASTM F1917– 2. The proposed rule would also clarify the definitions of terms such as "crib bumper/liner," and "conspicuous."

G. Impact of Proposed Rule on Small Manufacturers

If the proposal is finalized, manufacturers and importers of crib bumpers would be responsible for ensuring that their products comply with the rule. If their crib bumpers do not comply with the requirements, the manufacturers or importers will need to either modify the products or cease their manufacture or importation. Additionally, as required by section 14 of

the CPSIA and its implementing regulations, manufacturers and importers of crib bumpers would be required to certify that their crib bumpers comply with the requirements of the proposed rule based on the results of third party testing by an accredited conformity assessment body.

In 2018, CPSC collected a sample of crib bumpers to test them for compliance with the proposed rule. Although not a probability sample, CPSC tried to collect a wide variety of crib bumpers that included most types of crib bumpers that are available in the market place, including crib bumpers from the very small manufacturers or hand crafters. Although most of these crib bumpers would comply with many of the provisions of the proposed rule, the testing found that most models (7 out of 11 models tested) would not pass the proposed firmness test. Additionally, many models would need to modify their warning labels' content, placement, and formatting to comply with the proposed rule.

H. Costs Associated with Modifying Products to Comply with the Proposed Rule

Modifying most types of crib bumper designs to conform to the firmness requirement could be as simple as removing some of the filling material used in the bumper pad or using additional stitching to compact the loose fill material. The cost of making such modifications should not be significant. However, the braided type of crib bumper would likely fail the firmness requirement because the results depended upon where on the product it was tested. It is unclear if braided bumpers could be modified to meet this requirement. Moreover, the braided crib bumpers CPSC examined did not have any means by which they could be attached to the crib, which is also a requirement of the proposed rule.[24] This implies that the proposed rule may result in the removal of braided crib bumpers from commerce. All firms identified as supplying

[24] Some braided crib bumper manufacturers have begun modifying their product to include a means to attach the product to the side of a crib as of May 2019.

braided bumpers are importers and not domestic manufacturers and represent approximately 6 percent of the identified importers.[25]

Generally, the costs associated with providing instructional materials are low on a per unit basis. Many firms already provide instructions with their products, but they may have to change the content or formatting of the instructions to comply. Likewise, the cost of warning labels are generally low, especially if some warning labels are already present and the product itself does not have to be modified to accommodate new labels.

I. Third Party Testing Costs

The proposed rule would require all manufacturers and importers of crib bumpers to meet third party testing requirements under section 14 of the CPSA and 16 CFR part 1107.[26] The Commission estimates that testing costs associated with testing to ASTM F1917–12 would be between $600 and $900 per sample tested.[27] As the average number of crib bumper models per firm is two, this equates to a cost of at least $1,200 to $1,800 per firm, if no more than one sample per model to provide the required "high degree of assurance" that the model complies with the requirements. Under 16 CFR part 1107, manufacturers and importers will need to recertify their crib bumpers at least annually, unless the firm has also established a formal reasonable testing program, in which case they will have to recertify their crib bumpers at least every two years. Currently 21 of 207 small crib bumper manufacturers and importers are members of the JPMA, but it is unclear if any crib bumpers are certified to ASTM F1917–12. However, some of these firms produce other products that are already subject to other children's

[25] Currently total annual revenue and unit sales of braided bumpers is unknown but total annual revenue is expected to be under $150,000 as braided bumper importers appear to be firms with 1 to 2 employees.
[26] Third party testing will include any physical and mechanical test requirements specified in the final crib bumper rule.
[27] Based on quotes from testing laboratories that currently test children's products to ASTM standards.

product safety rules and, therefore, familiar with these requirements. Many of the small firms that are not members of JPMA or that do not produce other products subject to children's product safety rules may be unfamiliar with the third party testing requirements.

As noted, for a typical manufacturer or importer with two crib bumper models, the cost of third party testing will be at least $1,200 to $1,800 to test and certify both models and this cost will be incurred at least once every other year. Generally, we consider impacts that exceed one percent of revenue to be potentially significant. As discussed above there are a substantial number of very small firms that either hand craft or import crib bumpers that are often sold through websites, such as Etsy.com, and more than three quarters of these very small firms are estimated to have annual revenues of less than $25,000. Even if these firms needed to test only one sample of each crib bumper to obtain the "high degree assurance" that the product would meet all the requirements of the rule, the cost of the third party testing would be at least 5 percent of one year's revenue and possibly more if their revenue was much less than $25,000. This impact would be significant. Many of these firms could be expected to stop supplying crib bumpers to the U.S. market because they are not able to increase their prices to cover the testing costs.

The cost of the third party testing associated with the proposed rule could also be significant for small firms that are not among the very small firms discussed above. CPSC identified 13 small manufacturers and one importer of crib bumpers that have annual revenues between $25,000 and $250,000. If the third party testing costs are between $1,200 and 1,800, the cost could exceed one percent of the annual revenue of several of these firms as well and could be considered significant.

J. Summary of Impact on Small Manufacturers and Importers

CPSC expects that most crib bumpers currently on the market would comply with the requirements of the proposed rule or could comply with minimal cost and effort by making modifications, such as modifying the language in the instructional material that already comes with the products, removing loose fill material and or using additional stitching. However, braided bumpers would likely fail the test requirements in the proposed rule and would be removed from the market. This could significantly impact the firms that supply braided crib bumpers. As noted above, the cost of the third party testing that manufacturers and importers would require in order to certify compliance with the rule could be significant for a substantial number of small firms as the third party testing costs could easily exceed one percent of annual revenues for many of the small suppliers. For small handcrafter firms that offer crib bumpers through channels such as Etsy.com the third party testing costs will likely exceed 5 percent of their total annual revenue.

K. Other Federal Rules Which May Duplicate, Overlap, or Conflict with the Proposed Rule

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

L. Alternatives Considered to Reduce the Impact on Small Entities

1. Adopt ASTM F1917-12 without Modification. The Commission could propose to incorporate by reference ASTM F1917– 12 without any modifications and direct staff to work with ASTM to improve warning labels, test methods, and the firmness of crib bumpers in a future revision of the voluntary standard. This alternative could reduce the impact of the rule on small businesses, but the reduction would not be expected to be very significant. As discussed in the analysis above, modifying crib bumpers to comply with the firmness requirement could be accomplished by reducing the amount of filler material or by incorporating additional stitching to

compress the material. These modifications are not expected to be costly. Likewise the costs to modify or add warning labels or instructional material are expected to be low. The most significant impacts of the proposed rule would be associated with the third party testing requirements under section 14 of the CPSA and 16 CFR part 1107, which would be required once the proposed rule became a mandatory children's product safety rule. These costs, however, would be largely unaffected by this alternative.

2. Small Batch Exemption. Given the number of small crib bumper manufacturers using websites like Etsy, exempting small batch manufacturers from the testing requirements proposed under the rule might seem to be an alternative. However, under Section 14(d)(4)(C)(ii) of the CPSA, the Commission cannot "provide any alternative requirements or exemption" from third party testing for "durable infant or toddler products," as defined in section 104(f) of the CPSIA. Consequently, the Commission is not proposing a small batch exemption.

3. Reduce the Frequency of Periodic Testing for Very Small Crib Bumper Manufacturers. The Commission could amend 16 C.F.R. part 1107 to reduce the frequency of periodic testing for small home-based businesses that produce crib bumpers. Currently, under the requirements of 16 CFR 1107.21, these firms need to conduct periodic third party tests every year, or, if they have a formal production testing plan, every 2 years. The testing costs associated with third party periodic testing could be substantially reduced if the Commission amended existing regulations to allow small home-based producers of crib bumpers to conduct periodic testing less frequently. One alternative for manufacturers with established production testing plans, would be to require third party periodic testing only after a certain number of units of a product (to be determined at a later time) had been produced, even if it meant that periodic third party tests would be conducted less frequently than every 2 years. The details of this alternative would be determined

by the Commission; it might apply to all nursery products, or it might be limited to crib bumpers. However, all home-based firms would still be required to: (1) produce conforming products; (2) conduct the initial certification tests (16 CFR 1107.20); (3) re-certify whenever there is a material change to the product (16 CFR 1107.23); and (4) implement a production testing plan and conduct on going production tests (16 CFR 1107.21(c)).

4. Delay the Effective Date of the Requirements. Typically, the Commission recommends an effective date of 6 months for durable nursery product rules. Six months is generally considered sufficient time for suppliers to come into compliance with a proposed durable infant and toddler product rule, unless there are specific reasons for a longer effective date.

One alternative that could reduce the impact on small firms would be to set an effective date of 12 months. A later effective date could mitigate the effects of the rule on small businesses by delaying the need to conduct third party certification tests and allowing the businesses to spread the costs of bringing their crib bumpers into conformance over a longer period of time. For businesses that would choose to exit the crib bumper market (rather than produce conforming products), such a delay might also provide them with more time to adjust marketing towards other product offerings, sell inventory or consider alternative business opportunities.

5. Not Issue a Mandatory Standard. Another option available to the Commission that would reduce the burden on small firms is to not adopt a mandatory standard for crib bumpers. This would eliminate the cost impacts described in the previous sections, including those associated with third party testing, and allow the small handcrafter firms to continue operations.

M. Impacts of Test Laboratory Accreditation Requirements on Small Laboratories

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 NOR for third party conformity testing. CPSC has codified NORs in 16 CFR part 1112. The Commission proposes to amend 16 CFR part 1112 to establish an NOR for testing laboratories to test for compliance with the proposed crib bumper standard. This section assesses the impact a proposed amendment would have on small laboratories.

CPSC conducted a final regulatory flexibility analysis (FRFA) when it adopted part 1112. 78 FR 15836 (Mar. 12, 2013). The FRFA concluded that the accreditation requirements would not have a significant adverse impact on a substantial number of small laboratories because no requirements were imposed on laboratories that did not intend to provide third party testing services. The only laboratories CPSC expects to provide such services are laboratories that anticipated receiving sufficient revenue from the mandated testing to justify accepting the requirements as a business decision.

For the same reasons, including the NOR for crib bumpers in part 1112 would not have a significant impact on small laboratories. Moreover, CPSC expects that only a small number of laboratories would request accreditation to test crib bumpers, based on the number of laboratories that have applied for CPSC accreditation to test other juvenile products. Most laboratories would already have accreditation to test for conformance to other juvenile product standards; accordingly, the only cost would be to add the crib bumper standard to their accreditation. Test laboratories have indicated that this cost is extremely low when they are already accredited for other CPSIA section 104 rules. Therefore, the Commission certifies that the NOR for the crib bumper standard will not have a significant impact on a substantial number of small entities.

XIV. Environmental Considerations

The Commission's regulations address whether the agency must prepare an environmental assessment or an environmental impact statement. Under these regulations, 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 products come under this categorical exclusion. 16 CFR 1021.5(c)(1). The proposed rule falls within the categorical exclusion.

XV. 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 (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 Crib Bumpers/Liners

Description: The proposed rule would require crib bumpers/liners to comply with ASTM F1917-12, *Standard Consumer Safety Performance Specification for Infant Bedding and Related Accessories,* with several modifications, including modifications to their existing labels and new requirements for the provision of instructional literature. Section 8 of ASTM F1917-12 contains requirements for marking and labeling. Proposed section 9 contains requirements for instructional literature. These requirements fall within the definition of "collection of information," as defined in 44 U.S.C. 3502(3).

Description of Respondents: Persons who manufacture or import crib bumpers/liners.

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

Table 1 – Estimated Annual Reporting Burden

Burden Type	Number of Respondents	Frequency of Responses	Total Annual Responses	Hours per Response	Total Burden Hours
Labeling	220	2	440	1	440
Instructional literature	220	2	8,800	20	8,800
TOTAL BURDEN					**9,240**

Our estimate is based on the following:

There are 220 known entities supplying crib bumpers/liners to the U.S. market. All 220 firms are assumed to use labels already on both their products and their packaging, but the firms might need to make some modifications to their existing labels. The estimated time required to make these modifications is about 1 hour per model. Each entity supplies an average of two different models of crib bumper/liner; therefore, the estimated burden associated with labels is 1 hour per model × 220 entities × 2 models per entity = 440 hours. We estimate the hourly compensation for the time required to create and update labels is $34.61 (U.S. Bureau of Labor Statistics, "Employer Costs for Employee Compensation," March 2019, total compensation for all sales and office workers in goods-producing private industries, series id CMU201G000200000D: http://www.bls.gov/ncs/). Therefore, the estimated annual cost to industry associated with the labeling requirements is $15,228.20 ($34.61 per hour × 440 hours = $15,228.20). There are no operating, maintenance, or capital costs associated with the collection. The proposed rule would require instructions to be supplied with the product. Under the OMB's regulations (5 CFR 1320.3(b)(2)), the time, effort, and financial resources necessary to comply with a collection of information that would be incurred by persons in the "normal course of their activities" are excluded from a burden estimate, where an agency demonstrates that the disclosure activities required to comply are "usual and customary." Crib bumpers/liners require installation on an existing crib, which implies instructions for proper use, fit, position on a crib, and cleaning are necessary. Many of the firms already provide some instructional material, but some modifications to existing material may be necessary, and other firms supply little to no instructional information. Therefore, we have assumed that there will be a burden to all firms of modifying/creating instructional literature in this case. Each entity supplies an average of two

different models of crib bumper/liner; therefore, the estimated burden associated with instructional literature is 20 hour per model × 220 entities × 2 models per entity = 8,800 hours. We estimate the hourly compensation for the time required to create and update instructional material is $34.61 (U.S. Bureau of Labor Statistics, "Employer Costs for Employee Compensation," March 2019, total compensation for all sales and office workers in goods-producing private industries, series id CMU201G000200000D: http://www.bls.gov/ncs/). Therefore, the estimated annual cost to industry associated with the instructional material requirements is $304,568 ($34.61 per hour × 8,800 hours = $304,568). There are no operating, maintenance, or capital costs associated with the collection. Not all firms would incur these costs every year, but new firms that enter the market would and the market may be highly fluctuating, particularly for small handcrafters.

Based on this analysis, the proposed standard for crib bumpers/liners would impose a burden to industry of 9,240 hours, at an estimated cost of $319,796.40 annually.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), we have submitted the information collection requirements of this rule to the OMB for review. Interested persons are requested to submit comments regarding information collection by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**, to the Office of Information and Regulatory Affairs, OMB (see the ADDRESSES section at the beginning of this notice).

Pursuant to 44 U.S.C. 3506(c)(2)(A), we invite comments on:

- the estimated burden hours required to modify warning labels;
- the estimated burden hours required to modify instruction manuals;

- whether the collection of information is necessary for the proper performance of the CPSC's functions, including whether the information will have practical utility;
- the accuracy of the 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.

XVI. Preemption

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

XVII. Request for Comments

This NPR begins a rulemaking proceeding under section 104(b) of the CPSIA to issue a consumer product safety standard for crib bumpers, to amend part 1112 to add crib bumpers to

the list of children's product safety rules for which the CPSC has issued an NOR, and to amend part 1130 to identify crib bumpers as a durable infant or toddler product subject to CPSC consumer registration requirements. We invite all interested persons to submit comments on any aspect of this proposal. In addition to requests for specific comments elsewhere in this NPR, the Commission requests comments on the proposed effective date, and the costs of compliance with, and testing to, the proposed crib bumper safety standard. During the comment period, the ASTM F1917-12 *Standard Consumer Safety Performance Specification for Infant Bedding and Related Accessories*, is available as a read-only document at: http://www.astm.org/cpsc.htm.

Comments should be submitted 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 1240

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

For the reasons discussed in the preamble, the Commission proposes to amend 16 CFR Chapter II 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: 15 U.S.C. 2063; Pub. L. 110-314, section 3, 122 Stat. 3016, 3017 (2008).

2. Amend § 1112.15 by adding paragraph (b)(50) 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) * * *

(50) 16 CFR part 1240, Safety Standard for Crib Bumpers/Liners.

* * * * *

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

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

4. Amend § 1130.2 by revising paragraph (a)(12) to read as follows:

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

§ 1130.2 Definitions.

***** ***** ***** ***** *****

(a) * * *

(19) Crib bumpers/liners.

* * * * *

5. Add part 1240 to read as follows:

PART 1240-SAFETY STANDARD FOR CRIB BUMPERS/LINERS

Sec.

1240.1 Scope.

1240.2 Requirements for crib bumpers/liners.

Authority: Sec. 104, Pub. L. 110-314, 122 Stat. 3016 (August 14, 2008); Sec. 3, Pub. L. 112-28, 125 Stat. 273 (August 12, 2011).

§ 1240.1 Scope.

This part establishes a consumer product safety standard for crib bumpers/liners.

§ 1240.2 Requirements for crib bumpers/liners.

(a) Except as provided in paragraph (b) of this section, each crib bumper/liner must comply with all applicable provisions of ASTM F1917-12, *Standard Consumer Safety Performance Specification for Infant Bedding and Related Accessories*, approved on July 1, 2012. 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. You may obtain a copy from ASTM International, 100 Bar Harbor Drive, P.O. Box 0700, West Conshohocken, PA 19428; http://www.astm.org/cpsc.htm. You may inspect a copy at the Division of the Secretariat, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone 301-504-7923, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email, fedreg.legal@nara.gov , or go to: http://www.archives.gov/federal_register/code_of_federal regulations/ibr_locations.html.

(b) Comply with ASTM F1917-12 with the following additions or exclusions:

(1) Instead of complying with section 3.1.1 of ASTM F1917-12, comply with the following:

(i) 3.1.1 *attachment means. n*—flexible ribbons, strings, hook and loop straps, ties, and similar devices attached to a crib bumper/liner for the purpose of attaching to a crib.

(ii) [Reserved]

(2) Instead of complying with section 3.1.4 of ASTM F1917-12, comply with the following:

(i) 3.1.4 *infant bedding and related accessories, n*—includes the following items intended for use in a nursery: fitted sheets, blankets, dust ruffles, covers and drapes for canopies, pillows, mattress covers, diaper stackers, fabric wall hangings, crib bumpers/liners, and comforters.

(3) In addition to complying with section 3.1.6 of ASTM F1917-12, comply with the following:

(i) 3.1.7 *conspicuous, adj*—visible, when the product is in all manufacturer's recommended use positions, to a person standing near the product at any one position around the product, but not necessarily visible from all positions.

(ii) 3.1.8 *crib bumper/liner, n*—any product intended to be placed against any portion of the interior perimeter of a crib, and that reduces or eliminates an infant's access to the crib sides, slats, spindles, or the spaces between these components.

Discussion—Such products are commonly referred to as crib bumpers, crib liners, mesh liners, bumper pads, bumper guards, and headboard panels, but do not include products intended to cover only the top horizontal rail of a crib.

(4) Instead of complying with section 5.1 of ASTM F1917-12, comply with the following:

(i) 5.1 Attachment means on crib bumpers/liners shall not exceed 9.0 in. (230 mm) both before and after 7.4.1 testing when measured in accordance with 7.1.

(ii) [Reserved]

(5) Instead of complying with section 5.2 of ASTM F1917-12, comply with the following:

(i) 5.2 Decorative components as defined in 3.1.2 shall not exceed 7 in. (180 mm) when measured in accordance with 7.1. If any decorative components can tangle to form a loop, then the perimeter of the loop shall not exceed 14 in. (360 mm) when tested in accordance with 7.1. These requirements shall apply both before and after 7.4.3 testing.

(ii) [Reserved]

(6) Instead of complying with section 5.4 of ASTM F1917-12, comply with the following:

(i) 5.4 *Labeling*—Warning labels (whether paper or non-paper) shall be permanent when tested in accordance with 7.5.

(ii) 5.4.1 Warning statements applied directly onto the surface of the product by hot stamping, heat transfer, printing, wood burning, and so forth shall be permanent when tested in accordance with 7.6.

(ii) 5.4.2 Non-paper labels shall not liberate small parts when tested in accordance with 7.6.

(iii) 5.4.3 Crib bumper/liner warning labels that are attached to the fabric 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 7.5.3.

(7) Instead of complying with section 6.2 of ASTM F1917-12, comply with the following:

(i) 6.2 *Maximum Crib Bumper/Liner Thickness*—For all crib bumpers/liners, each bumper/liner section shall slide through the crib bumper/liner thickness test fixture (see Fig. 1) over its entire length at a rate no less than 0.5 inch per second when tested in accordance with 7.3. The bumper shall be tested in its pre-washed state and also after three wash/dry cycles performed according to the manufacturer's care instructions.

(ii) Note: Test fixture shall be fabricated from aluminum and have a smooth finish. The test fixture slot and fillet finish shall be 1.6 Ra.

(iii) **FIG. 1 Crib Bumper/Liner Thickness Test Fixture**

(8) Instead of complying with section 6.3 of ASTM F1917-12, comply with the following:

(i) 6.3 *Strength of Crib Bumper/Liner Attachments and Seams*

(ii) 6.3.1 *Attachment Means*—Following the testing specified in 7.4.1, the attachment means for a crib bumper/liner shall not fully detach from the crib bumper/liner. Partial detachment or tearing is allowed.

(iii) 6.3.2 *Seams*—Following the testing specified in 7.4.2, no seam shall have an opening that allows a 0.22-inch diameter steel rod to enter.

(iv) 6.3.3 *Decorative Components*—Following the testing specified in 7.4.3 the decorative component shall not fully detach from the crib bumper/liner. Partial detachment or tearing is allowed.

(v) 6.4 *Crib Bumper/Liner Firmness*—For crib bumpers/liners with an installed thickness of 0.59 in. (15 mm) or greater, no part of the bumper shall contact the feeler arm of the firmness test fixture (see Fig. 2), when tested in accordance with 7.7.

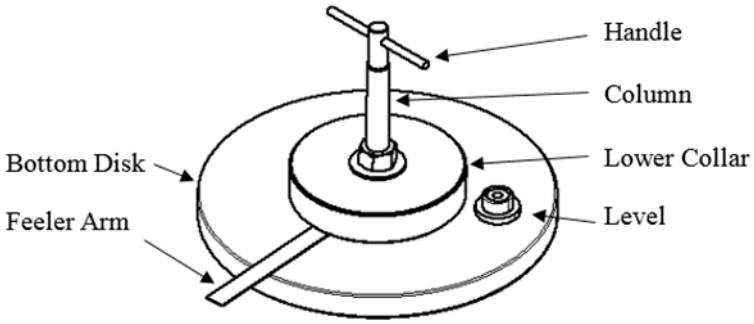

FIG. 2 Firmness Test Fixture

(vi) 6.5 *Crib Bumper/Liner Entrapment in Openings*—When tested in accordance with the head probe test specified in 7.8, no opening shall allow passage of the small head test probe (Fig. 3). Passage is defined as admitting the base of the probe.

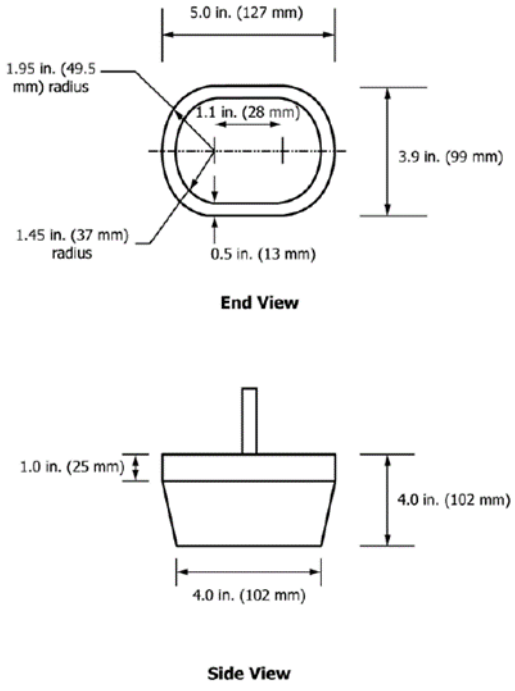

FIG. 3 Head Probe for Entrapment in Openings Testing

(9) Instead of complying with section 7.3 of ASTM F1917-12, including Note 1, comply with the following:

(i) 7.3 *Crib Bumper/Liner Thickness Test*-- Align the crib bumper/liner thickness test fixture so that the surface of the fixture with the opening is horizontal. Insert a bumper end into the opening so that the bumper end protrudes just beyond the lower surface of the test fixture and attach a 5-lb static weight to the midpoint of the protruding bumper end. Keeping the bumper positioned vertically, allow the weight to slowly draw the bumper through the opening.

Note 1—If the attachment means or other localized means provided to secure the bumper to the crib interfere with the bumper sliding through the bumper thickness test fixture, ease the ties or other attachment means through the fixture and then continue the test.

(10) Instead of complying with section 7.4 of ASTM F1917-12, including Note 2, comply with the following:

(i) 7.4 *Crib Bumper/Liner Strength Tests*—Tensile tests of attachment means, decorative components, and seams shall be conducted using clamps as described in 7.4.1, 7.4.2, 7.4.3. The force in each test shall be applied evenly within a period of 5 s, and maintained for additional 10 s. The loading device shall be a self-indicating gauge or other appropriate means having an accuracy of +/-0.5 lb (+/-2 N).

(ii) 7.4.1 *Attachment Means Strength*—Apply a tensile force of 20 lb on the bumper attachment means by clamping the free end in a perpendicular direction away from the attachment point to the bumper.

(iii) 7.4.1.1 Attachment means that share a common attachment point shall be tested together, as if one attachment means.

Note 2—There is no single clamp or method of attachment specified for the crib bumper/liner attachment means strength test. Any suitable means may be used to apply the force specified in 7.4.1.

(iv) 7.4.2 *Seams Strength*—Apply a tensile force of 20 lb in a direction most likely to pull the seam apart. The clamps used to grip the material on either side of the seam to be tested shall have jaws to which are attached 3⁄4-in. (19-mm) diameter washers (see Fig. 4). The clamps shall be attached to the cover material of a completely assembled crib liner in a manner such that the outside diameter of the 3⁄4-in. (19-mm) washers at a point nearest the seam shall be close to, but no closer than 1⁄2 in. (13 mm) from the edge of the seam stitching thread.

(v) 7.4.3 *Decorative Components, Attachment Strength*—Apply a tensile force of 20 lb on the decorative component in a perpendicular direction away from the attachment point of the decorative component to the crib liner. With the crib liner held in a convenient position, an appropriate clamp shall be attached to the decorative component. The clamp shall be applied in a manner that will not affect the structural integrity of the attachment between the decorativecomponent and the crib bumper/liner.

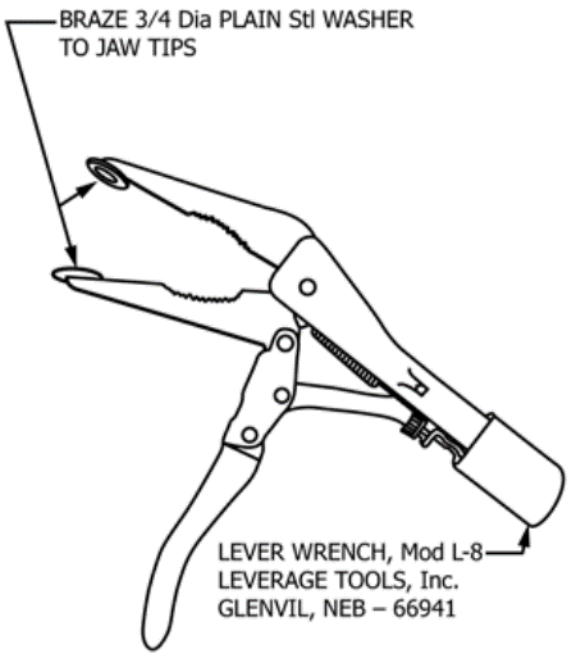

FIG. 4 Seam Clamp

(vi) 7.5 *Permanency of Labels and Warnings:*

(vii) 7.5.1. 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.

(viii) 7.5.2. 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.

(ix) 7.5.3. 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 most likely to

cause failure using a 0.75 in. (19 mm) diameter clamp surface. Gradually apply the force over 5 s and maintain for an additional 10 s.

(xi) 7.6. *Adhesion Test for Warnings Applied Directly onto the Surface of the Product.*

(xii) 7.6.1. Apply the tape test defined in Test Methods D3359, Test Method B—Cross-Cut Tape Test of Test Methods, eliminating parallel cuts.

(xiii) 7.6.2. Perform this test once in each different location where warnings are applied.

(xiv) 7.6.3. 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.

(xv) 7.6.4. A non-paper label, during an attempt to remove it without the aid of tools or solvents, shall not fit entirely within the small parts cylinder defined in 16 CFR 1501 if it can be removed.

(xvi) 7.7. *Crib Bumper/Liner Firmness Test*—Select one side of the crib bumper/liner. All marks described in this section shall be made at mid-bumper/liner height. For each crib bumper/liner intended for a short side of a crib, or segments of a crib bumper/liner intended for a short side of a crib, mark two points along the bumper/liner length: one at 1/3 of the total length, and one at 2/3 of the total length (see Figure 5). For each crib bumper/liner intended for a long side of a crib, or segments of a crib bumper/liner intended for a long side of a crib, mark three points along the bumper/liner length: 1/4, 1/2, and 3/4 of the total length (see Figure 5). There will be 10 marks in total for a single continuous bumper/liner intended to cover all four sides of a standard full-size rectangular crib. For each crib bumper/liner intended for a circular crib, divide the total bumper/liner length into 10 equal segments and mark the centroid of each segment. For crib bumpers/liners no wider than 8 inches (203 mm), with the long axis intended to be installed vertically on the crib side, mark the centroid of the bumper/liner (see Figure 5). Place the center

of the firmness test fixture (Figure 2) on each mark with the feeler arm oriented in a way that is most likely to contact the bumper/liner surface when the fixture is set down, such as over a plush construction. The firmness test fixture may be rotated such that the feeler arm is in any orientation that is completely over the crib bumper/liner.

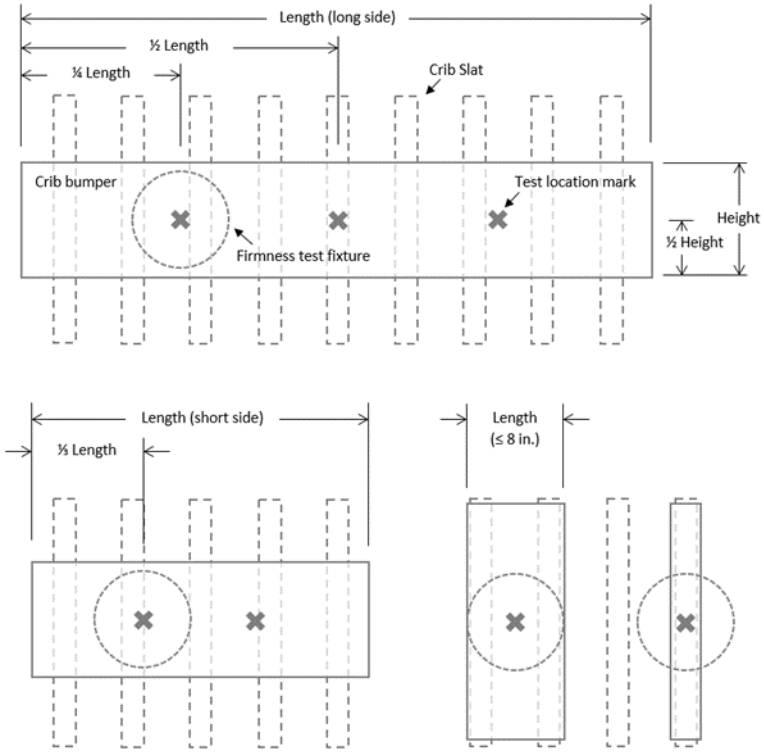

FIG. 5 Firmness Test Locations

(xvii) 7.7.1. Test Equipment – The Firmness Test Fixture of Figure 2 shall be constructed with the following components:

(xviii) 7.7.1.1. A Bottom Disk with a diameter of 203 mm (7.99 in.), thickness of 15 mm (0.59 in.) with a bottom radius of 1 mm (0.039 in.).

(xix) 7.7.1.2. A Feeler Arm of high speed steel comprising a flat bar, 12 mm (0.47 in.) wide, 0.51 mm to 0.76 mm (0.02 to 0.03 in.) thick, with square-cut ends that is positioned over a

radial axis of the Bottom Disk and attached to the Bottom Disk such that the Feeler Arm overhangs the edge of the Bottom Disk by 40 mm (1.57 in.).

(xx) 7.7.1.3. A Level Indicator attached to the Bottom Disk near the Feeler Arm, without touching, and such that it indicates level with minimum accuracy of.11.7 mm/m (0.14 in./ft) parallel to the feeler arm and does not overhang the edge of the Bottom Disk in a way that interferes with testing.

(xxi) 7.7.1.4. A Vertical Column with Handle and Collar attached to the center of the Bottom Disk.

(xxii) 7.7.1.5. Total mass of the Apparatus shall be 5.2 kg (11.5 lb) including all components and fasteners.

(xxiii) 7.7.1.6. Mass of the Bottom Disk shall be not less than 70% of the total mass.

(xxiv) 7.7.1.7. Vertical height of assembled apparatus shall not exceed 203.2 mm (8 in.) and the height of the collar shall not exceed 50.8 mm (2 in.) to minimize the bias to the Bottom Disk.

(xxv) 7.7.2. Test Procedure

(xxvi) 7.7.2.1. Preconditioning of Sample—The crib bumper/liner shall be tested in its pre-washed state and also after three wash/dry cycles performed according to the manufacturer's care instructions. The crib bumper/liner shall be conditioned for 48 hours prior to testing in an environment of 23 +/- 2 Celsius (73.4 +/- 3.6 Fahrenheit) and a relative humidity of 50 +/- 5%. The crib bumper/liner shall be fully assembled and dry prior to testing.

(xxvii) 7.7.2.2. Shake the crib bumper/liner to aerate and distribute any filling materials evenly. Allow the crib bumper/liner to settle for 5 minutes.

(xxviii) 7.7.2.3. Place the side to test face up on a horizontal, flat, rigid surface for

testing. The crib bumper/liner may be secured to the horizontal surface using the attachment means in a manner that approximates securing the crib bumper/liner to crib rails.

(xxix) 7.7.2.4. Test each placement marked in 7.7 by lowering the firmness test fixture with the bottom disk horizontal until the fixture is supported by the crib bumper/liner. Gently adjust the orientation of the base manually if needed until it is horizontal while resting. Record any contact with the feeler gauge at each placement as a failure of the firmness requirement. Repeat steps 7.7.2.2 and 7.7.2.3 if any placement is within 457 mm (18 in.) of a prior placement, or if 5 minutes have elapsed since completing 7.7.2.2.

(xxx) 7.7.2.5. Repeat firmness testing 7.7.2.1 to 7.7.2.4 until all remaining located placements have been tested or a failure has been recorded.

(xxxi) 7.7.2.6. Repeat firmness testing on the other side of the bumper/liner. Testing the other side is not required for crib bumpers/liners that cannot be reasonably installed on the other side.

(xxxii) 7.8 *Crib Bumper/Liner Entrapment in Openings Test*—Choose a location most likely to admit the head probe, including between the top and bottom edges of the crib bumper/liner and the test platforms or mattress. Create an accessible opening by exerting a force on the bumper/liner using an appropriate clamping device, equal to 3-lbf (13 N) and directed horizontally away from, and perpendicular to, the test platform. The force is be applied gradually over a 5 s period and maintained throughout the head probe test. Insert the head test probe, tapered end first, into any opening created between the crib bumper/liner and the test platform or mattress, and rotate the small head test probe to the orientation most likely to fail. Apply a force of 10 lbf (45 N) at the base of the small head test probe in a direction that is perpendicular to the plane of the opening. The force is be applied gradually over a 5 s period and maintained

throughout the head probe test. Repeat this test at any other locations on the crib bumper/liner most likely to fail.

(xxxiii) 7.8.1. *Test Equipment*

(xxxiv) 7.8.1.1. Head Probe—The head probe specified in ASTM F963 (see Fig. 3) shall be used for entrapment tests.

(xxxv) 7.8.1.2. Test Platforms—Testing shall be conducted on all test platforms in this section. All test platforms shall have four vertical sides, be rectangular in plan, and have an internal length of 52-3/8 +/- 5/8 in and internal width of 28 +/- 5/8 in. Test platforms shall have a rectangular mattress support that supports a standard 5-in full-size crib mattress. Spacing between components, including between slats, shall be 2-3/8 +0/-1/32 in. Each of the long and short panels shall be rectangular in form with a top, bottom, left, and right side rails. Top rail shall be 26 in above a horizontal mattress support. All spindles shall have ends secured into top and bottom rails. Left and right side rails shall end into top and bottom rails. All rails shall be 1.0 in thick. The top and bottom rail shall have 1.5 in depth. Each long and short panel shall form a vertical corner between the left or right sides when assembled. Round spindles shall be 5/8 in diameter. Flat spindles shall be 1-1/8 in wide by 3/8 in thick with 1/16 in radius edges. Crib bumpers/liners intended for circular cribs shall be tested on a commercially available circular crib.

Test Platform A—This test platform is composed of two long panels with 16 round spindles each and two short panels with eight round spindles each.

Test Platform B—This test platform is composed of one long panel with 16 round spindles, one solid long panel, and two short panels with eight round spindles each.

Test Platform C—This test platform is composed of two long panels with 16 round

spindles each and two solid short panels.

Test Platform D—This test platform is composed of two long panels with 14 rectangular spindles each and two short panels with seven rectangular spindles each.

Test Platform E—This test platform is composed of one long panel with 14 rectangular spindles, one solid long panel, and two short panels with seven rectangular spindles each.

Test Platform F—This test platform is composed of two long panels with 14 rectangular spindles each and two solid short panels.

(11) Instead of complying with section 8 of ASTM F1917-12, comply with the following:

(i) **8. Marking and Labeling**

(ii) 8.1. Each product and its retail package shall be marked or labeled clearly and legibly to indicate the following:

(iii) 8.1.1. The name, place of business (city, state, and mailing address, including zip code), and telephone number of the manufacturer, distributor, or seller.

(iv) 8.1.2. A code mark or other means that identifies the date (month and year as a minimum) of manufacture.

(v) 8.2. The marking and labeling on the product shall be permanent.

(vi) 8.3. Any upholstery labeling required by law shall not be used to meet the requirements of this section.

(vii) 8.4. Crib bumpers/liners shall be marked or labeled clearly and legibly, in the English language at a minimum, to identify which segments of the bumper/liner are intended for the short and long sides of the crib, unless the bumper/liner is intended for a circular crib or is less than 28 inches in length, not including attachment means.

(viii) 8.5. *Warning Design for Product:*

(ix) 8.5.1. The warnings shall be easy to read and understand and be in the English language at a minimum.

(x) 8.5.2. 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.

(xi) 8.5.3. The warning statements shall be conspicuous and permanent.

(xii) 8.5.4. 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.

(xiii) 8.5.4.1. In sections 6.2.2, 7.3, 7.5, and 8.1.2 of ANSI Z535.4-2011, replace "should" with "shall."

(xiv) 8.5.4.2. In section 7.6.3 of ANSI Z535.4-2011, replace "should (when feasible)" with "shall."

(xv) 8.5.4.3. Strike the word "safety" in ANSI Z535.4-2011 when used immediately before a color (for example, replace "safety white" with "white").

Note—For reference, ANSI Z535.1 provides a system for specifying safety colors.

(xvi) 8.5.5. 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 uppercase shall be at least 0.1 in. (2.5 mm) high.

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.

(xvii) 8.5.6. *Message Panel Text Layout*:

(xviii) 8.5.6.1. 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. Please see Fig. 6 for examples of left aligned text.

FIG. 6 Examples of Left Aligned Text

(xix) 8.5.6.2. 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.

(xx) 8.5.7. An example in the format described in this section is shown in Fig. 7.

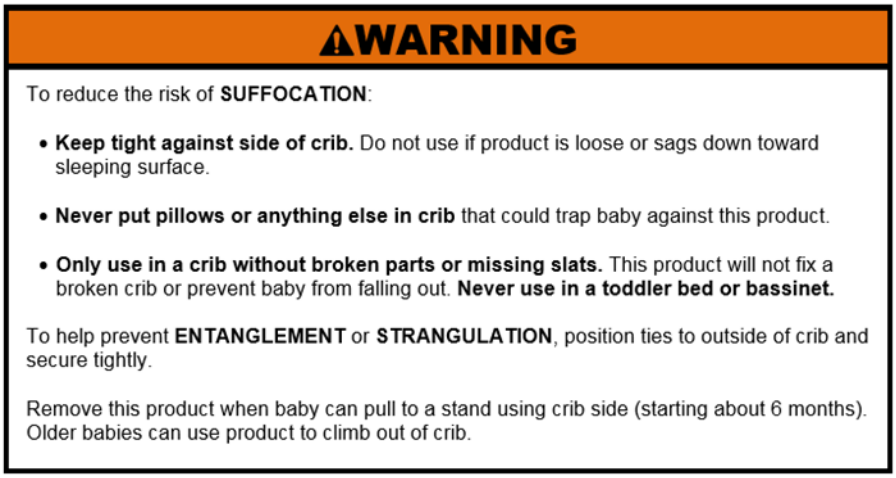

FIG. 7 Example—Warning Statement Text Layout

(xxi) 8.6. *Warning Statements for Crib Bumpers/Liners*—Each crib bumper/liner, or each crib bumper/liner panel if the bumper/liner is sold as multiple panels that can be used separately, shall have warning statements to address the following, at a minimum:

"To reduce the risk of **SUFFOCATION**:

- **Keep tight against side of crib.** Do not use if product is loose or sags down toward sleeping surface.
- **Never put pillows or anything else in crib** that could trap baby against this product.
- **Only use in a crib without broken parts or missing slats.** This product will not fix a broken crib or prevent baby from falling out. **Never use in a toddler bed or bassinet**.

To help prevent **ENTANGLEMENT** or **STRANGULATION**, position ties to outside of crib and secure tightly. [Exception: If product does not include an attachment means greater than 7 inches in length, this statement may be omitted.]

Remove this product when baby can pull to a stand using crib side (starting about 6 months). Older babies can use product to climb out of crib."

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.

(12) Instead of complying with section 9 of ASTM F1917-12, comply with the following:

(i) **9. Instructional Literature**

(ii) 9.1. 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, installation, maintenance, cleaning, and use, where applicable.

(iii) 9.2. The instructions shall include all warnings specified in 8.6, where applicable.

9.3 The warnings in the instructions shall meet the requirements specified in 8.5.4, 8.5.5 and 8.5.6, except that sections 6.4 and 7.2–7.6.3 of ANSI Z535.4 need not be applied. However, the signal word and safety alert symbol shall contrast with the background of the signal word panel, and the warnings shall contrast with the background of the instructional literature.

Note—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.

(C) 9.4 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.

Note—For additional guidance on the design of warnings for instructional literature, please refer to ANSI Z535.6, American National Standard: Product Safety Information in Product Manuals, Instructions, and Other Collateral Materials.

Dated: _____

_____
Alberta E. Mills,
Secretary, Consumer Product Safety Commission

Staff Briefing Package

Staff's Draft Notice of Proposed Rulemaking for Crib Bumpers under the Danny Keysar Child Product Safety Notification Act

September 4, 2019

Table of Contents

Briefing Memorandum

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

MEMORANDUM

DATE: September 4, 2019

TO: The Commission
Alberta E. Mills, Secretary

THROUGH: Patricia M. Hanz, General Counsel
Mary T. Boyle, Executive Director
DeWane Ray, Deputy Executive Director for Safety Operations

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

Timothy P. Smith, Project Manager, Crib Bumpers Project,
Division of Human Factors, Directorate for Engineering Sciences

SUBJECT: Staff's Draft Notice of Proposed Rulemaking for Crib Bumpers under the Danny Keysar Child Product Safety Notification Act

I. INTRODUCTION

The Danny Keysar Child Product Safety Notification Act, *i.e.*, 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.

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." The statute also specifies 12 categories of products that fall within the definition. Crib bumpers are not listed among the products in section 104(f); however, on October 19, 2016, the Commission voted to amend the agency's fiscal year 2017 (FY 2017) Operating Plan to initiate rulemaking under section 104 of the CPSIA to promulgate a mandatory consumer product safety standard to address the risk of injury associated with the use of padded crib bumpers.[1]

[1] The final, approved FY17 Operating Plan can be found here: https://www.cpsc.gov/s3fs-public/CPSCFY2017OpPlan.pdf. The Commission reaffirmed this decision in the FY 2018 Operating Plan, which can be found here: https://www.cpsc.gov/s3fs-public/FY_2018_Operating_Plan_August302017.pdf.

Specifically, the Commission directed CPSC staff to prepare notice of proposed rulemaking (NPR) briefing packages that:

- propose to include crib bumpers as "durable infant or toddler products" requiring consumer registration under section 104(b) of the CPSIA; and

- propose a mandatory consumer product safety standard for crib bumpers under section 104 of the CPSIA that is more stringent than the current ASTM voluntary standard and will further reduce the risk of injury associated with these products.

The current NPR briefing package addresses both of these elements in a single briefing package.

In the FY 2017 Operating Plan, the Commission stated that the proposed rule must endeavor to address the hazards of suffocation; wedging and entrapment; falls; use patterns, such as installation difficulties, using crib bumpers for children past the recommended age, and using crib bumpers outside a crib; and mixed messaging about padded objects in cribs. The FY 2017 Operating Plan also states that CPSC staff shall, at a minimum:[1]

- "develop a performance requirement and test method to show that a crib bumper is firm enough not to conform to the face of an infant, based on known anthropometric parameters;"

- "develop a performance requirement and test method based on known infant inhalation and exhalation requirements and anthropometric parameters to demonstrate that a crib bumper matches or exceeds the airflow characteristics of mesh or mesh-like materials, taking into account the safety of infants with compromised breathing;" and

- "compose warnings and instructions on the product that explain all of the types of cribs on which the product can and cannot be installed, clear advice about how to install the product and at what age of the child to stop using the product."

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 the relevant voluntary standards. This consultation process has been ongoing with staff's participation in the ASTM juvenile products subcommittee meetings. ASTM subcommittee members represent producers, users, consumers, government, and academia.[2] Staff began the consultation process for this rulemaking in December 2016, in a letter to ASTM requesting that the ASTM F15.19 Subcommittee on Infant Bedding form task groups related to (1) firmness requirements, (2) airflow requirements, and (3) warning and instructional requirements, to update ASTM F1917, *Standard Consumer Safety Performance Specification for Infant Bedding and Related Accessories*, with more stringent requirements that will further reduce the risk of injury associated with crib bumpers. Since then, staff has been actively participating in the ASTM subcommittee activities to address these issues.

[2] ASTM International website: www.astm.org, About ASTM International.

This briefing package assesses the effectiveness of the ASTM voluntary standard requirements for crib bumpers and presents staff's recommendations for a draft proposed rule. This package also includes a proposal to include crib bumpers as "durable infant or toddler products" requiring consumer registration under section 104(b) of the CPSIA.

II. BACKGROUND

A. ASTM Voluntary Standard

ASTM F1917, *Standard Consumer Safety Performance Specification for Infant Bedding and Related Accessories*, contains requirements for infant bedding and related accessories, including crib bumpers. ASTM developed the voluntary standard in response to incident data supplied by CPSC staff. The introduction to the standard states that the standard "cannot prevent incidents that occur as the result of unforeseeable abuse and misuse." The current version of the voluntary standard was published in 2012 (ASTM F1917 – 12). This is the third revision since the standard was first published in 1999.

The voluntary standard does not define "crib bumpers" but does include several performance and labeling requirements that are specific to or relevant to crib bumpers, including limits on the thickness of crib bumpers, limits on the length of ties used to secure bumpers to cribs, strength requirements for bumper ties, and minimum intervals or locations at which bumpers must be "capable of being secured" to a crib. In addition, the voluntary standard specifies warning language that must appear on each bumper. The relevant requirements identify these products using the following terms: "bumper pad," "bumper guards," "headboard bumper guards," "headboard/bumper set," "bumper," and "crib bumper."

B. The Products

Traditionally, crib bumpers are infant bedding accessories that attach to the interior perimeter of a crib and function as a barrier between the infant and the sides of the crib. However, the design of these products can vary. The most common type of crib bumper consists of one or more rectangular fabric panels, constructed of cotton or polyester, with filling material for padding, and with fasteners to attach the bumper to a crib. The fasteners are often ties that are secured to the crib corner posts, crib slats or spindles, or both; however, other fastening methods exist. These products commonly are marketed as preventing injury to infants from impacts against the sides of a crib and preventing limb entrapments between crib slats. Bumpers also are used to decorate the infant's sleep environment and might be promoted as making a crib more "cozy" or comfortable. The product warnings recommend that bumpers be removed when a child can sit up unassisted or can pull to a standing position, but the warnings do not specify the age at which children can perform these actions. An infant may start to engage in these activities at about 5 months, and generally would reach one of these milestones at about 6 months old.

Less common designs of crib bumpers include so-called "vertical" bumpers or liners, which essentially are a series of small bumpers that individually enshroud each vertical crib slat or spindle. These products generally claim to offer benefits that are comparable to traditional bumpers, while allowing airflow through the sides of a crib. More recent crib bumper variants

FIGURE 1. Examples of a traditional crib bumper (left), vertical bumpers (middle), braided bumpers (top right), and a mesh liner (bottom right).

are braided bumpers, which consist of two or more fabric sleeves, containing filling material, and that are braided together. Other bumper variants exist that look similar to traditional bumpers but are marketed with claims of being "breathable." Mesh crib liners are similar in their marketing claims that the products are breathable, but these products tend to be thinner than traditional bumpers, with minimal padding, if any, because they are not aimed at preventing impact injuries. Figure 1 shows examples of a traditional crib bumper, vertical bumpers, braided bumpers, and a mesh liner.

Although the Commission directed staff to promulgate a mandatory consumer product safety standard that will address the risk of injury associated with the use of "padded crib bumpers," staff recommends that all of the products identified above be included within the scope of the proposed rule because all these products line the interior sides of a crib and functionally limit or prevent access to the crib sides, just like traditional crib bumpers. Thus, in principle, all these products might present similar hazards and benefits to infants. Through the remainder of this memorandum, the term "crib bumpers" or "bumpers" includes these other products, unless specifically excluded.

As staff of CPSC's Directorate for Economic Analysis (EC) discusses in Tab A, crib bumpers range in price from $12 to $500, and also are sold in bedding sets, which can range in price from $80 to $1,200. Manufacturers typically produce only a few models, with differences in color, art design, cover material, and filling material being the primary identifying factors. Those products at the higher end of the price range typically are decorated with detailed paint or woven art.

Information from the 2013 CPSC Durable Nursery Products Exposure Survey of U.S. households with children younger than 6 years old indicates that about 9.9 million crib bumpers are owned by U.S. households, and 5.3 million of these bumpers are in use. The total number of bumpers in use might be somewhat higher than this number, because some bumpers may be in use in households in which young children do not reside, such as the homes of older adults who provide care for grandchildren. In addition, the survey did not include childcare facilities and

lodging establishments, such as hotels. However, bumper usage in these other households and facilities is probably low.[3]

C. Legislative Activities

Since 2012, some state and local jurisdictions have banned the sale of crib bumpers:

- *Chicago, IL*: Beginning on April 5, 2012, the sale or lease of any "crib bumper pad," as a separate item or as an accessory to a crib, became illegal in Chicago.[4] The Chicago code defines a "crib bumper pad" as: "any padding material, including but not limited to a roll of stuffed fabric, which is designed for placement within a crib to cushion one or more of the crib's inner sides adjacent to the crib mattress."

- *Maryland*: Effective June 21, 2013, Maryland's Department of Health and Mental Hygiene (DHMH) published final regulations that declare "baby bumper pads" to be a hazardous material that may not be shipped or sold to a purchaser in Maryland, effective June 21, 2013.[5] The Maryland regulation defines "baby bumper pad" as: "a pad or pads of non-mesh material resting directly above the mattress in a crib, running the circumference of the crib or along the length of any of the interior sides of the crib, and intended to be used until the age that an infant pulls to a stand." The regulation also states that a "new" ASTM voluntary standard for these products might replace the ban if the DHMH Secretary determines that products complying with the ASTM standard are not a danger to public health and safety, and that the Secretary may suspend the regulation if the CPSC affirmatively finds that the benefits of certain bumpers exceed the risks. The ban does not apply to mesh crib liners or to vertical bumpers that wrap tightly around each individual crib rail.[6]

- *Watchung, NJ*: On December 15, 2016, the borough of Watchung, NJ, amended its police regulations to prohibit the sale or lease of "crib bumper pads,"[7] which are defined as: "any padding material, including but not limited to a roll of stuffed fabric or breathable liner, which is designed for placement within a crib to cushion one or more of the crib's inner sides adjacent to the crib mattress." The ordinance explicitly states that mesh liners are not included in the definition of "crib bumper pad."

- *Ohio*: Effective April 6, 2017, Ohio banned the manufacture, sale, or delivery of "crib bumper pads,"[8] which are defined as: "any padding material, including a roll of stuffed fabric, that is designed for placement within a crib to cushion one or more of the crib's inner sides adjacent to the crib mattress." The definition also states that "Crib bumper pad" excludes mesh crib liners, regardless of whether CPSC includes mesh liners in its definition of "crib bumper pad." The ban excludes mesh crib liners for no more than 3 years after the effective date, unless such liners comply with consumer product safety

[3] Daycare and hotel establishments contacted by staff reported no crib bumper use in their facilities.
[4] Chicago, Ill., Mun. Code § 7-36-112.
[5] Md. Code Regs. 10.11.07.
[6] See https://phpa.health.maryland.gov/mch/Pages/crib-bumpers.aspx.
[7] Revised General Ordinances of the Borough of Watchung, Chapter VI § 6-13, Ord. No. 2016-15.
[8] 37 Ohio Rev. Code § 3713.

standards promulgated by CPSC to ensure sufficient permeability and breathability to prevent infant suffocation.

The states of Missouri, New York, and Vermont are considering similar bans. In addition, in June 2019, a bill to ban the manufacture, importation, and sale of crib bumpers in the United States, the "Safe Cribs Act of 2019" (H. R. 3170 and S. 1816), was introduced in Congress. The bill, as introduced, defined the term "crib bumper" broadly to include not only traditional padded crib bumpers, but also mesh crib liners and vertical bumpers, or crib slat covers. However, on July 10, 2019, the House Committee on Energy and Commerce, Subcommittee on Consumer Protection and Commerce, amended the definition of "crib bumper" in H. R. 3170 to exclude mesh liners.

III. INCIDENT DATA

As staff of CPSC's Directorate for Epidemiology, Division of Hazard Analysis (EPHA) discusses in Tab B, staff's search of the Consumer Product Safety Risk Management System (CPSRMS) and National Electronic Injury Surveillance System (NEISS) databases identified 113 fatal incidents associated with crib bumpers that reportedly occurred from January 1, 1990, through March 31, 2019, and 113 nonfatal incidents and concerns that involved crib bumpers and were reported to CPSC from January 1, 2008, through March 31, 2019. Seventeen of these bumper-related cases—3 reported fatalities and 14 nonfatal cases—were from the NEISS database. These data do not meet the minimum criteria for computing a national estimate of bumper-related, emergency department-treated injuries to children.

Because reporting is ongoing, the number of reported fatalities and nonfatal incidents and concerns may change in the future. Specifically, data for years 2017 through 2019 are not complete.

A. Fatalities

CPSC has identified 113 fatalities associated with crib bumpers (*i.e.*, cases in which a crib bumper was present in the sleep environment) from January 1, 1990, through March 31, 2019. This nearly 30-year timeframe is considerably longer than the 10-year timeframe that is more commonly employed in other section 104 rulemaking activities. However, CPSC staff's 2016 briefing package to the Commission concluded that all the reported fatalities that staff examined and considered most likely to be addressable occurred before 2008 (see Smith, 2016). Thus, to be as inclusive as possible, staff chose to retain reported fatalities as far back as 1990.

To staff's knowledge, all bumpers involved in these incidents were traditional crib bumpers. All but 8 of the 113 reported fatalities involved a bumper inside a crib. Of the eight reported fatalities that involved a bumper outside a crib, three occurred in a toddler bed, three in a bassinet, one in a play pen, and one on a mattress on the floor. CPSC staff classified 30 of the 113 reported fatalities as "incidental," because although a crib bumper was present in the sleep environment, there was no evidence of bumper contact or involvement in the fatality.[9] Thus, for

[9] Examples include a case in which a child was found prone with nothing near the face and the crib bumper 6 inches away, a case in which a child was found within foam wedge positioners with his face pressed against one side of the

these 30 fatalities, improved performance, warning, or similar requirements for crib bumpers would likely have no effect.

Of the remaining 83 reported fatalities, 75 (90 percent) involved infants younger than 12 months, and 51 (61 percent) involved infants 4 months old or younger. Only three of the 83 reported fatalities involved children 2 years old or older; one of these children had health issues, one was developmentally delayed, and the third went into cardiac arrest about a year after the bumper-related incident, when the child was likely an infant.[10]

B. Nonfatal Incidents and Concerns

CPSC staff is aware of 113 bumper-related, nonfatal incidents and concerns that were related to crib bumpers and were reported to CPSC from January 1, 2008, through March 31, 2019 (more than 11 years). Of these 113 nonfatal reports, 60 resulted in injury, 50 did not result in injury, and the disposition of 3 is unknown. Fifteen (13 percent) of the 113 nonfatal incidents and concerns reportedly involved a breathable bumper or mesh liner. Thirty-five cases did not report the child's age. Of the remaining 78 nonfatal incidents and concerns, 47 (60 percent) involved infants younger than 12 months.

C. Hazard Patterns

The reported fatalities generally identify the cause of death as asphyxia, suffocation, sudden unexpected infant death (SUID), or sudden infant death syndrome (SIDS), a sub-type of SUID. Even with a full autopsy, it can be difficult, and often impossible, to distinguish between SIDS/SUID deaths and accidental or deliberate suffocations with a soft object.[11] Thus, for the purposes of this analysis, staff is treating the causes of these deaths as the same. These cases often involved the presence of soft bedding, such as pillows or blankets, or similar products (*e.g.*, stuffed dolls), in addition to the crib bumper.

As staff noted, 30 of the 113 reported fatalities associated with crib bumpers were classified as "incidental" because there was no evidence of bumper contact or involvement in the fatality.[9] CPSC staff classified the remaining 83 fatalities into the following hazard patterns or scenarios:

- *Contact Outside Crib (5 fatalities)*: The child was in contact with a crib bumper outside a crib.

- *Entrapment/Wedging (44 fatalities)*: The child was entrapped or wedged against the crib bumper. These cases are broken down further, as follows:

positioner, a case in which a child was found prone and facedown with a quilt wrapped around her neck, and a case in which a child was found on his back with a nursing pillow and a large stuffed animal over his face. In three cases, the cause of death was considered to be exclusively medical in nature, and therefore, unrelated to the presence of the bumper.

[10] Staff also is aware of a fourth incident involving a 2-year-old; however, this incident was classified as incidental, because the cause of death was determined to be cardiorespiratory arrest due to a seizure. The victim reportedly had a history of seizures.

[11] See the memorandum prepared by staff of CPSC's Directorate for Health Sciences (HS), in Tab D, for more on this issue.

- *Against Object in Crib (25 fatalities)*: The child was entrapped or wedged between the bumper and another object in the crib, such as a bed pillow, infant recliner, or cushion.

- *In Perimeter of Crib (13 fatalities)*: The child was entrapped between the mattress and the side of the crib (onto which a bumper was installed), such as scenarios in which the child slipped into a gap between these two items. Nine of these cases involved a crib that was structurally compromised, with features such as detached crib side rails, or missing or detached crib slats.

- *Other (6 fatalities)*: The child was entrapped between crib slats, under the bumper, or in some other scenario not covered by the previously identified entrapment or wedging categories.

- *Contact Without Entrapment/Wedging (27 fatalities)*: The child was in contact with the crib bumper, but there was no indication of entrapment or wedging against the bumper.

- *Contact With Possible Entrapment/Wedging (7 fatalities)*: The child was in contact with the bumper, but staff could not determine whether the child was entrapped or wedged against the bumper.

CPSC staff classified the 113 nonfatal incidents and reported concerns as follows:

- *Slat Entrapments (38 incidents)*: The child's arm or leg became entrapped between the slats of the crib, even though a crib bumper was present. In these cases, there was no indication that the bumper played a role in the entrapment. Seven of the 38 slat entrapments reportedly involved a breathable bumper or mesh liner.

- *Climbing or Climb-Outs (12 incidents)*: The child reportedly used the bumper as a step to climb, often resulting in a fall back into the crib or out of the crib. All children involved in these incidents were at least 7 months old.

- *Under or Behind Bumper (10 incidents)*: The child, or some part of the child, was found under or behind (*i.e.*, against the crib side) the crib bumper. Seven cases reportedly involved entrapment by the bumper. Some cases reported that the bumper was missing bottom ties.

- *Near-Strangulation or Entanglements (8 incidents)*: Parts of the crib bumper, such as the ties, threads, or stitched-on decorative patterns, wrapped around the neck, limb, or digit of the child. Half of these incidents specifically mention the head, mouth, or neck being wrapped up by a piece of a crib bumper. However, none involved a bumper tie wrapping around a child's neck.

- *Entrapped Against Object in Crib (7 incidents)*: The child was entrapped between a crib bumper and another object in the crib, such as a sleep positioner or an infant recliner.

- *Choking or Ingestion of Small Parts (7 incidents)*: The child ingested or choked on part of the crib bumper, such as a decorative stitched-on pattern or the bumper's filling material.

- *Other (14 incidents)*: Other bumper-related incidents involving a child, but not identified above, including: bumper integrity issues such as ties detaching or being pulled off, stitching being pulled out, and paint rubbing off; injuries from impacting or rubbing against the bumper; injuries, such as cuts and bruises on the crib rail, that occurred despite the presence of the bumper; an injury from a needle found in the bumper; a case in which a child, whose head was in contact with a bumper, became entrapped between a crib toy and the crib mattress; a case in which a crib side detached and the bumper held the crib side in place; and a case in which crib slats broke and the bumper kept the child in the crib.

- *Concerns (17 reports)*: Reports of crib bumper-related complaints or problems foreseen by a consumer, but not involving an actual incident with a child. Examples include bumper integrity issues, such as ties detaching or the bumper coming apart; concerns about poor bumper fit or bumpers missing lower ties; and general concerns about bumpers posing a safety hazard.

IV. DISCUSSION

A. Adequacy of ASTM F1917 – 12 and Draft Proposed Rule

CPSC staff assessed the adequacy of ASTM F1917 – 12 on the basis of the incident data and hazard patterns discussed above, and on staff's review of the voluntary standard for issues requiring clarification. In accordance with section 104 of the CPSIA, staff determined that substantial changes and additions to the existing voluntary standard requirements are necessary to provide a CPSC standard that is more stringent than the current voluntary standard, and would further reduce the risk of injury associated with crib bumpers. See Tabs C, D, and E for detailed discussions of the following issues by staff of CPSC's Directorate for Laboratory Sciences, Division of Mechanical Engineering (LSM); CPSC's Directorate for Health Sciences (HS); and CPSC's Directorate for Engineering Sciences, Division of Human Factors (ESHF); respectively. Tab F includes a series of tables that show staff's specific recommendations for the proposed rule relative to the voluntary standard, based on these assessments.

i. Crib Bumper Definition

ASTM F1917 – 12 includes several performance and labeling requirements that are specific to or relevant to crib bumpers, but the voluntary standard identifies these products inconsistently using the following terms: "bumper pad" (section 6.3, 7.4, 7.4.1, Note 2), "bumper guards" (3.1.4, 5.1, 5.4), "headboard bumper guards" (3.1.4, 5.1), "headboard/bumper set" (8.2.1), "bumper" (3.1.1, 6.2, Figure 1 caption, 7.3, 8.2.1), and "crib bumper" (6.2). The voluntary standard does not define any of these terms. CPSC staff believes that the proposed rule must explicitly define the products that are subject to the rule using consistent terms. Doing so would reduce the risk of injury associated with crib bumpers by providing clarity to manufacturers and testing laboratories about which products are subject to the requirements of the proposed rule.

Some other standards and legislative actions include definitions for crib bumpers. For example:

- The *Standard for the Flammability of Mattress and Mattress Pads*, 16 CFR part 1632, and the *Standard for the Flammability (Open Flame) of Mattress Sets*, 16 CFR part 1633, include the following definition for "crib bumper": "Padded cushion which goes around three or four sides inside a crib to protect the baby. Can also be used in a playpen." (16 CFR § 1632.8(j) and 16 CFR § 1633.9(i), respectively.) This definition serves only to distinguish crib bumpers from mattresses and mattress pads, and staff does not believe it is a useful definition for the proposed rule for crib bumpers.[12]

- State and local bans on crib bumpers, and similar pending legislative actions, differ somewhat in their definitions of affected products, but generally define the products as pads or padding material that line the inner sides of a crib, adjacent to the crib mattress. Mesh liners typically are explicitly excluded from the definition.

- The European Standard, EN 16780:2018, *Textile child care articles – Safety requirements and test methods for children's cot bumpers*, includes requirements for crib bumpers, which the standard identifies as "cot bumpers,"[13] and defines "cot bumper" as: "product intended to be attached to the inner vertical surface of one or more cot sides."

CPSC staff has been working with the ASTM Infant Bedding Subcommittee, which formed a task group to develop an appropriate definition. The consensus of the task group is that the voluntary standard requirements that currently apply to crib bumpers also should apply to similar products that line the interior of a crib, such as mesh liners. For this reason, the task group developed, and in September 2018 balloted, a definition of "crib liner" that broadly covered any product intended to be placed against the inside of the crib, including crib bumpers, mesh liners, and crib rail covers. The ballot item received one persuasive negative vote, which expressed concern about the definition including products like teething rail covers that are not within the sleep area of the infant. The task group reconvened and revised the ballot to define "crib bumper/liner" and to remove the specific reference to "crib rail covers" as an example of products that would be included within the definition. The revised definition was balloted in February 2019. That ballot item also received a negative, which expressed the same concern about the definition being broad enough to encompass crib rail covers.

Staff agrees with the idea of using a broad definition that encompasses traditional crib bumpers as well as mesh crib liners, but also recognizes that crib rail covers intended to cover only the top rail of a crib side do not cover the crib sides, slats, spindles, or the spaces between these components, and therefore, do not serve the same function as a crib bumper or mesh liner. Taking these issues into account, CPSC recommends that the proposed rule define products that are subject to the rule in the following way:

[12] For example, crib bumpers generally are intended only for full-size cribs, and could be used in circular cribs, which would not necessarily have three or four "sides."
[13] "Cot" is the British English equivalent term for "crib" in American English.

crib bumper/liner, n—any product intended to be placed against any portion of the interior perimeter of a crib, and that reduces or eliminates an infant's access to the crib sides, slats, spindles, or the spaces between these components.

Discussion—Such products are commonly referred to as crib bumpers, crib liners, mesh liners, bumper pads, bumper guards, and headboard panels, but do not include products intended to cover only the top horizontal rail of a crib.

The ASTM Infant Bedding subcommittee intends to ballot this definition as part of its revisions to the F1917 standard.

ii. Crib Bumper Thickness

The current voluntary standard employs a bumper thickness test fixture that is intended to address the suffocation hazard posed by crib bumpers by limiting the maximum thickness of crib bumpers to about 2 inches, thereby eliminating soft, pillow-like crib bumpers from the marketplace.[14,15] Pillows, and other soft, pillow-like objects can pose a suffocation hazard to infants by conforming to the face and blocking the nose and mouth. However, ASTM F1917 – 12 only applies this test to bumpers manufactured of fabric and filled with a fibrous material. CPSC staff recommends that the proposed rule apply this thickness requirement to all crib bumpers, regardless of their construction because bumpers constructed from other materials (*e.g.*, filled with foam) still could be soft and pillow-like, and pose the same hazard. Thus, broadening the existing requirement to apply to all crib bumpers would further reduce the risk of suffocation. The ASTM Infant Bedding subcommittee intends to ballot a similar change to the F1917 standard.

Staff's testing of crib bumper samples also identified some bumpers that passed through the bumper test fixture, but at such an extremely slow rate that staff found it difficult to determine whether the bumper technically passed or failed the test. Thus, staff recommends that the proposed rule include a minimum rate at which the bumper must pass through the fixture to more clearly delineate a pass from a fail. Specifically, staff recommends a rate of no less than 0.5 inches per second. Because the surface finish of the slot in the bumper thickness test fixture can affect how quickly a bumper can slide through it and can introduce variation among test laboratories and fixtures, staff also recommends that the proposed rule include a minimum finish requirement for the test fixture. Specifically, staff recommends a surface finish of 1.6 Ra (roughness average), which is a common "smooth" specification and is practical to achieve. Both of these additional requirements—the recommended rate and the recommended surface finish—should further reduce the risk of suffocation by improving a test laboratory's ability to identify crib bumpers that would fail the thickness test.

[14] ASTM F1917 – 12, Section X1.1.

[15] Petition CP 12-2, "Petition Requesting a Performance Standard to Distinguish and Regulate Hazardous Pillow-Like Crib Bumpers from Non Hazardous Traditional Crib Bumpers Under Sections 7 and 9 of the Consumer Product Safety Act," from the Juvenile Products Manufacturers Association (JPMA).

iii. Crib Bumper Firmness

Although the F1917 – 12 maximum thickness requirement for crib bumpers is intended to address the suffocation hazard by eliminating "soft" pillow-like crib bumpers,[15] thickness is not the same as softness, and the ability of a surface to conform around a child's face is an important factor related to suffocation hazards. Currently, one could make a crib bumper that would pass the maximum thickness requirement in ASTM F1917 – 12, but still would be soft enough to readily conform to the face of an infant. In fact, a crib bumper that is especially soft could be thicker than the bumper thickness test fixture and still pass the maximum thickness test because of its very pliable, pillow-like quality. Thus, to further reduce the risk of injury associated with crib bumpers, CPSC staff recommends that the proposed rule include an additional firmness requirement.

Staff recommends a firmness requirement and test method that is based on an Australian/New Zealand standard, AS/NZS 8811.1:2013, *Methods of Testing Infant Products: Part 1: Sleep Surfaces—Test for Firmness*, which is intended to assess the firmness of infant mattresses and other horizontal sleep surfaces for "excessive compression."

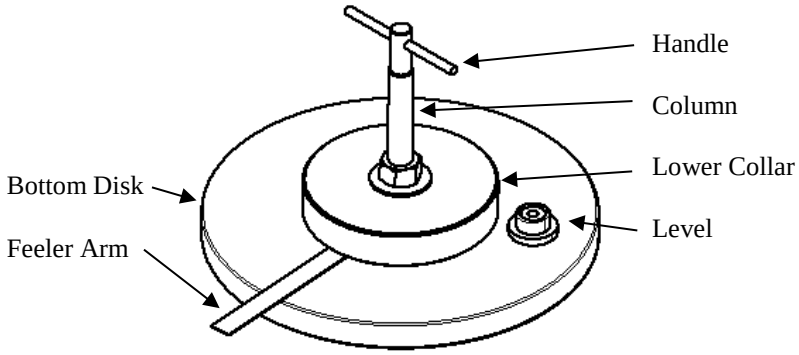

FIGURE 2. CPSC staff construction of test device from AS/NZS 8811.1:2013.

The test is performed using 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. An illustration of this device appears in Figure 2. The device is placed on the product, which compresses under the device's weight. If the compression is enough to cause the feeler arm to touch the surface of the product, the product fails. The test device was developed based on a device that was used in a German study to objectively measure the softness of mattresses and underlay surfaces as part of a case-control study of SIDS.[16]

Staff recognizes that the AS/NZS 8811.1 device and test method were developed for assessing horizontal surfaces. However, this test method is one of the only known tests from an existing published standard for measuring product firmness in a consistent and repeatable manner. Additionally, the failure criteria for this test purportedly identifies soft surfaces that pose a three-fold increase in the risk of SIDS. Staff testing of crib bumper samples to the ASTM F1917 – 12 thickness requirement and to staff's proposed firmness requirement found that many bumpers that passed the thickness requirement would fail the proposed firmness requirement. Although

[16] Prior CPSC staff testing of 26 sample crib bumpers and liners using the AS/NZS 8811.1 and German devices yielded practically identical results (Massale, 2016). Both devices passed the same 22 samples and failed the same 4 samples. The only discrepancy was for one sample, which failed using both devices, but whose failure using the AS/NZS 8811.1 device depended on its placement on the sample. Staff's recommended firmness requirement for the proposed rule would require the AS/NZS 8811.1 test device to be oriented in a way that would be most likely to fail (*i.e.*, most likely for the feeler arm to contact the bumper surface), when placed on the product.

testing was done on a limited number of samples, staff found that all bumper samples up to 0.8 inches thickness passed the firmness test, while all bumper samples 1.2 inches or greater failed the test; bumpers 1 inch thick had mixed results. Nevertheless, it is possible that the market contains some bumpers greater than 1 inch thick that are firm enough to pass the test, and some bumpers less than 1 inch that are soft enough to fail. Staff notes that one of the samples that failed the firmness test yet passed the F1917 maximum thickness test measured 2.5 inches thick, which is a half-inch thicker than the 2-inch slot that is used to test thickness. Its very pliability, or softness, is what allowed it to pass the test.

CPSC staff has been working with the ASTM Infant Bedding Subcommittee task group on crib bumper firmness. The consensus among CPSC staff and members of the task group is that staff's proposed requirement and test method would address a worst-case scenario in which the crib bumper separates from the crib side or otherwise protrudes into the sleep area and gets underneath an infant. In this scenario, the bumper would present a smothering-type suffocation hazard similar to a quilt or any other piece of soft bedding that is able to conform to, and occlude, airway openings. Staff is aware of nonfatal incidents involving bumpers without lower ties or with ties detaching from the bumper, either of which would allow for this scenario. Some reported fatalities have limited or conflicting details about the infant's face relative to the crib bumper and might have involved this scenario. In addition, staff's examination of crib bumper samples found that long continuous bumpers could be mistakenly installed on a crib in ways that would result in a loose fit and possible sagging. Although staff is recommending additional attachment and marking requirements to help address this potential (see below), the effectiveness of those requirements still depends on the consumer installing the product correctly. Staff's proposed firmness requirement would reduce the risk of injury of bumpers in the event that consumers incorrectly install these products and the product enters the sleep area.

Staff also concludes that its proposed firmness requirement could improve the safety of crib bumpers by offering some protection against other smothering-type suffocation deaths where the victim's face is forcefully pressed against a bumper to fully or partially occlude external airway openings. Scenarios involving infant wedging or entrapment against a bumper, in general, and infant entrapment between the bumper and another object in the crib in particular, are especially common in the reported fatalities. Some of these incidents involve the face being pressed against the bumper, and a firmness requirement would reduce the risk of injury associated with this scenario, provided the applied pressure was not sufficient to compress and close nostril openings.

The ASTM Infant Bedding subcommittee is preparing a ballot that includes staff's recommended firmness requirement.

iv. Crib Bumper Attachment

ASTM F1917 – 12 requires crib bumpers to be "capable of being secured at or near all corners and at the midpoints of the long sides of the crib," and specifies that bumpers intended for circular cribs must be capable of being secured at intervals not exceeding 26 inches (section 5.4). CPSC staff has several concerns with this requirement:

- The existing language is unclear about how "near" a bumper would need to be capable of securing to the corner of a crib to pass the requirement.

- The intervals at which crib bumpers must be capable of being secured—from 26 inches for a circular crib to 28 inches corner to corner for the short end of a crib—is large enough to easily allow a bumper to sag or to pull away from the crib side. Staff is aware of reported fatalities involving bumpers that were sagging, and consumers have reported concerns about poor fit between bumpers and the crib in which they were installed.

- Crib bumpers can meet the requirement without having to be secured or flush at both the top and bottom edges of the bumper. Staff is aware of reported fatalities and nonfatal incidents in which the victim was entrapped or able to slip beneath the bottom edge of the bumper, and there have been nonfatal incidents involving entrapment behind the bumper (*i.e.*, between the bumper and the crib side). In addition, some consumers have reported concerns about bumpers that did not include ties along the bottom of the bumper.

CPSC staff recommends a new performance requirement that would replace the existing F1917 attachment requirements. Staff's proposed replacement would not allow passage of a small head probe between an installed crib bumper and the interior crib side, at any location around the perimeter of the bumper most likely to fail. The small head probe is the same one used in ASTM F963, *Standard Consumer Safety Specification for Toy Safety*, and approximates the 5th percentile head size of an infant 0 to 3 months old.[17] Staff believes that this alternative attachment requirement and test method would reduce the risk of suffocation associated with infants accessing the spaces under and behind installed crib bumpers. The ASTM Infant Bedding subcommittee has formed a Bumper/Liner Attachment task group, which is developing a similar requirement for the F1917 voluntary standard.

v. Crib Bumper Strength

1. Attachment Means, Decorative Components, and Seams

ASTM F1917 – 12 includes a strength requirement for crib bumper ties. Staff believes that this requirement addresses the nonfatal incidents and reported consumer concerns involving crib bumper ties separating from bumper. However, the standard does not define "ties," but rather "attachment means." Ties are merely one form of attachment means. Thus, CPSC staff recommends that the proposed rule revise the strength requirement for bumper ties to apply to all attachment means. The ASTM Infant Bedding subcommittee currently is considering an identical change to the F1917 standard.

In addition, staff recommends that the proposed rule include strength requirements for decorative components and bumper seams, as staff is aware of nonfatal incidents and reported concerns involving detached decorative components and crib bumpers separating at seams. Because decorative components may be subjected to similar stressors as attachment means, staff recommends similar strength requirements for both. Staff's recommended seam strength requirement includes a criterion that, after testing, there shall not be an opening that permits

[17] This probe, which is used to test for hazardous loops and cords, is based on the 5th percentile head length and breadth dimensions of an infant 0 to 3 months old (ASTM F963 – 03, Section A5.7.13).

insertion of a 0.22-inch diameter rod, which is based on the finger entrapment probe that is employed in many children's product tests.

2. Component Dimensions

ASTM F1917 – 12 specifies certain dimensional limits (*e.g.*, measured lengths or perimeters) for attachment means (section 5.1) and decorative components (5.2). However, the current language would pass crib bumpers that include components that exceed these limits after having been subjected to the strength testing. CPSC staff recommends that the proposed rule require crib bumpers to meet these dimensional limits both before and after strength testing.

vi. Crib Bumper Warnings and Instructions

ASTM F1917 – 12 includes marking and labeling requirements—primarily warning requirements—for crib bumpers. However, CPSC staff concludes that these requirements do not adequately address the risk of injury and death associated with crib bumpers. Staff believes that the current warning content, format, and placement requirements are deficient, and that additional requirements, including requirements for warning permanence and instructional literature, are needed to further reduce the risk of injury associated with crib bumpers.

1. Warning Content and Format

The current F1917 warning provides incomplete and insufficient information about steps that consumers can take to reduce the risk of suffocation, and lacks key details about when and why crib bumpers should be removed from the crib. For example, staff is aware of reported fatalities involving entrapments between the bumper and another object in the crib,[18] use of the bumper outside a crib (*e.g.*, in a toddler bed or bassinet), and use of the bumper in a broken crib. None of these use patterns is addressed in the current warning. Staff also is aware of nonfatal incidents involving climbing or climb-outs, which are not addressed explicitly in the current warning.

In addition, the specified labeling and warning-format requirements are not consistent with the recommendations of the ASTM Ad Hoc Language task group. ASTM juvenile products standards have begun adopting these "Ad Hoc" recommendations since 2016 to increase the consistency of on-product warning design among juvenile products, and to address numerous warning format issues related to capturing consumer attention, improving readability, and increasing hazard perception and avoidance behavior.

On the basis of the issues identified above, CPSC staff recommends that the proposed rule replace the ASTM F1917 – 12 warning requirements to produce the following warning, in terms of content and general format:

[18] Staff also is aware of nonfatal incidents classified as near-suffocations, head entrapments, and wedge entrapments that involved entrapments between a bumper and another product (*e.g.*, toy, infant recliner, infant positioner) in the crib.

⚠WARNING

To reduce the risk of **SUFFOCATION**:

- **Keep tight against side of crib.** Do not use if product is loose or sags down toward sleeping surface.
- **Never put pillows or anything else in crib** that could trap baby against this product.
- **Only use in a crib without broken parts or missing slats.** This product will not fix a broken crib or prevent baby from falling out. **Never use in a toddler bed or bassinet.**

To help prevent **ENTANGLEMENT** or **STRANGULATION**, position ties to outside of crib and secure tightly.

Remove this product when baby can pull to a stand using crib side (starting about 6 months). Older babies can use product to climb out of crib.

Because crib bumper ties or other attachment means up to 7 inches long do not pose a strangulation hazard, staff also recommends that the warning statement about entanglement and strangulation be required only for those bumpers with any attachment means exceeding 7 inches in length.[19]

CPSC staff has been working with the ASTM Infant Bedding subcommittee on revisions to the marking and labeling requirements of the F1917 voluntary standard, and the subcommittee intends to ballot revised warning requirements that are consistent with staff's recommendations.

2. Warning Placement

ASTM F1917 – 12 requires the warnings for crib bumpers to be "conspicuous" but does not define this term. Numerous ASTM juvenile products standards include a requirement for warnings to be "conspicuous," and define this term in a way that enables one to assess conformance, typically in terms of when the warning must be visible. Thus, to clarify the required placement of the warning on the product, CPSC staff recommends that the proposed rule include a definition of "conspicuous" that is consistent with the definition used in many other ASTM juvenile products standards.[20] The ASTM Infant Bedding subcommittee intends to ballot the same definition for the F1917 voluntary standard.

3. Warning Permanence

ASTM F1917 – 12 requires the warnings for crib bumpers to be "permanent"; however, the standard neither defines "permanent," nor specifies how one would assess conformance to this

[19] ASTM F1917 – 12 specifies that bumper ties cannot be longer than 9 inches, and staff recommends that the proposed rule apply this limit to all attachment means.

[20] For example, ASTM F404 – 18, *Standard Consumer Safety Specification for High Chairs*, defines "conspicuous" as: "visible, when the high chair is in all manufacturer's recommended use positions and an occupant is sitting in the high chair, to a person standing near the high chair at any one position around the high chair but not necessarily visible from all positions."

requirement. Thus, CPSC staff recommends that the proposed rule include warning permanence requirements that are consistent with similar requirements in other ASTM juvenile products standards. Staff also recommends that the warning permanence requirements include a requirement that warnings that are attached to the fabric with seams must remain in contact around the entire perimeter of the warning. This latter requirement is based on a requirement that previously had been added to the final rule for sling carriers to avoid so called "free-hanging" labels, which can be removed easily, either intentionally or otherwise. The ASTM Infant Bedding subcommittee is preparing a ballot that contains the same warning permanence requirements that staff is recommending.

4. Additional Crib Bumper Markings

CPSC staff recommends that the proposed rule include a new requirement for permanent markings on the crib bumper that indicate the portions of the bumper intended for the long and short sides of the crib, except for those crib bumpers intended for circular cribs. Staff believes that this requirement is needed to reduce the likelihood of consumers installing the bumper incorrectly, and thus would reduce the potential for loose or sagging bumpers. Staff is aware of fatal incidents involving sagging bumpers, and consumers have reported concerns about installation difficulties and poor bumper fit.

5. Instructional Literature

ASTM F1917 – 12 does not include requirements for instructional literature to accompany crib bumpers. Numerous ASTM juvenile products standards include an "Instructional Literature" section that requires manufacturers to provide instructions with the product. Given the importance of proper installation, staff concludes that instructional literature regarding installation is essential to adequately address the risk of injury and death associated with bumpers. In addition, the ASTM Ad Hoc Language task group has published recommended requirements for instructional literature and for the formatting of warnings in instructional literature. Thus, CPSC staff recommends that the proposed rule include requirements for instructional literature, largely based on the Ad Hoc Language recommended requirements. The ASTM Infant Bedding subcommittee intends to ballot the same requirements for the F1917 voluntary standard.

B. Other Directions from the Commission

As staff discussed in the *Introduction*, the Commission stated in the FY 2017 Operating Plan that in developing a proposed standard, CPSC staff shall:

- develop a performance requirement and test method to show that a crib bumper is firm enough not to conform to the face of an infant, based on known anthropometric parameters;

- develop a performance requirement and test method based on known infant inhalation and exhalation requirements and anthropometric parameters to demonstrate that a crib bumper matches or exceeds the airflow characteristics of mesh or mesh-like materials, taking into account the safety of infants with compromised breathing; and

- compose warnings and instructions on the product that explain all of the types of cribs on which the product can and cannot be installed, clear advice about how to install the product and at what age of the child to stop using the product.

Each of these issues is discussed, in turn, below.

i. Firmness

Staff recommends a firmness requirement for crib bumpers, and details about the requirement and its associated test method appear earlier in this memorandum, in staff's discussion of the adequacy of the voluntary standard. However, staff's recommended firmness requirement is not "based on known anthropometric parameters," as requested by the Commission. The reasons for the difference in approach are described below.

Staff performed some preliminary work to develop a probe or test device for firmness based on the anthropometric dimensions of at-risk infants. This work is discussed by ESMC staff in Tab G. In essence, the anthropometry-based probe was a modified version of the probe specified in BS 4578:1970, with a truncated cone representing an infant's nose and mouth, and weighted to approximate a 6-month-old infant's head weight. This work demonstrates that, in principle, one could develop an infant anthropometry-based probe to use for firmness testing. However, staff is uncertain whether the probe would accurately measure or relate to the risk of suffocation, because the rigidity of the probe's cone-shaped protrusion does not necessarily represent the highly flexible cartilage in young infants' noses, and therefore, might not account for the potential of the nose to compress and close the nostrils when pressure is applied. In addition, LSM staff performed preliminary testing of crib bumper samples using the anthropometry-based probe (see Tab C) and was unable to establish a clear pass-fail criterion. Staff's initial hypothesis was that a failure could be defined as contact of the probe with the crib bumper around the entire perimeter of the probe. However, the anatomical protrusion on the probe tended to create wrinkles or voids that prevented complete contact around the perimeter, making it difficult to assess whether the degree to which the bumper conformed to the probe was, or should be, enough to constitute a failure.

In contrast, the probe recommended by CPSC staff, and under consideration by the ASTM Infant Bedding subcommittee is from an existing voluntary standard (AS/NZS 8811.1:2013), has a clear pass-fail criterion, and was designed to identify, or "fail," soft underlay surfaces that is said to pose a three-fold increase in the risk of SIDS. Thus, it is reasonable to conclude that a mandatory standard that adopts staff's proposed requirement and test method would reduce the risk of injury and death associated with crib bumpers that get beneath the face of an infant. Further activities related to the development of an anthropometry-based probe could be undertaken, including attempts to develop an anthropometry-based probe that matches the performance of the probe staff recommends in the current package. However, given that the performance would match that of the probe already recommended by staff, staff is uncertain what would be gained by such action, aside from the possible ability to test smaller samples.[21]

[21] Staff's preliminary anthropometry-based probe is smaller than the AS/NZS 8811.1:2013 test device, so a final anthropometry-based probe whose performance matches that of the test device currently recommended by staff would likely be smaller as well.

Thus far, staff has not encountered difficulties testing all sample products with the AS/NZS 8811.1:2013 test device.

ii. Airflow

The current ASTM voluntary standard for crib bumpers does not include an airflow-related performance requirement for crib bumpers. In April 2017, at CPSC staff's request, the ASTM Infant Bedding subcommittee formed a task group focused on developing an airflow-based requirement and test method for crib bumpers. However, by February 2018, the task group had concluded that the available incident data do not support an airflow requirement for crib bumpers, particularly in light of ongoing work by the subcommittee to develop a firmness requirement. Nevertheless, CPSC staff continued to work on the Commission's requested airflow requirement.

Staff has developed a test method for assessing the airflow of crib bumpers that is based on an existing standard intended to address infant suffocations on infant pillows, and modified to use a "breathing" rate that is physiologically representative of a sleeping 3-month-old infant. This test method could be used to distinguish current padded crib bumpers from mesh liners, and could serve as the basis for a performance requirement for all crib bumpers and similar products to have airflow characteristics that match or exceed the airflow characteristics of current mesh liners. However, at this time, staff is unable to conclude that including such a requirement in the proposed rule would reduce the risk of injury associated with crib bumpers. The progression of staff's test method development, and the basis for staff's conclusion, are explained below.

The most relevant existing standard related to product airflow intended to address mechanical suffocations (*i.e.*, smothering) to infants is the British standard BS 1877-8:1974, *Specification for Domestic bedding — Part 8: Pillows and bolsters for domestic use (excluding cellular rubber pillows and bolsters)*, which specifies a maximum pressure differential when the product is tested in accordance with BS 4587:1970, *Specification for Methods of test for hardness of, and for air flow through, infants' pillows*. The test method, illustrated in Figure 3, involves pressing the product onto the open tube of the test apparatus with a force of 10 Newtons (1.0 kgf or 2.2 lbf), passing air through the tube at a flow rate of 200 milliliters per second (ml/sec) (12 L/min), and measuring the increased pressure that is needed to maintain that level of air flow. BS 1877-8:1974 states that the resulting pressure differential must not exceed 20 mm (0.79 inches) H_2O.[22] This

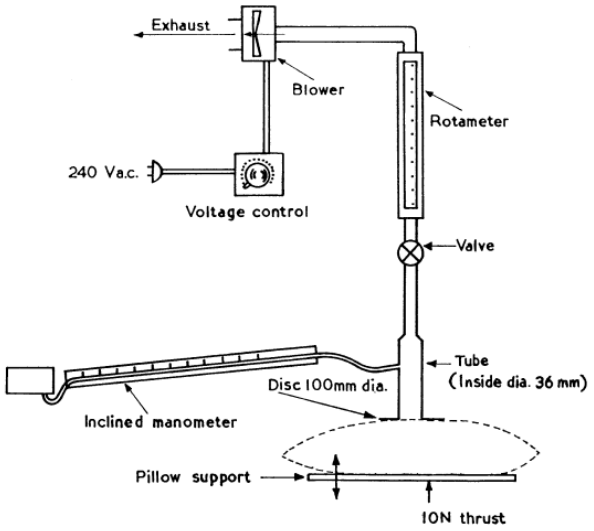

FIGURE 3. Test setup for BS 4587:1970.

[22] The voluntary standard does not provide a rationale for this pressure differential level, and staff has been unable to identify the basis for this level.

standard and associated test method served as the basis for CPSC staff's airflow testing of crib bumpers.

1. Testing on Slatted Crib Side: Unable to Distinguish Bumpers and Mesh

As ESMC staff discusses in Tab G, staff tested sample crib bumpers and mesh liners using the British test method, with some modifications. One inconsequential modification was that rather than pressing the product sample into the test apparatus with the specified force, the test apparatus was pressed into the sample with this force. A more significant change from the British test method was to the support platform on which the sample was tested. The British standard specifies that the test platform on which the product is placed must be a "rigid unperforated support." However, during staff's testing of the bumper and liner samples, staff used a slatted crib side as the test platform, because this represents a typical surface onto which a crib bumper would be installed in a real-life use scenario. Testing products on this test platform did not enable staff to distinguish between padded crib bumpers and mesh liners, in part because the crib slats in the test platform appeared to block airflow for some products, particularly thin or mesh-liner products. For example, staff found that the highest pressure differential readings were taken directly over a crib slat, and that for the crib bumpers and bumper-like products that were tested, a mesh liner was among those with the highest pressure readings when tested in this location. Thus, airflow testing to BS 1877-8:1974 using a platform that represents a real-life use scenario was unable to distinguish between crib bumpers and mesh liners. Staff's testing also suggests that if staff *had* tested products on a "rigid unperforated support," as specified in BS 4587:1970—a scenario analogous to the products being installed over a solid crib side panel—that mesh liners would likely perform worse than padded crib bumpers.

2. Testing Product Alone: All Sample Bumpers Pass BS 1877-8:1974 Level

Staff performed additional testing on sample crib bumpers and mesh liners, but with a metal grille (*i.e.*, a rigid perforated support) replacing the slatted crib side as a test platform, to minimize airflow restrictions introduced by the platform. Although this does not reflect the real-life installation and use of these products, this change enabled staff to assess the airflow characteristics of the product itself. For this testing, staff obtained additional mesh liner samples, in an attempt to capture the broader range of mesh liner products available on the market. The results of this additional testing revealed the following, when tested at the 12 L/min airflow rate specified in standard:

- Staff was able to identify a pressure differential level that appears to distinguish mesh liners from padded crib bumpers (0.13 mm H_2O, or 0.005 inches H_2O).

- This pressure differential level is orders of magnitude lower than the level permitted by BS 1877-8:1974 (20 mm H_2O, or 0.79 inches H_2O).

- All products tested, both mesh liners and padded crib bumpers, had pressure differential levels below that specified in BS 1877-8:1974.[23]

Staff could include a requirement in the draft proposed rule for all crib bumpers and liners to meet the airflow requirements of BS 1877-8:1974, using staff's modified test method. However, under section 104 rulemaking, the Commission may adopt requirements that are more stringent than the voluntary standard requirements only if these more stringent requirements would further reduce the risk of injury associated with crib bumpers.[24] Given that staff's testing found that all sample products tested would already meet the maximum pressure differential specified BS 1877-8:1974, often by a substantial amount, staff is uncertain whether such a requirement would reduce the risk of injury associated with these products.

Alternatively, and in keeping with the Commission's direction to staff to "develop a performance requirement and test method . . . to demonstrate that a crib bumper matches or exceeds the airflow characteristics of mesh or mesh-like materials,"[1] staff could add a requirement for all crib bumpers to not exceed the 0.13 mm (0.005 inches) H_2O pressure differential level identified by staff that distinguished padded crib bumper samples from mesh liner samples when tested to BS 1877-8:1974, as modified. As HS staff discusses in Tab D, it is logical to conclude that materials that are difficult to breathe through will pose an increased risk of suffocation if they are pressed against airway openings, and it is possible that an airflow test with appropriate limits could improve bumper safety. However, the suffocation potential of these materials depends on whether the pressure differential is likely to be physiologically relevant, *i.e.*, significantly impair an infant's breathing. At this time, HS staff is unable to recommend a reliable infant-based pressure limit for infants, particularly at the standard's specified flow rate of 12 L/min (see staff's discussion related to flow rate, below). Thus, staff has little basis for concluding that a pressure differential level that would distinguish padded crib bumpers from mesh liners, 0.13 mm (0.005 inches) H_2O, reduces the risk of injury relative to the level already specified in the British standard. This is especially the case because staff deliberately identified the 0.13 mm (0.005 inches) H_2O level to meet the goal of distinguishing between padded crib bumpers and mesh liners, not because that level is inherently "safe." As noted in Tab D and discussed later in this memorandum, the differences that are physiologically meaningful are likely to be orders of magnitude higher than the differences identified in this testing. In addition, the level identified by staff to distinguish padded crib bumpers and mesh liners could be established only by using a test platform that did not interfere with airflow, so the real-life relevance of this threshold is questionable. As staff noted earlier, when the product is installed on a typical slatted crib side, as would be the case during actual use, airflow through portions of a mesh liner could be more restricted compared to a padded crib bumper.

[23] The maximum pressure differential reading for all sample crib bumpers and mesh liners tested using the modified test method was 14.9 mm (0.585 inches) H_2O, compared to the level of 20 mm (0.787 inches) H_2O specified in BS 1877-8:1974.

[24] The Commission acknowledged this in its direction to staff in the FY17 Operating Plan, which stated that the crib bumpers rulemaking project shall produce an NPR package that proposes a mandatory product safety standard under section 104 of the CPSIA that is more stringent than the current ASTM voluntary standard "and will further reduce the risk of injury associated with this product" (p. 18).

3. Testing at Infant-Appropriate Airflow: Pressure Measurements Very Low

In addition to the issues discussed above, staff notes that the airflow test method specified in BS 4587 uses an airflow rate of 12 L/min. As HS staff discusses in Tab D, this rate is considerably higher than the rate that would be representative of a sleeping 3-month-old infant,[25] which staff estimates to be closer to 2 L/min. Given that a 12 L/min flow rate does not reasonably reflect the breathing of at-risk infants, and that the Commission directed staff to develop an airflow requirement "based on known infant inhalation and exhalation requirements,"[1] basing such a requirement on an airflow rate of 12 L/min seems inappropriate.[26]

Staff performed the same airflow testing discussed previously, on the modified test platform, using the lower, 2 L/min airflow rate recommended by HS staff as representative of a sleeping 3-month-old infant. Once again, staff was able to identify pressure differential that distinguished padded crib bumpers from mesh liners (0.076 mm H_2O, or 0.003 inches H_2O). However, when tested at this more infant-representative airflow rate, the pressure differential readings for all sample products were very low, with a maximum reading of only 1.04 mm (0.041 inches) H_2O. As explained below, these results present difficulties for establishing an airflow standard.

BS 1877-8:1974 does not specify a maximum pressure differential at this reduced airflow rate, and HS staff has been unable to identify a definitive, appropriate pressure differential limit, aside from concluding that an appropriate level is likely between 10 and 100 mm H_2O. The lower pressure differential level of 10 mm H_2O would allow for easier breathing through the product, but this level is still an order of magnitude greater than the maximum pressure reading staff obtained from padded crib bumpers using the more infant-representative airflow rate of 2 L/min (1.04 mm H_2O, or 0.041 inches H_2O), meaning that all tested crib bumpers and mesh liners would easily pass such a limit.

Staff could include in the draft proposed rule an airflow requirement that would require all crib bumpers to measure a pressure differential of no more than 0.076 mm (0.003 inches) H_2O, when tested to BS 1877-8:1974, as modified, and using an airflow rate of 2 L/min, so that all crib bumpers would have airflow characteristics similar to those of current mesh liners when tested in this manner. However, because all crib bumpers would likely pass even HS staff's lower pressure differential limit of 10 mm H_2O, staff is unable to conclude that padded crib bumpers with pressure differential values even as high as 1.04 mm (0.041 inches) H_2O—the maximum value recorded during staff's testing—would pose an increased a risk of suffocation, despite being higher than the values recorded for mesh liners. In other words, such a requirement would not necessarily make a meaningful distinction between crib bumpers that are more likely to pose a risk of suffocation and those that are less likely.

[25] This age was selected because the 2 to 4 month age range is common to the majority of reported fatalities associated with crib bumpers, the peak age range for SIDS deaths, and the developmental timeframe when homeostatic systems are actively adapting and maturing.

[26] LSM staff also performed airflow testing on crib bumper and liner samples to ASTM D737 – 18, *Standard Test Method for Air Permeability of Textile Fabrics*. Similar to the results of testing via BS 4587, staff was able to distinguish between mesh liners and padded crib bumpers. However, the D737 test is not intended to address infant suffocations, and testing is performed at a high pressure level that does not relate to infant breathing.

4. Lack of Mesh Liner Fatalities and Risk of Injury

Despite the above findings, one might argue that the lack of reported fatalities involving mesh liners could be sufficient to conclude that requiring all crib bumpers to exhibit airflow matching that of mesh liners would reduce the risk of injury associated with crib bumpers. However, many fatalities associated with crib bumpers do not involve scenarios in which the infant's face was pressed into the bumper (see Smith, 2016). Therefore, changing the airflow properties of the bumper in these cases would likely have no practical effect on the risk of suffocation. In addition, there are other reasonable explanations for the lack of liner-related fatalities.[27]

For example, mesh liners have been on the market far less time than padded crib bumpers, having been introduced in 2002.[28] Although staff does not have data on the number of mesh liners on the market relative to padded crib bumpers, fewer manufacturers produce mesh liners, so it stands to reason that fewer mesh liners are in consumers' hands and that infant exposure to mesh liners is considerably less than to padded bumpers. Mesh liners also tend to be considerably thinner than traditional padded crib bumpers—particularly those bumpers sold prior to 2012, when the maximum thickness requirement was added to ASTM F1917—and would pass the firmness requirement recommended by staff for the proposed rule for all crib bumpers. This characteristic, not air permeability, could account for the lack of reported fatalities with mesh liners, in the same way that a crib bumper that is firm enough not to conform to the face presumably would not pose a suffocation risk.[29] Thus, particularly in light of staff's proposal to include a firmness requirement in the proposed rule that would apply to all crib bumpers, and presumably would reduce the risk of suffocation posed by crib bumpers, staff is unable to conclude that requiring all crib bumpers and liners to have airflow that matches that of current mesh liners would necessarily further reduce the risk of injury associated with these products.

On the basis of the discussion above, CPSC staff is not recommending an airflow requirement and associated test method for crib bumpers at this time.

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[27] Although staff is not aware of any reported fatalities on mesh crib liners, staff recently became aware of a reported fatality involving a 2-month-old who was found with her face pressed into the mesh side of a bassinet (Doc. No. X1970195A). This case suggests that mesh or mesh-like products still can pose a risk of death. This incident did include a confounding factor of a blanket covering the infant's head, but bumper-related fatalities often include similar confounding factors.

[28] In its response to staff's 2016 Request for Information, the primary manufacturer of mesh liners, noted that it introduced mesh crib liners to the market in 2002 (See Docket ID CPSC-2012-0034-0018 at regulations.gov). In the current briefing package, CPSC staff is reporting fatalities as early as 1990, and staff is aware of earlier reported fatalities.

[29] A policy paper on the hazards of padded crib bumpers, released by Commissioner Kaye on May 17, 2017, drew a similar conclusion. Specifically, the policy paper states: "Many cribs are made with solid panels and these solid panels are not associated with suffocation hazards. It stands to reason that the facial conformity characteristics of a hazardous bumper fall somewhere between a solid board and a pillow. A bumper that does not allow for airflow needs to be firm enough or shaped in such a manner so that it cannot conform to the face of an infant or hold pockets of carbon dioxide" (p. 17).

iii. Warnings and Instructions

Staff addresses the Commission's request related to warnings and instructions by recommending revisions to ASTM F1917 – 12 for the proposed rule, discussed earlier. Specifically, CPSC staff has recommended revisions to the voluntary standard that includes:

- new warning statements about only using crib bumpers in unbroken, full-size cribs, and not using bumpers in toddler beds or bassinets;
- more explicit descriptions of how the bumper should fit when properly installed; and
- more details about when and why consumers should remove crib bumpers from a crib.

In addition, as discussed earlier, CPSC staff has recommended that crib bumpers have permanent markings that indicate the portions of the bumper intended for the long and short sides of the crib, to reduce the likelihood of incorrect installation and consequent bumper sagging.

C. 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:

> (f) DEFINITION OF DURABLE INFANT OR TODDLER PRODUCT.—As used in this section, the term "durable infant or toddler product"—
> (1) means a durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years; and
> (2) includes—
> (A) full-size cribs and nonfull-size cribs;
> (B) toddler beds;
> (C) high chairs, booster chairs, and hook-on chairs;
> (D) bath seats;
> (E) gates and other enclosures for confining a child;
> (F) play yards;
> (G) stationary activity centers;
> (H) infant carriers;
> (I) strollers;
> (J) walkers;
> (K) swings; and
> (L) bassinets and cradles.

In 2009, the Commission issued a rule, commonly known as the product registration card rule, implementing product registration as section 104 required (16 CFR part 1130). As part of that rule, the Commission added six products—children's folding chairs, changing tables, infant

bouncers, infant bath tubs, bed rails, and infant slings—to the list of durable infant or toddler products that the CPSIA specifically identified.

Crib bumpers are not included in either list. However, the preamble to the product registration card rule stated that the specified statutory categories of durable infant or toddler products were not exhaustive, and that the Commission should explicitly identify the product categories that are covered. Specifically, the preamble stated: "Because the statute has a broad definition of a durable infant or toddler product but also includes 12 specific product categories, additional items can and should be included in the definition, but should also be specifically listed in the rule. . . . The Commission could add other products in the future through notice and comment rulemaking." 74 FR 68668 (Dec. 29, 2009).

On October 19, 2016, the Commission voted to amend the CPSC's FY 2017 Operating Plan to initiate rulemaking under section 104 of the CPSIA to promulgate a mandatory consumer product safety standard that will address the risk of injury associated with the use of padded crib bumpers.[30] As part of this action, the Commission directed CPSC staff to develop a proposed rule to include crib bumpers as "durable infant or toddler products" requiring consumer registration under section 104(b) of the CPSIA. Staff's draft proposed rule would add "crib bumpers/liners" to the list of durable infant or toddler products requiring registration under section 104(b) of the CPSIA.

D. Potential Small Business Impact

As EC staff discusses in Tab A, aside from small handcrafters selling products on electronic commerce websites, staff has identified 46 crib bumper manufacturers, distributors, and importers, of which 33 meet the U.S. Small Business Administration (SBA) criteria for small businesses. A majority of the 46 firms have under 25 employees, with 8 firms meeting the criteria of a large firm. Most firms are domestic manufacturers (28), with domestic importers (7) and domestic distributors (6) accounting for a small minority. The lowest annual revenue among the 46 manufacturers, distributors, and importers firms was $135,000.

There are also a large number of producers supplying crib bumpers to the U.S. market via electronic commerce websites such as Etsy. CPSC staff has identified 174 firms that supply crib bumpers to the U.S. market via such electronic commerce websites as Etsy; 86 of these 174 firms are importers. Staff considered these firms to be small manufacturers/importers, because many are one-person firms providing handcrafted nursery products with large varieties in materials and designs. These firms would be considered small by SBA size standards. The revenues for 81 of the small importers most likely are below $25,000, based estimates from the Nonemployer Statistics from the U.S. Bureau of the Census. Of the five remaining small importers, one has annual revenue between $25,000 and $250,000 and four have revenues between $250,000 and $500,000.

EC staff believes that most crib bumpers currently on the market would comply with the requirements of the draft proposed rule, or could be made to comply with the draft proposed rule,

[30] The final, approved FY17 Operating Plan can be found here: https://www.cpsc.gov/s3fs-public/CPSCFY2017OpPlan.pdf. The Commission reaffirmed this decision in the FY 2018 Operating Plan, which can be found here: https://www.cpsc.gov/s3fs-public/FY_2018_Operating_Plan_August302017.pdf.

with minimal cost and effort by making modifications, such as modifying the language in the instructional material that already comes with the products, removing loose fill material, or using additional stitching. However, braided bumpers would likely fail the test requirements in the draft proposed rule and would be removed from the market. This could significantly impact the firms that supply braided crib bumpers. The cost of the third party testing that manufacturers and importers would require in order to certify compliance with the rule could be significant for a substantial number of small firms as the third party testing costs could easily exceed 1 percent of annual revenues for many of the small suppliers. For small handcrafter firms that offer crib bumpers through channels such as Etsy.com the third party testing costs will likely exceed 5 percent of their total annual revenue.

Staff is not recommending an airflow requirement and associated test method for crib bumpers at this time. However, as discussed by EC staff in Tab H, if the Commission were to direct staff to adopt an airflow requirement that differentiates padded crib bumpers from mesh liners, such a requirement could effectively remove all padded crib bumpers from the market. Manufacturers of padded crib bumpers might be able to meet such a requirement by removing the bumper padding or otherwise changing the design of their products. However, because a majority of crib bumper firms supply padded crib bumpers, the addition of such an airflow requirement could have an impact on a substantial number of small firms if they are unable to modify their products. The size of the impact would depend upon factors such as the cost to modify the products, and the importance of padded crib bumpers to the firm in terms of revenue or consumer preference for a padded crib bumper over a thin mesh liner. Nearly all firms supplying the U.S. market with crib bumpers also supply other infant products including but not limited to crib mattresses, crib sheets, and blankets. Staff also concludes that an airflow testing requirement would increase third party testing costs. Staff estimates these additional testing costs to be between $150 and $350 per sample tested, which equates to an expected annual cost between $300 and $750 per firm, based on an average of two crib bumper models per firm. This cost could be considered a significant impact on the very small firms identified previously, some of which have annual revenues of less than $25,000.

E. Compliance Recall Information

As staff of CPSC's Office of Compliance (EXC) discusses in Tab I, staff reviewed recalls involving crib bumpers that occurred from July 9, 1990, through April 17, 2019. Staff identified five consumer-level recalls during that period to mitigate against risks of entanglement, entrapment, suffocation, and choking from loose threads (*e.g.*, unraveling ties, breaking threads and seams) and from bumper ties that either detached from the product or were too long.

V. 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. A proposed rule for crib bumpers, if issued as a final rule, would be a children's product safety rule that requires issuing an NOR.

The Commission published a final rule, *Requirements Pertaining to Third Party Conformity Assessment Bodies*, 16 CFR part 1112 (78 Fed. Reg. 15836 (March 12, 2013), referred to here as part 1112). This rule took effect on June 10, 2013. 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 crib bumpers, would require an amendment to Part 1112 to create an NOR. Therefore, staff recommends that the Commission propose to amend Part 1112 to include crib bumpers in the list of children's product safety rules for which the CPSC has issued NORs.

As EC staff discusses in Tab A, staff concludes that including the NOR for third party conformity testing of crib bumpers would not have a significant impact on small laboratories. Moreover, CPSC expects that only a small number of laboratories would request accreditation to test crib bumpers, based on the number of laboratories that have applied for CPSC accreditation to test other juvenile products. Most laboratories would already have accreditation to test for conformance to other juvenile product standards; accordingly, the only cost would be to add the crib bumper standard to their accreditation. Test laboratories have indicated that this cost is extremely low when they are already accredited for other CPSIA section 104 rules. Therefore, the Commission could certify that the NOR for the crib bumper standard will not have a significant impact on a substantial number of small entities.

VI. 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 6-month effective date. Barring evidence to the contrary, staff generally considers 6 months to be sufficient time for suppliers to come into compliance with a new 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. Staff invites comments, particularly from small businesses, regarding the amount of time they will need to come into compliance.

VII. STAFF RECOMMENDATIONS

Staff recommends that the Commission issue a proposed rule for crib bumpers that incorporates by reference ASTM F1917 – 12, *Standard Consumer Safety Performance Specification for Infant Bedding and Related Accessories*, with substantial modifications that would reduce the risk of injury or death from crib bumpers. Staff's recommended modifications are discussed in Section IV.A and can be summarized as follows:

- Add a "crib bumper/liner" definition.
- Revise the crib bumper thickness requirement to apply to all crib bumpers and liners, and revise the test method to improve consistency among test labs.

- Add a crib bumper firmness requirement and a test method.
- Replace the existing requirement for crib bumpers to be capable of being secured at certain locations with a new crib bumper attachment requirement and test method.
- Revise the strength requirement for crib bumper ties to apply to all attachment means, and add new strength requirements and test methods for decorative components and seams.
- Revise the crib bumper warning content, format, and placement requirements; add warning permanence requirements and test methods; and add a requirement for additional crib bumper markings that indicate the portions of the bumper intended for the long and short sides of the crib.
- Add crib bumper instructional literature requirements.

Staff also recommends an effective date of 6 months after publication of the final rule to allow time for crib bumper manufacturers to bring their products into compliance and to arrange for third party testing. The draft proposed rule provided with this briefing package includes these recommended provisions.

VIII. REFERENCES

Massale, J. (2016). Existing Voluntary Standards and Testing Methods Associated with Crib Bumpers. In T. P. Smith, *Briefing Package: CPSC Staff Response to the Record of Commission Action on Crib Bumpers* (Tab G). U.S. Consumer Product Safety Commission, Bethesda, MD. Available: https://www.cpsc.gov/s3fs-public/StaffResponsetotheRecordofCommissionActiononCribBumper.pdf.

Smith, T. P. (2016). *Briefing Package: CPSC Staff Response to the Record of Commission Action on Crib Bumpers*. Available: https://www.cpsc.gov/s3fs-public/StaffResponsetotheRecordofCommissionActiononCribBumper.pdf.

TAB A: EC Staff Memorandum, "Initial Regulatory Flexibility Analysis for Crib Bumper NPR"

TAB A

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

Date: August 22, 2019

TO**:** Timothy P. Smith
Project Manager, Crib Bumper Project
Directorate for Engineering Sciences

THROUGH**:** Gregory B. Rodgers
Associate Executive Director
Directorate for Economic Analysis

Robert Franklin
Senior Staff Coordinator
Directorate for Economic Analysis

FROM**:** Mark Bailey
Directorate for Economic Analysis

SUBJECT**:** Initial Regulatory Flexibility Analysis for Crib Bumper NPR

In October 2016, the U.S. Consumer Product Safety Commission (CPSC) voted to amend the fiscal year 2017 Operating Plan of the CPSC to initiate rulemaking under section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA) to promulgate a mandatory consumer product safety standard that will address the risk of injury associated with the use of padded crib bumpers. The Commission directed the staff to propose a standard that is more stringent than the current voluntary standard, ASTM F1917 – 12 for Infant Bedding and Related Accessories, and that would further reduce the risk of injury or death associated with crib bumpers. CPSC staff recommends that the Commission issue a proposed rule under the requirements of section 104 of the CPSIA that incorporates by reference the sections concerning crib bumpers of ASTM F1917 – 12 standard with some modifications.

This memorandum describes the possible economic impact of the draft proposed rule on small entities, including small businesses, as required by the Regulatory Flexibility Act (RFA). Under section 603 of the RFA, if a notice of proposed rulemaking is required, agencies must prepare an initial regulatory flexibility analysis (IRFA) and make it available to the public for comment when the general notice of proposed rulemaking is published, unless the head of the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The IRFA must describe the impact of the proposed rule on small entities and identify significant alternatives that could accomplish the statutory objective while minimizing any significant economic impact. Specifically, 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 subject to the requirements and the type of professional skills necessary for the preparation of reports or records; and
5. an identification, to the extent possible, of all relevant federal rules which may duplicate, overlap, or conflict with the proposed rule.

Objectives and Legal Basis of the Proposed Rule

The objective of the draft proposed rule is to reduce the risk of injury and death associated with crib bumpers. CPSC staff identified 113 fatalities from 1990 to March 2019 and 113 nonfatal incidents from 2008 to 2019 associated with crib bumpers.[31]

The legal basis of the draft proposed rule is Section 104 of the CPSIA, which requires the CPSC to examine and assess the effectiveness of any voluntary consumer product safety standards for durable infant or toddler products, and promulgate 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 requirements would further reduce the risk of injury associated with the products.

The Product

CPSC staff has defined crib bumpers as any product intended to be attached to the side of a crib to reduce or eliminate an infants' access to the crib panels or to the openings in crib panels.[32] Crib bumpers are marketed as preventing injury to infants from impacts against the crib slats and preventing limb entrapments between the slats. Crib bumpers are sold as either a single continuous piece or as multiple independent panels (typically four) and have a small variety of designs. The most common type of crib bumper is a cotton or polyester cover with a filling material to provide a soft cushion, rectangular in shape and secured to the crib with some type of fastener. Other, less common designs include braided bumpers which are two or more sleeves filled with cotton (or other material) braided together to form a soft bumper and mesh liners which are simply a thin layer or two of mesh material (typically polyester) secured to the crib to prevent access to the crib slats. Another type of design, generally referred to as "vertical" bumpers, consist of a series of narrow bumpers that individually attach to each crib slat. Crib bumpers are also used to decorate the sleep environment of children and purport to make the sleep environment more comfortable.

[31] Suchy, Adam. CPSC Memorandum to Timothy P. Smith, "Overview of Crib Bumper Fatalities Reported from January 1, 1990, to March 31, 2019, and Non-Fatal Incidents Reported from January 1, 2008, to March 31, 2019" U.S. Consumer Product Safety Commission, Bethesda, MD (August 21, 2019).
[32] ASTM F1917 – 12 does not define crib bumpers.

Crib bumpers range in price from $12 to $500 with the more expensive bumpers typically decorated with detailed painted or woven art. Crib bumpers are also sold in bedding sets which can range in price from $80 to $1,200. Manufacturers typically produce only a few models with differences in color, art design, cover material, and filling material being the primary identifying factors. Crib bumpers are recommended by manufacturers only for infants that cannot pull themselves up to the standing position.[33]

Crib Bumpers In Use

Based on information from the 2013 CPSC Durable Nursery Products Exposure Survey of U.S. households with children under 6 years old:

- An estimated 9.2 million cribs were in use in households with young children in 2013. This represented about 73 percent of the estimated 12.6 million total cribs owned by households (*i.e.*, about 3.4 million cribs were owned, but not in use).

- Among the 9.2 million cribs in use, an estimated 5.3 million were equipped with bumpers. This represents about 55 percent of the 9.9 million total bumpers owned by households (*i.e.*, about 4.5 million bumpers were owned, but not in use).

The household use estimates may understate, somewhat, total crib and bumper usage. In addition to the products in use in households with young children, as estimated from the survey, cribs and bumpers are probably in use in some households without young children (*e.g.*, unsurveyed homes of older adults providing care for grandchildren). Additionally, the survey did not cover child care facilities. One childcare industry group's 2018 directory[34] lists more than 115,000 licensed childcare centers and more than 137,000 home daycare providers, some of which may use cribs and bumpers. Furthermore, the survey did not cover hotels or other commercial lodging establishments. The U.S. Bureau of Labor Statistics (BLS) reports that there are about 70,000 lodging establishments in the accommodation industry sector, North American Industry Classification System (NAICS) code 721.[35] Based on staff's contacts with childcare and lodging facilities, bumper usage in such establishments is probably low.[36]

Small Entities to Which the Draft Proposed Rule Would Apply

Manufacturers of crib bumpers are typically categorized under the North American Classification System (NAICS) category 314120 (Curtain and Linen Mills) but may also fall under code 314999 (All Other Miscellaneous Textile Product Mills). Curtain and linen mills are considered small if they have fewer than 750 employees; miscellaneous textile product mills are

[33] Review of manufacturer's websites, product labels and material.
[34] Child Care Centers estimate entire U.S. (2018, April 27). http://childcarecenter.us/.
[35] U.S. Bureau of Labor Statistics, "Quarterly Census of Employment and Wages," April 2018. http://www.bls.gov/iag/tgs/iag721.htm.
[36] Staff contacts included phone and email inquiries with daycare and hotel establishments.

considered small if they have fewer than 500 employees.[37] Importers of crib bumpers are typically categorized under NAICS code 423220 (Home Furnishing Merchant Wholesalers) and would be considered small if they have fewer than 100 employees.

Aside from small handcrafters selling products on electronic commerce websites, staff identified 46 manufacturers, distributors and importers. A total of 33 of these 46 firms meet the SBA criteria for small businesses.[38,39,40] A majority of the 46 firms have under 25 employees with 8 firms meeting the criteria of a large firm. Most of the firms are domestic manufacturers (28), with domestic importers (7) and domestic distributors (6) accounting for a small minority. The lowest annual revenue among the 46 manufacturers, distributors, and importers was $135,000.

There are a large number of producers supplying crib bumpers to the U.S. market via electronic commerce websites such as Etsy. CPSC staff has identified 174 of these firms of which 86 are importers.[41,42] CPSC staff considered these firms as small manufacturers/importers as many are one-person firms providing handcrafted nursery products with large varieties in materials and designs. These firms would be considered small by SBA size standards. The revenues for 81 of the small importers is most likely below $25,000 based estimates from the Nonemployer Statistics from the U.S. Bureau of the Census. Of the five remaining small importers, one has annual revenue between $25,000 and $250,000 and the revenue of the other four is between $250,000 and $500,000.

Requirements of the Draft Proposed Rule

The draft proposed rule would incorporate by reference those sections of ASTM F1917 – 12 that pertain to crib bumpers with modifications that CPSC staff believes may further reduce the risk of injury. The draft proposed rule would also make some changes to the definitions and terminology used in the standard to better clarify the requirements. If promulgated by the Commission, the draft proposed rule would, among other things:

- Establish a test crib bumper firmness test that is partly adopted from the Australian/New Zealand Standard (AS/NZS 8811.1) for testing infant products. The test involves using a test fixture to measure firmness of the crib bumper at multiple points along its length.
- Establish maximum lengths for the attachments means and decorative components on bumper pads
- Establish that the requirements for the length of attachment means and decorative components shall apply both before and after testing
- Prohibit the use monofilament thread
- Establish a minimum thickness for accessible, unsupported vinyl material
- Establish a test for limiting the maximum thickness of all crib bumpers.

[37] The size guidelines are established by the U.S. Small Business Administration (SBA).
[38] Based on size and revenue data from Reference USA and firm financial reports, websites, and press releases.
[39] Staff could not determine the status of five firms but they are most likely small.
[40] Eleven of the forty-six firms identified supply mesh liner or similar mesh type products.
[41] Review of electronic commerce websites that specialize in handmade products.
[42] Approximately 90 percent of these small handcrafters provide traditional crib bumpers with mesh liner handcrafters accounting for only 4.6 percent.

- Establish minimum strength requirements for attachment means and decorative components
- Establish a strength requirement for bumper seams
- Require crib bumpers to have labels identifying the manufacturer, distributor, or seller.
- Establish requirements for appropriate warning labels on crib bumpers.
- Establish requirements for the permanence of the warning labels.
- Require instructional literature to be provided with crib bumpers detailing the proper installation methods and the hazards associated with the crib bumpers.
- Establish a test to ensure bumper remains securely attached to crib side. The test involves inserting a probe between the crib bumper and the crib slat.

In addition to the requirements outlined above, the draft proposed rule would modify or clarify some of the terms and definitions used in ASTM F1917 – 12. For example, the draft proposed rule would consistently refer to "crib bumpers/liners" and not "bumper pads," "bumper guards," and similar terms that are sometimes used in ASTM F1917 – 12. The draft proposed rule would also clarify the definitions of terms such as "crib bumper/liner," and "conspicuous."

Staff also considered an airflow performance requirement similar to those in BS 4578:1970 *Specification for Methods of test for hardness of, and for air flow through, infants' pillows* and ASTM D737 – 18 *Standard Test Method for Air Permeability of Textile Fabrics*. However, as explained by staff of CPSC's Directorate for Engineering Sciences, Division of Mechanical and Combustion Engineering (ESMC), in Tab G, although staff has developed a test that could be used to distinguish mesh liners from most padded crib bumpers, it has not been able to link the test method to infant breathing abilities.[43,44] Therefore, an air flow test is not included in the draft proposed rule. An analysis of the impact of an airflow requirement on small businesses is provided in Tab H.

Impact of Draft Proposed Rule on Small Manufacturers

Manufacturers and importers of crib bumpers would be responsible for ensuring that their products comply with the requirements of the draft proposed rule. If their crib bumpers do not comply with the requirements, the manufacturers or importers will need to either modify the products or cease their manufacture or importation. Additionally, as required by section 14 of the CPSIA and its implementing regulations, manufacturers and importers of crib bumpers would be required to certify that their crib bumpers comply with the requirements of the draft proposed rule based on the results of third party testing by an accredited conformity assessment body.

In 2018, CPSC collected a sample of crib bumpers to test them for compliance with the draft proposed rule. Although not a probability sample, CPSC staff tried to collect a wide variety of crib bumpers that included most types of crib bumpers that are available in the market place,

[43] Inkster, Sandra E. CPSC Memorandum to Timothy P. Smith, "Crib bumper firmness and airflow, considering infant vulnerability to respiratory compromise," U.S. Consumer Product Safety Commission, Rockville, Maryland (August 22, 2019).
[44] Nesteruk, Hope, Adams, Brynn. CPSC Memorandum to Timothy P. Smith, "Testing Methods to Measure Airflow through Crib Bumpers and Other Types of Infant Bedding," U.S. Consumer Product Safety Commission, Rockville, Maryland (August 14, 2019).

including crib bumpers from the very small manufacturers or hand crafters. Although most of these crib bumpers would comply with many of the provisions of the draft proposed rule, the testing found that most models (7 out of 11 models tested) would not pass the firmness test that would be established by the draft proposed rule.[45] Additionally, the content, placement, and formatting of the warning labels for many models would need to be modified to comply with the requirements of the draft proposed rule.[46]

Costs Associated with Modifying Products to Comply with the Draft Proposed Rule

Modifying most types of crib bumper designs to conform to the firmness requirement could be as simple as removing some of the filling material used in the bumper pad or the use of additional stitching to compact the loose fill material. The cost of making modifications such as these should not be significant. However, the braided type of crib bumper would likely fail the firmness requirement because the results depended upon where on the product it was tested.[47] It is unclear if braided bumpers could be modified to meet this requirement. Moreover, the braided crib bumpers examined by CPSC staff did not have any means by which they could be attached to the crib, which is also a requirement of the draft proposed rule. [48] This implies that the draft proposed rule may result in the removal of braided crib bumpers from commerce. CPSC staff notes that all firms identified as suppling braided bumpers are importers and not domestic manufacturers and represent approximately 6 percent of the identified importers.[49]

Generally, the costs associated with providing instructional materials are low on a per unit basis. Many firms already provide instructions with their product but may have to change the content or formatting of the instructions to comply. Likewise, the cost of warning labels are generally low, especially if some warning labels are already present and the product itself does not have to be modified to accommodate new labels.

Third Party Testing Costs

Promulgating the draft proposed rule would require all manufacturers and importers of crib bumpers to meet third party testing requirements under section 14 of the Consumer Product Safety Act (CPSA) and section 1107 of 16 CFR.[50] Staff estimates that testing costs associated with testing to ASTM F1917 – 12 to be between $600 and $900 per sample tested.[51] As the

[45] Eilbert, Mark. CPSC Memorandum to Timothy P. Smith, "Existing Voluntary Standards Associated with Crib Bumpers, Sleep Surfaces, and Fabrics," U.S. Consumer Product Safety Commission, Rockville, Maryland (August 23, 2019).
[46] Smith, Timothy P. CPSC Memorandum to The Crib Bumpers Rulemaking Project File, "Human Factors Assessment of ASTM F1917 Requirements for Crib Bumpers (CPSIA Section 104)," U.S. Consumer Product Safety Commission, Rockville, MD (August 21, 2019).
[47] CPSC staff discussions on testing a braided crib bumper for firmness.
[48] Some braided crib bumper manufacturers have begun modifying their product to include a means to attach the product to the side of a crib as of May 2019.
[49] Currently total annual revenue and unit sales of braided bumpers is unknown but total annual revenue is expected to be under $150,000 as braided bumper importers appear to be firms with one to two employees.
[50] Third party testing will include any physical and mechanical test requirements specified in the final crib bumper rule.
[51] Based on quotes from testing laboratories that currently test children's products to ASTM standards.

average number of crib bumper models per firm is two, this equates to a cost of at least $1,200 to $1,800 per firm, if no more than one sample per model is required to provide the required "high degree of assurance" that the model complies with the requirements. Under the requirements of 16 CFR 1107, manufacturers and importers will need to recertify their crib bumpers at least annually, unless the firm has also established a formal reasonable testing program, in which case they will have to recertify their crib bumpers at least every two years. Currently 21 of 207 small crib bumper manufacturers and importers are members of the Juvenile Products Manufacturers Association (JPMA), but it is unclear if any crib bumper products are certified to ASTM F1917 – 12.[52] However, some of these firms produce other products that are already subject to other children's product safety rules and, therefore, familiar with these requirements. Many of the small firms that are not members of JPMA or that do not produce other products subject to children's product safety rules may be unfamiliar with the third party testing requirements.

As noted, for a typical manufacturer or importer with two crib bumper models, the cost of third party testing will be at least $1,200 to $1,800 to test and certify both models, and this cost will be incurred at least once every other year. Generally, we consider impacts that exceed 1 percent of revenue to be potentially significant.[53]As discussed, there are a substantial number of very small firms that either hand craft or import crib bumpers that are often sold through websites, such as Etsy.com, and more than three quarters of these very small firms are estimated to have annual revenues of less than $25,000. Even if these firms needed to test only one sample of each crib bumper to obtain the "high degree assurance" that the product would meet all the requirements of the rule, the cost of the third party testing would be at least 5 percent of one year's revenue and possibly more if their revenue was much less than $25,000. This impact would be significant. Many of these firms could be expected to stop supplying crib bumpers to the U.S. market because they are not able to increase their prices to cover the testing costs.

The cost of the third party testing associated with promulgating the draft proposed rule could also be significant for small firms that are not among the very small firms discussed above. CPSC staff identified 13 small manufacturers and 1 importer of crib bumpers that have annual revenues between $25,000 and $250,000. If the third party testing costs are between $1,200 and 1,800, the cost could exceed one percent of the annual revenue of several of these firms as well and could be considered significant.

Summary of Impact on Small Manufacturers and Importers

CPSC staff believes that most crib bumpers currently on the market would comply with the requirements of the draft proposed rule or could be made to comply with the draft proposed rule with minimal cost and effort by making modifications, such as modifying the language in the instructional material that already comes with the products, removing loose fill material and or using additional stitching. However, braided bumpers would likely fail the test requirements in the draft proposed rule and would be removed from the market. This could significantly impact the firms that supply braided crib bumpers. As noted above, the cost of the third party testing that manufacturers and importers would require in order to certify compliance with the

[52] These manufacturers/ importers are members of JPMA but crib bumpers are not listed as a category of JPMA certified products.

[53] Small Business Administration. (2017). *A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act*. Washington, DC. SBA

rule could be significant for a substantial number of small firms as the third party testing costs could easily exceed one percent of annual revenues for many of the small suppliers. For small handcrafter firms that offer crib bumpers through channels such as Etsy.com the third party testing costs will likely exceed 5 percent of their total annual revenue.

Other Federal Rule Which May Duplicate, Overlap, or Conflict with the Draft Proposed Rule

CPSC staff has not identified any other federal rules that duplicate, overlap, or conflict with the draft proposed rule.

Alternatives Considered to Reduce the Impact on Small Entities

There are some alternatives to the draft proposed rule that the Commission could consider to reduce the impact on small businesses. CPSC staff requests comments on these alternatives or other alternatives that could reduce the burden on small entities.

Adopt ASTM F1917 – 12 without modification

The Commission could propose to incorporate by reference ASTM F1917 – 12 without any modifications and direct staff to work with ASTM to improve warning labels, test methods, and the firmness of crib bumpers in a future revision of the voluntary standard. This alternative could reduce the impact of the rule on small businesses, but the reduction would not be expected to be very significant. As discussed in the analysis above, modifying crib bumpers to comply with the firmness requirement could be accomplished by reducing the amount of filler material or by incorporating additional stitching to compress the material. These modifications are not expected to be costly. Likewise the costs to modify or add warning labels or instructional material are expected to be low. CPSC staff believes that the most significant impacts of the draft proposed rule would be associated with the third party testing requirements under section 14 of the CPSA and 16 CFR part 1107, which would be required once the draft proposed rule became a mandatory children's product safety rule. These costs, however, would be largely unaffected by this alternative.

Small Batch Exemption

Given the number of small crib bumper manufacturers using websites like Etsy, the Commission might have interest in exempting small batch manufacturers from the testing requirements proposed under the rule.[54] However, under Section 14(d)(4)(C)(ii) of the Consumer Product Safety Act, the Commission cannot "provide any alternative requirements or exemption" from third party testing for "durable infant or toddler products," as defined in section 104(f) of the Consumer Product Safety Improvement Act of 2008. Consequently, staff cannot recommend a small batch exemption absent a statutory change.

[54] According to Section 14(d)(4)(E) of the Consumer Product Safety Act, small batch manufacturers means a manufacturer that has no more than $1,000,000 in total gross revenues from sales of all consumer products in the previous calendar year. (The dollar amount is adjusted annually for inflation.) Hence, the revenues of the small manufacturers using websites like Etsy are substantially smaller than the limits for a small batch manufacturer.

Reduce the Frequency of Periodic Testing for Very Small Crib Bumper Manufacturers

The Commission could amend 16 CFR part 1107 to reduce the frequency of periodic testing for small home-based businesses that produce crib bumpers. Currently, under the requirements of 16 CFR § 1107.21, these firms need to conduct *periodic* third party tests every year, or, if they have a formal production testing plan, every 2 years. The testing costs associated with third party *periodic* testing could be substantially reduced if the Commission amended existing regulations to allow small home-based producers of crib bumpers to conduct periodic testing less frequently. One alternative for manufacturers *with established production testing plans*, would be to require third party periodic testing only after a certain number of units of a product (to be determined at a later time) had been produced, even if it meant that periodic third party tests would be conducted less frequently than every 2 years. The details of this alternative would be determined by the Commission; it might apply to all nursery products, or it might be limited to crib bumpers. However, all home-based firms would still be required to: (1) produce conforming products; (2) conduct the initial certification tests (16 CFR § 1107.20); (3) re-certify whenever there is a material change to the product (16 CFR § 1107.23); and (4) implement a production testing plan and conduct on going production tests (16 CFR § 1107.21(c)).

Delay the Effective Date of the Requirements

Typically, staff recommends an effective date of 6 months for durable nursery product rules. Six months is generally considered sufficient time for suppliers to come into compliance with a proposed durable infant and toddler product rule, unless there are specific reasons for a longer effective date.

One alternative that could reduce the impact on small firms would be to set an effective date later than 12 months. Implementing a later effective date could mitigate the effects of the rule on small businesses by delaying the need to conduct third party certification tests and allowing the businesses to spread the costs of bringing their crib bumpers into conformance over a longer period of time. For businesses that would choose to exit the crib bumper market (rather than produce conforming products), such a delay might also provide them with more time to adjust marketing towards other product offerings, sell inventory or consider alternative business opportunities.

Not Issue a Mandatory Standard

Another option available to the Commission that would reduce the burden on small firms is to not adopt a mandatory standard for crib bumpers. This would eliminate the cost impacts described in the previous sections, including those associated with third party testing, and allow the small handcrafter firms to continue operations.

Impacts of Test Laboratory Accreditation Requirements on Small Laboratories

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 CFR part 1112. Staff recommends that the Commission propose to amend 16 CFR part 1112 to establish an NOR for testing laboratories to test for compliance with the proposed crib bumper standard. This section assesses the impact of a proposed amendment would have on small laboratories.

CPSC conducted a final regulatory flexibility analysis (FRFA) when it adopted part 1112. 78 FR 15836 (Mar. 12, 2013). The FRFA concluded that the accreditation requirements would not have a significant adverse impact on a substantial number of small laboratories because no requirements were imposed on laboratories that did not intend to provide third party testing services. The only laboratories that were expected to provide such services were laboratories that anticipated receiving sufficient revenue from the mandated testing to justify accepting the requirements as a business decision.

For the same reasons, including the NOR for crib bumpers in part 1112 would not have a significant adverse impact on small laboratories. Moreover, CPSC expects that only a small number of laboratories would request accreditation to test crib bumpers, based on the number of laboratories that have applied for CPSC accreditation to test other juvenile products. Most laboratories would already have accreditation to test for conformance to other juvenile product standards; accordingly, the only cost would be to add the crib bumper standard to their accreditation. Test laboratories have indicated that this cost is extremely low when they are already accredited for other CPSIA section 104 rules. Therefore, the Commission could certify that the NOR for the crib bumper standard will not have a significant impact on a substantial number of small entities.

References

ASTM Standard F1917 – 12, "*Standard Consumer Safety Performance Specification for Infant Bedding and Related Accessories*," ASTM International, West Conshohocken, PA, 2012

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TAB B: EPHA Staff Memorandum, "Overview of Crib Bumper and Liner-Related Fatalities from January 1, 1990, to March 31, 2019, and Nonfatal Incidents from January 1, 2008, to March 31, 2019"

TAB B

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

MEMORANDUM

Date: August 21, 2019

To: Timothy P. Smith, Project Manager, Crib Bumpers Project
Division of Human Factors, Directorate for Engineering Sciences

Through: Steve Hanway, Associate Executive Director,
Directorate for Epidemiology

Risana Chowdhury, Division Director
Division of Hazard Analysis

From: Adam Suchy, Mathematical Statistician,
Division of Hazard Analysis

Subject: Overview of Crib Bumper and Liner-Related Fatalities from January 1, 1990, to March 31, 2019, and Nonfatal Incidents from January 1, 2008, to March 31, 2019

I. Introduction

This memorandum characterizes the number of incidents and concerns and the hazard patterns associated with the use of crib bumpers and liners, including breathable bumper pads and mesh crib liners, as reported to CPSC staff. Throughout this memorandum, the reader should assume that the term "crib bumpers" includes crib liners, unless specifically excluded. The fatalities were reported to have occurred between January 1, 1990, and March 31, 2019, and the nonfatal incidents reportedly occurred between January 1, 2008, and March 31, 2019. The incidents are based on reports received by CPSC staff; some of these reports include cases in which a crib bumper was present, but not involved in the incident.

II. Incident Data[55]

Staff of CPSC's Directorate for Epidemiology, Division of Hazard Analysis (EPHA) searched the Consumer Product Safety Risk Management System (CPSRMS) and the National Electronic Injury Surveillance System (NEISS) databases for reports to CPSC involving crib bumpers. The fatalities were reported to have occurred between January 1, 1990, and March 31, 2019, and the nonfatal incidents reportedly occurred between January 1, 2008, and March 31, 2019. Because there is no product code exclusively used for coding crib bumpers, CPSC staff performed multiple searches consisting of a combination of product codes and narrative keyword searches to find all crib bumper incidents. The first data search included reports with the product codes for *portable cribs* (NEISS code 1529), *baby mattresses or pads* (1542), *cribs (excluding portable*

[55] Incidents presented in this memorandum represent a minimum for the number of incidents that have occurred during this timeframe. There may be additional incidents not reported to CPSC in which crib bumpers were present.

cribs) (1543), *cribs (not specified)* (1545), and *playpens and play yards* (1513), and that had the word "bump," "pad," "breathab," "thable," "mesh," or "crib line" in the narrative field. The second data search included any incident that contained both words "bumper" and "pad" in the narrative field, with no restriction on the product code. Upon careful review of the data from these two searches, CPSC staff selected the final in-scope set of data. The incidents were characterized as fatal or nonfatal. Other than pictures from investigations and the occasional information about the manufacturer or model, the incidents did not include sufficient detail for staff to determine the thickness of the bumpers.

In April 2016, EPHA staff prepared a memorandum in support of staff's 2016 briefing package to the Commission. In that memorandum, the time period for both fatal and nonfatal incidents was from January 1, 1990, to March 31, 2016. For this memorandum, nonfatal incidents that occurred *only* since January 1, 2008, have been retained. There are two reasons for changing the time period for the nonfatal incidents. First, about 10 years is generally consistent with the timeframes used for other Section 104 rulemaking activities. Second, the next to last revision to the ASTM voluntary standard, on which the proposed crib bumpers rule is based, was published in 2008 (ASTM F1917 – 08). For fatalities, however, staff has chosen to include fatalities dating back to January 1, 1990. This longer timeframe was retained for the reported fatalities because, in staff's April 2016 briefing package, staff identified nine fatal incidents as being potentially addressable, and all nine occurred before 2008. Using the same timeframe selected for the nonfatal incidents would have excluded all of these incidents.

CPSC staff also received a letter in 2000, from a state's Department of Social Services noting their awareness of four fatalities "within the last year" that were associated with "unsafe crib bedding." Although the term "bedding" generally includes crib bumpers, there is no additional information about the four fatalities mentioned in the letter. It is unclear how many of these four fatalities are already included among the 113 deaths that staff examined, or if any of the four fatalities even involved a crib bumper. Staff was unable to identify any crib bumper-related fatalities that occurred in that state within a year of the date the letter was written. However, staff is aware of a bumper-related fatality in 1998, which is included in staff's fatality count. Thus, the four fatalities have not been added to the 113 fatalities in the tables below.

There were 3 fatalities identified through NEISS between January 1, 1990, and March 31, 2019, and 14 injuries identified through NEISS between January 1, 2008, and March 31, 2019, with a crib bumper present in the sleeping environment. Because the data do not meet the minimum criteria for computing an estimate,[56] EPHA staff was unable to estimate the number of emergency department-treated injuries to children interacting with crib bumpers. However, the 3 NEISS fatalities and 14 NEISS injuries were included with the rest of the incident data described in this memorandum.

During staff's re-review of the nonfatal incidents for this briefing package, the team identified and excluded 32 nonfatal incidents that occurred after January 1, 2008, which had previously been included among the nonfatal incidents reports in the April 2016 memorandum. Staff concluded that these cases were out of scope because the incident or complaint involved a

[56] NEISS data are a weighted sample from which national estimates can be produced, provided the sample count is greater than 20, the estimate is greater than 1,200, and the coefficient of variation (CV) is less than 0.33.

product other than a crib bumper, no bumper was present at the time of the incident, or a bumper was present but was incidental to the incident (*e.g.*, a complaint about the drop-side of a crib detaching and a bumper happened to be mentioned as being present). EPHA staff also identified one fatality that appeared in the April 2016 memorandum that was included twice in fatality counts; this fatality now is counted correctly as a single fatality in this memorandum.

Table 1 shows the breakdown of crib bumper incidents by injury severity of the child involved.

Table 1: Reported Incidents and Injury Severity
January 1, 1990 - March 31, 2019 (Fatalities)[57]
January 1, 2008 - March 31, 2019 (Non-Fatalities)

Incidental Fatalities	Non-Incidental Fatalities	Injury	No Injury	Unknown
30	83	60	50	3

Source: CPSRMS and NEISS databases,
Reporting is ongoing for these databases, especially for 2017-2019.

As shown in Table 1, CPSC staff has identified 113 fatal incidents from January 1, 1990, to March 31, 2019, and 113 nonfatal incidents from January 1, 2008, to March 31, 2019. Of the 113 nonfatal incidents, 60 resulted in an injury, 50 reported no injury, and in three cases, injury was coded as "unknown." The incidents without injury range from a concern about a crib bumper not fitting properly, to an incident that without intervention by a caregiver, might have resulted in a fatality. Incidents in which injury was coded as "unknown" consisted of a child being entrapped between a sleep positioner and a crib bumper, a slat entrapment, and a bumper tie detachment. Of the 113 nonfatal incidents, 13 percent (15 out of 113) reportedly involved a breathable bumper or mesh crib liner.

All of the 113 reported fatalities appear to have involved a traditional, padded crib bumper, and all but eight involved the crib bumper inside a crib. Of these eight fatal incidents, three occurred in a toddler bed,[58] three in a bassinet, one in a playpen, and one on a mattress on the floor.

CPSC staff classified 30 of the 113 crib bumper-related fatalities as incidental, because although a crib bumper was present, there was no evidence of crib bumper contact or involvement in the fatality. For example, in three of the incidental fatalities, the cause of death was known to have been exclusively medical in nature, and therefore, unrelated to the crib bumper. Aside from these three cases, fatalities were not classified as incidental if the victim was known to be in contact with the crib bumper at the time of the incident.

For the rest of this discussion, fatality counts will include only the 83 non-incidental fatalities (113 minus the 30 incidental) that involved bumper contact. Table 2 shows breakdowns by age

[57] These fatal incidents reported to CPSC do not constitute a statistical sample of known probability and do not necessarily include all fatalities from January 1, 1990, to March 31, 2019, where a bumper pad was present in the sleeping environment. However, the reported fatalities do provide at least a minimum number of fatalities that occurred during the time period.
[58] One of these three fatalities originally identified the bumper as having been installed in a "day bed." However, based on the reported dimensions of the bed, CPSC staff concludes that the product is likely to be a toddler bed.

in months for fatalities, injuries, non-injuries, and cases in which the injury severity status is unknown. Intervals of 4 months were used to correspond with developmental milestones.

Table 2: Reported Incidents and Injury Severity by Age
January 1, 1990 - March 31, 2019 (Fatalities)
January 1, 2008 - March 31, 2019 (Non-Fatalities)

Age	Fatalities	Injuries	No Injury	Injury Severity Unknown
0 to 4 months	51	4	8	1
5 to 8 months	20	10	8	0
9 to 11 months	4	12	4	0
12 to 23 months	5	23	5	1
2 years and older	3	1	1	0
Unknown	0	10	24	1
Total	**83**	**60**	**50**	**3**

Source: CPSRMS and NEISS databases
Reporting is ongoing for these databases, especially for 2017-2019.

Ninety percent (75) of the 83 reported fatalities involving bumper contact were infants younger than 12 months old, and 61 percent (51 out of 83) were infants 4 months old or younger. Only three fatalities involved children older than the age of 23 months: one was a 2-year-old, one a 3-year-old, and one a 5-year-old. Among these three, one child had health issues, and one was developmentally delayed. Of the known-aged children involved in the nonfatal incidents, a majority were younger than 12 months of age. It is worth noting that when an incident reports no injury, the age of the victim is often coded as "unknown." Age was unknown in about half of the no-injury incidents. Table 3 provides the distribution of incidents for each 5-year period since 1990, except for the most recent period, which covers just over 4 years. Dashes indicate no reportable data, because nonfatal incident data prior to 2008 have been excluded in this analysis.

Table 3: Reported Incidents and Injury Severity by Year
January 1, 1990 - March 31, 2019 (Fatalities)
January 1, 2008 - March 31, 2019 (Non-Fatalities)

Year	Fatalities	Injuries	No Injury	Injury Severity Unknown
1990 to 1994	11	-	-	-
1995 to 1999	8	-	-	-
2000 to 2004	14	-	-	-
2005 to 2009	19	15	18	1
2010 to 2014	24	39	26	2
2015 to 2019[59]	7	6	6	0
Total	**83**	**60**	**50**	**3**

Source: CPSRMS and NEISS databases
Reporting is ongoing for these databases, especially for 2017-2019.

[59] Fatality counts should be considered incomplete for years 2017-2019, due to a time lag in reporting to CPSC.

CPSC staff notes that more than half of the fatalities that CPSC staff is aware of thus far were reported to have occurred since 2005. However, fluctuations in the numbers of reported incidents could simply reflect changes in reporting rather than an actual change in incident frequency. As new reports come in, these numbers may change. Table 4 presents age and gender for fatalities and injuries.

Table 4: Reported Incidents and Injury Severity by Age and Gender
January 1, 1990 - March 31, 2019 (Fatalities)
January 1, 2008 - March 31, 2019 (Non-Fatalities)

Age	Fatalities		Injuries		
	Male	Female	Male	Female	Unknown
0 to 4 months	27	24	2	2	0
5 to 8 months	13	7	3	7	0
9 to 11 months	2	2	6	6	0
12 to 23 months	3	2	15	8	0
2 years and older	1	2	1	0	0
Unknown	0	0	2	7	1
Total	**46**	**37**	**29**	**30**	**1**

Source: CPSRMS and NEISS databases
Reporting is ongoing for these databases, especially for 2017-2019.

III. Hazard Patterns

Fatal Incidents

None of the reported fatal incidents was witnessed; often, details about how the child was positioned when initially found were limited or vague; a second- or third-hand account might be all the evidence that was available about a fatality. In some cases, additional items in the crib environment may have been a contributing cause of the fatality; or there were conflicting reports from multiple sources describing the details of the fatality.

Generally, the cause of death in the fatal incidents was reported as asphyxia, suffocation, or Sudden Infant Death Syndrome (SIDS). A number of reports indicated that in addition to the presence of a crib bumper, the sleeping environment contained multiple additional items, such as pillows, blankets, and stuffed dolls. In many of these incidents, it is unclear what role, if any, the crib bumper played in the death of the child. CPSC staff, through group consensus, categorized the fatalities into hazard scenarios based on the best available account information about the position of the child when found and the cause of death ruled by the medical examiner.

Table 5 shows the distribution of the 83 reported non-incidental fatalities by hazard scenarios.

Table 5: Reported Fatalities by Hazard Scenario
January 1, 1990 - March 31, 2019

Hazard	Reported Fatalities	Percent[60]
Entrapment/Wedging	**44**	**53**
Against Object in Crib	*25*	*30*
In Perimeter of Crib	*13*	*16*
Other	*6*	*7*
Contact Without Entrapment/Wedging	**27**	**33**
Contact With Possible Entrapment/Wedging	**7**	**8**
Contact Outside Crib	**5**	**6**
Total	**83**	**100**

Source: CPSRMS and NEISS databases
Reporting is ongoing for these databases, especially for 2017-2019.

1. Entrapment/Wedging: In 53 percent (44 out of 83 fatalities) of the reported fatalities, the child was found wedged or entrapped against the bumper. This category was divided into three scenarios in which the child was found wedged or entrapped.

***a. Against Object in Crib*:** In 30 percent (25 out of 83 fatalities) of the reported fatalities, the child was entrapped or wedged between a crib bumper and another object in the crib, such as a bed pillow, an infant recliner, or a cushion.

***b. In Perimeter of Crib*:** In 16 percent (13 out of 83 fatalities) of the reported fatalities the child was found entrapped between the mattress and the side of the crib, on which a crib bumper was installed. Nine of these cases involved a crib that was structurally compromised, with features such as detached crib side rails, or missing or detached crib slats.

***c. Other*:** Seven percent (6 out of 83 fatalities) of the reported fatalities involved entrapment against a crib bumper in some scenario not covered by the two prior Entrapment/Wedging hazard patterns, such as a child being found wedged under the crib bumper.

2. Contact Without Entrapment/Wedging: In 33 percent (27 out of 83 fatalities) of the reported fatalities, the child was reportedly in contact with, but not entrapped or wedged against, the crib bumper.

3. Contact With Possible Entrapment/Wedging: In eight percent (7 out of 83 fatalities) of the reported fatalities, the child was found to be in contact with the crib bumper, but the incident scenario lacked sufficient details for CPSC staff to determine whether the child was entrapped or wedged against the bumper. These fatalities typically described the child as being found with his or her face between the mattress and the crib bumper. The incident descriptions often used the phrase "wedged between" to describe the position of the child's face when found. However, staff discovered that some incidents without entrapment or wedging used similar language to describe the orientation of the child's face relative to the two surfaces. In other words, the word

[60] Percentages may not sum to 100 due to rounding.

"wedging" described the face position, not whether the infant was entrapped or being held against the bumper. Thus, incidents in this category did not include sufficient details to enable staff to conclude whether the child was truly entrapped or wedged against the bumper.

4. Contact Outside Crib: Six percent (5 out of 83 fatalities) of the reported fatalities were cases in which the child was in contact with a crib bumper that was outside a crib. Specifically, three reported fatalities involved a bumper being used in a toddler bed, and two reported fatalities involved a bumper being used in a bassinet. Staff is aware of three other incidents involving a bumper outside a crib, but in those incidents there was no evidence of contact with the crib bumper, and thus these three fatalities were ruled *incidental* and not included.

Table 6 summarizes fatal incidents by year and hazard scenario.

Table 6: Reported Fatalities by Hazard Scenario and Year
January 1, 1990 - March 31, 2019

Year	Entrapment/ Wedging	Contact Without Entrapment/Wedging	Contact With Possible Entrapment/Wedging	Contact Outside Crib	Total
1990 to 1994	6	5	0	0	11
1995 to 1999	4	2	0	2	8
2000 to 2004	7	5	1	1	14
2005 to 2009	8	6	4	1	19
2010 to 2014	16	5	2	1	24
2015 to 2019[61]	3	4	0	0	7
Total	**44**	**27**	**7**	**5**	**83**

Source: CPSRMS and NEISS databases
Reporting is ongoing for these databases, especially for 2017-2019.

Any change in reported fatalities could simply reflect changes in reporting of crib bumper presence, rather than an actual increase in fatalities where a crib bumper may have played a role.

Nonfatal Incidents

Table 7 summarizes the hazard patterns for the bumper-related nonfatal incidents. In cases where multiple hazards were mentioned, the hazard that could have caused the most severe injury was used.

[61] Fatality counts should be considered incomplete for years 2017-2019, due to a time lag in reporting to CPSC.

Table 7 Reported Nonfatal Incidents or Concerns by Hazard Pattern
January 1, 2008 - March 31, 2019

Hazard	Incidents/Complaints	Percent[62]
Slat Entrapments	38	34
Climbing or Climb-Outs	12	11
Under or Behind Bumper	10	9
Near-Strangulation or Entanglements with the Bumper	8	7
Entrapped Against Object in Crib and a Bumper	7	6
Choking or Ingestion of Small Parts of a Bumper	7	6
Other	14	12
Concerns	17	15
Total	**113**	**100**

Source: CPSRMS and NEISS databases
Reporting is ongoing for these databases, especially for 2017-2019.

1. Slat Entrapments: Thirty-four percent (38 out of 113 non-fatalities) of reported nonfatal incidents involve arm or leg entrapments between the slats of the crib, even though a crib bumper was present. Seven of the 38 slat entrapments reportedly involved a breathable bumper or mesh liner. Of the 38 slat entrapments, 27 incurred injuries.

2. Climbing or Climb-Outs: Eleven percent (12 out of 113 non-fatalities) of reported nonfatal incidents occurred when a child, old enough to stand up, reportedly used the bumper as a step to climb. The child often fell back into the crib or fell out of the crib. The youngest children in these incidents were two 7-month-old children.

3. Under or Behind Bumper: In nine percent (10 out of 113 non-fatalities) of reported nonfatal incidents, the child or some part of the child was found under or behind (*i.e.*, against the crib side) the crib bumper. In seven cases, the child reportedly was trapped under or behind the bumper. In two cases, the bumper covered the child's face, but the child was not entrapped. In one case, the face was under the bumper while the legs were trapped in the slats. Some of these cases reported that the bumper was missing bottom ties.

4. Near-Strangulation or Entanglements with the Bumper: Seven percent (8 out of 113 non-fatalities) of reported nonfatal incidents involved the tie, threading, or stitched-on components of a crib bumper becoming loose and wrapping around body parts of the child. Half of these incidents specifically mention the head, mouth, or neck being wrapped up by a piece of a crib bumper. However, none of these incidents involved a bumper tie wrapping around a child's neck.

5. Entrapped Against Object in Crib and a Bumper: In six percent (7 out of 113 non-fatalities) of reported nonfatal incidents, the child was entrapped between a crib bumper and another object in the crib, such as a sleep positioner or an infant recliner.

[62] Percentages may not sum to 100 due to rounding.

6. Choking or Ingestion of Small Parts of a Bumper: Six percent (7 out of 113 non-fatalities) of reported nonfatal incidents involved choking or ingestions. These incidents generally involved the child putting a piece of the crib bumper, such as decorative stitched-on patterns, the ties, or the stuffing from inside the bumper, into their mouth.

7. Other: Twelve percent (14 out of 113 non-fatalities) of reported nonfatal incidents were other issues involving a child, including: bumper integrity issues such as ties detaching or being pulled off, stitching being pulled out, and paint rubbing off; injuries caused by contact with crib bumpers; needles found in the padding of the bumper; injuries, such as cuts and bruises on the crib rail, that occurred despite the presence of the bumper; portions of the crib (*e.g.*, crib rails or slats, crib side) breaking or separating while bumpers were in use; and an entrapment between a crib toy and the crib mattress while in contact with the bumpers.

8. Concerns: Fifteen percent (17 out of 113 non-fatalities) of reported nonfatal incidents and concerns did not involve an actual incident with a child, but instead, were general crib bumper-related problems foreseen by the parent or complainant. Common examples of concerns with crib bumpers were: bumper integrity issues such as ties detaching or the bumper coming apart; concerns about poor bumper fit or bumpers missing the lower ties; and general concerns about bumpers posing a safety hazard.

TAB C: LSM Staff Memorandum, "Laboratory Sciences Assessment and Proposed Revisions to ASTM F1917 *Standard Consumer Safety Performance Specification for Infant Bedding and Related Accessories* (CPSIA Section 104), and Related Subjects"

TAB C

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
ROCKVILLE, MD 20850

MEMORANDUM

Date: August 23, 2019

To:	Timothy P. Smith, Project Manager Crib Bumper Rulemaking, Division of Human Factors, Directorate for Engineering Sciences
Through:	Andrew Stadnik, Associate Executive Director Directorate for Laboratory Sciences
	Michael Nelson, Director, Division of Mechanical Engineering
From:	Mark Eilbert, Mechanical Engineer Mechanical Engineering, Directorate for Laboratory Sciences
Subject:	Laboratory Sciences Assessment and Proposed Revisions to ASTM F1917 *Standard Consumer Safety Performance Specification for Infant Bedding and Related Accessories* (CPSIA Section 104), and Related Subjects

I. INTRODUCTION

This memorandum assesses the effectiveness of ASTM F1917 – 12, *Standard Consumer Safety Performance Specification for Infant Bedding and Related Accessories*, and provides background and analyses for other existing voluntary standards that address, or could potentially be adapted to address, suffocation, wedging, and entrapment with crib bumper/liners. Suffocation, wedging, and entrapment are hazards that are most related to the material characteristics firmness and air permeability. Staff presents test data from testing the firmness or thickness requirements for crib bumper/liners to three voluntary safety standards. This memorandum includes a discussion on the adequacy of ASTM F1917 – 12 and staff recommendations.

Dimensional units are stated in this memorandum with the primary unit first, followed by an informational unit (in parentheses).[63]

II. REVIEW OF STANDARDS

This section will review existing standards that have requirements: (1) related to crib bumpers/liners; (2) for firmness potentially relatable to crib bumpers/liners; (3) for air flow

[63] A reported measurement, for example from an instrument, will be the primary unit. The unit that is stated in a standard, for example ASTM, AS/NZS, etc., will be the primary unit.

through bedding products or fabrics potentially relatable to crib bumpers/liners. A brief discussion on the relevance to crib bumpers/liners follows each standard's review.

A. Standards with Crib Bumper/liner Requirements

Staff is aware of two standards that contain performance requirements for crib bumpers/liners: ASTM F1917 – 12 *Standard Consumer Safety Performance Specification for Infant Bedding and Related Accessories*, and EN 16780:2018, *Textile child care articles - Safety requirements and test methods for children's cot bumpers.*

Summary of ASTM F1917 – 12 *Standard Consumer Safety Performance Specification for Infant Bedding and Related Accessories*

The following is a summary of the general and performance requirements in ASTM F1917 – 12 pertaining to crib bumper/liners. A discussion of the Product/Package Marking requirements is provided in the Human Factors (ESHF) staff memorandum.

Section 5 has general requirements for "attachment means" length and intervals, decorative components, and threads. Attachment means can be any device, such as ties, to secure the crib bumper to the crib.

- Section 5.1 requires that attachment means be no longer than 9 in (229 mm) when measured in accordance with section 7.1 under a 5-lb (22 N) load.
- Section 5.2 requires that decorative components shall not exceed 7 in (178 mm), and if they can "tangle to form a loop" have a loop perimeter of no more than 14 in (356 mm), when measured in accordance with section 7.1 under a 5-lb (22 N) load.
- Section 5.3 prohibits the use of monofilament thread.
- Section 5.4 requires that crib bumper/liners "shall be capable of being secured at or near all corners and at the midpoints of the long sides of the crib. Bumper guards intended for circular cribs shall be capable of being secured at intervals not exceeding 26 in. (66 cm)."

Section 6 has performance requirements for vinyl that is not bonded to other material, crib bumper thickness, and crib bumper/liner tie strength.

- Section 6 has performance requirements for unsupported vinyl, maximum bumper thickness, and bumper tie strength. Unsupported vinyl is defined as vinyl that is not integrated to a backing material. These requirements refer to tests specified in section 7: a vinyl thickness measurement, the bumper thickness test, and the bumper pad tie attachment strength test.
- In section 6.1, unsupported vinyl that is accessible to an infant is required to be 0.012-in (0.3 mm) thickness or greater. Vinyl is measured at four locations using a micrometer.
- Section 6.2, Maximum Bumper Thickness. For fabric crib bumpers with fibrous fill, section 6.2 requires that the entire length of the crib bumper pass through a 2-in (51 mm) slot. The stated rationale is to limit the maximum thickness of crib bumper/liners "to a thickness that has not been known to present a hazard." According to the section 7.3 bumper thickness test method, the crib bumper is positioned vertically into a 2-in (51 mm) horizontal slot (Figure 1) and allowed to be pulled through by a 5 lbm (2.4 kg) static

weight secured to the end. If crib bumper ties interfere in the slot, the ties may be "eased" through and the test continued. The test is conducted both before and after three washings.

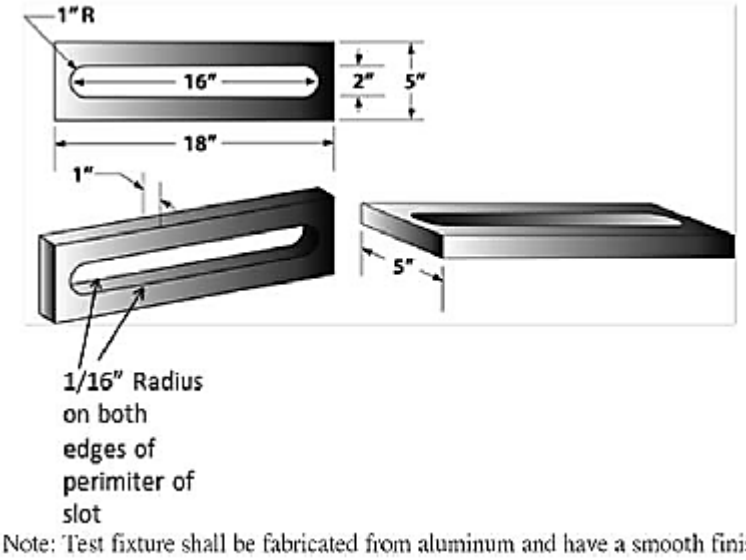


Figure 1. ASTM F1917 – 12 Bumper Thickness Test Fixture[64]

- Section 6.3, Bumper Pad Tie Strength. Section 6.3 requires that after the Bumper Pad Tie Attachment Strength test, the tie(s) must not detach; however, partial detachment or tearing is allowed. The test assesses the strength of the means of attachment of ties to the crib bumper by applying a separation force of 20 lbf (89 N), applied evenly over 5 seconds and held for 10 seconds. Multiple ties that share a common attachment are tested together, as if one tie.

Staff has concerns with ASTM F1917 – 2012 requirements that may not adequately protect the infant's face from a too-soft crib bumper/liner. The thickness requirement does not appear to directly assess a firmness requirement, with no requirement for crib bumpers/liners less than 2-in (51 mm) thick. The attachment requirement seems to have somewhat arbitrary attachment intervals. There is no strength requirement for decorative features. There are other concerns that will be discussed. Notwithstanding, staff considers ASTM F1917 – 12 to be the more comprehensive standard for crib bumpers/liners than the other standard reviewed.

Summary of EN 16780:2018, *Textile child care articles - Safety requirements and test methods for children's cot bumpers.*

As stated in the foreword to the standard, EN 16780:2018 partially supersedes an earlier British standard that included crib bumper requirements, BS 1877-10:2011+A1:2012, *Domestic bedding, Part 10: Specification for mattresses and bumpers for children's cots, perambulators*

[64] ASTM F1917 – 12, Figure 1.

and similar domestic articles. The latter standard has length and strength requirements for crib bumper ties that are similar to those in EN 16780:2018.

The following is a summary of the requirements in EN 16780:2018 pertaining to crib bumper/liners. The word "cot" refers to cribs. The word "bumper" refers to crib bumper/liner. Annex A of the standard lists rationales for many of the requirements.

Section 4.1 *Design Characteristics* has requirements to address falls from the crib, suffocation on materials, strangulation on cords, entrapment of fingers/toes, sharp or abrasive edges, choking, and internal injuries from magnets.

- Sections 4.1.1.1 and 4.1.1.4 pertain to fall hazards and require that the cot design not present footholds, including pockets.

- Section 4.1.1.2 pertains to head entrapment hazards and requires the bumper be designed without horizontal gaps that could entrap a child's head.

- Sections 4.1.1.3, 4.1.2.1, 4.1.5.3 and 4.1.9 pertain to suffocation hazards and require cot attachments be designed such that the bumper not "collapse or be drawn inside the cot" and prohibits the use of impermeable plastic coatings on the bumper. The rationale for 4.1.2.1 states "it is assumed that, in general, air flow can go through the fabrics as well as filling material but can be blocked by airtight surface".

- Sections 4.1.2.2, 4.1.4.5, 4.1.5.1, 4.1.5.2, and 4.1.7.2 pertain to sharp or abrasive edges.

- Sections 4.1.3.1, 4.1.6.1, 4.1.6.3, 4.1.6.4, 4.1.6.5, 4.1.7.1, and 4.1.7.3 pertain to finger, toe, and generally ischemia[65]-causing entrapment hazards in loose or frayed threads and thread loops.

- Section 4.1.3.2 pertains to strangulation in bumper attachment cords and requires pairs be ties at the same point on the bumper.

- Sections 4.1.3.3 and 4.1.7.4 pertain to strangulation in other cords and free-ended labels, respectively, and require in each the length be less than 75 mm (3 in).

- Sections 4.1.4.1, 4.1.4.2, 4.1.4.3, 4.1.4.4, 4.1.6.2, 4.1.6.6, and 4.1.8 pertain to choking hazards with small parts associated with cords and with fabrics and "embellishments" on the bumpers.

- Section 4.1.10 pertains to the hazard of swallowing magnets and prohibits magnetic components.

Section 4.2 *Mechanical and physical hazards* has requirements for entrapment, strangulation, choking, cuts and abrasions.

[65] Ischemia is the restriction in blood supply to tissues.

- Section 4.2.1 *Entrapment of fingers and toes, ischemia* requires there be no openings in fabric that can pass a conical probe to a 7 mm (0.28 in) depth, and that no opening in rigid material have dimensions between 5 mm and 12 mm (0.20 to 0.47 in) unless the depth is less than 10 mm (0.40 in).

- Section 4.2.2 *Strangulation* requires bumper attachments be less than 220 mm (8.7 in) in length and have a minimum pull strength of 70 N (15.7 lbf).

- Section 4.2.3 *Small part aspiration or ingestion, internal asphyxiation (choking)* requires that components remain attached after a 70 N pull force or that remain attached to fabric after a washing/drying regime.

Other requirements include 4.3 *Chemical hazards,* 4.4 *Fire hazards,* and 4.5 *Hygiene hazards.*

EN 16780:2018 requires that the design of the product prevent the crib bumper/liner from falling into the crib. Staff recognizes the importance of keeping soft bedding products out of the crib, but this design requirement does not have a test method. Staff is also concerned that the standard does not have a requirement for the firmness of crib bumpers/liners. Additionally, although there are specific requirements (prohibitions) for plastic surfaces that could affect breathability, the rationale for that requirement assumes the air flow characteristics of the underlying woven fabric and filling materials are adequate. That rationale has no basis and also lacks a test method. The contact of an infant's face into a soft crib bumper/liner is not addressed.

B. Summary of Standards with Firmness Requirements for Bedding Products

As previously discussed, ASTM F1917 – 12 has performance requirements for thickness, but not firmness. Staff is aware of two standards that contain performance requirements for firmness that potentially could be applied to crib bumper/liners. One standard is the Australian/New Zealand standard, AS/NZS 8811.1, *Methods of testing infant products Method 1: sleep surfaces-test for firmness*. The other is the British standard, BS 4578:1970 , *Test for Hardness of and for Air Flow Through Infants Pillows,* with the performance requirements specified in BS 1877-8:1974, *Specification for Domestic bedding -Part 8: Pillows and bolsters for domestic use (excluding cellular rubber pillows and bolsters).*

Summary of AS/NZS 8811.1 *Methods of testing infant products Method 1: sleep surfaces-test for firmness*

The test method in AS/NZS 8811.1 determines a firmness threshold—pass or fail—for horizontal sleep surfaces such as mattresses that, according to the standard, addresses "good quality research" that "has pointed to an association between infant mortality and overly soft sleep surfaces." That research[66] is reported to have found that through three studies of actual infant deaths on softer bedding, the likelihood of death was between three and 20 times that of

[66] AS/NZS 8811.1 reports the research from three studies: Ponsonby, et al (N Engl J Med 1993; 329)-1993; Kemp, et al (Pediatr Res 1994; 36)-1994, and Schlaud et al (Int J Legal Med 2010; 124).

conventional bedding. In one study by Schlaud and colleagues,[67] sleep surface firmness was assessed by measuring deflection resulting from an applied weight. A 2 kg (4.4 lb) cylinder with a diameter of 6 cm (2.4 in) is placed through a support gage on the sleep surface. If the cylinder passes more than 1.45 cm (0.57 in) through the gage, the sleep surface is a failure. The test method in AS/NZS 8811.1 gives similar results[68] as the Schlaud test method. In neither method is the test device based on infant anthropometrics. Rather, in each, the measured firmness threshold was determined by correlation with the relative firmness of the sleep surfaces among the actual SIDS and control cases in the Schlaud study.

The firmness test apparatus in AS/NZS 8811.1 is shown in Figure 2. The method applies the force of a 5.2 kg (11.5 lb) total fixture mass to a horizontal sleep surface through a 203 mm (8.00 in) diameter bottom disk that has a thickness of 15 mm (0.59 in). A feeler arm extends 40 mm (1.57 in) past the top edge of the disk. Test locations are at the ¼, ½, and ¾ points along the medial line of the sleep surface, with the feeler arm aligned with the medial line. A fourth location is chosen with the feeler arm rotated such that the location is most likely to fail. The bottom disk is placed horizontally on the sleep surface to begin the test. If the test device does not remain horizontal, the test must be restarted. If the sample material compresses under the weight of the apparatus to the point where the feeler arm also touches the sample, the sample fails the test.

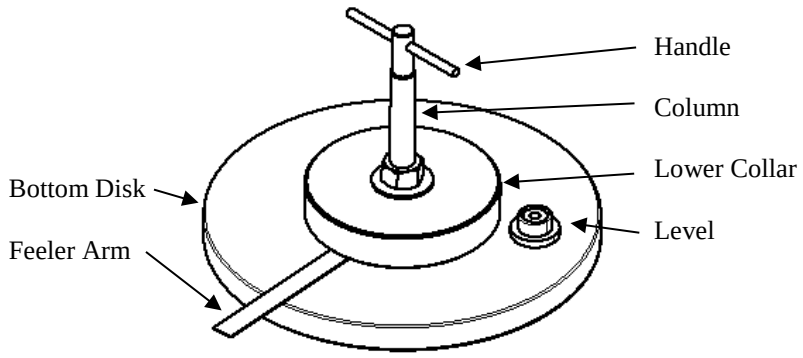


Figure 2. AS/NZS 8811.1 Firmness Test Apparatus[69]

Crib bumper/liners could be tested using the AS/NZS 8811.1 test method, since crib bumper/liners typically are wider than that of the 203 mm (8.00 in) base of the test apparatus. However, crib bumper/liners must be tested horizontally rather than in their normal vertical orientation when using the test method. Although under normal use, an infant would seldom rest on a horizontal surface of a crib bumper, the firmness of this infant bedding product does figure in a safe sleep environment. Several key points that support applying the AS/NZS 8811.1 test method to crib bumper/liners are:

[67] Schlaud, et al. The German case-control scene investigation study on SIDS: epidemiological approach and main results. International Journal of Legal Medicine. Sprenger International, Heidelberg. 2010 January 124: 19-26.
[68] *Australia and New Zealand's proposed new test for infant mattress firmness: A brief summary, August 2012*
[69] CPSC staff construction based on AS/NZS 8811.1 Figure 1.

- Infants can rest on a crib bumper if its attachment means cannot prevent the crib bumper from sliding down a crib side.
- Soft bedding, pillows, blankets, duvets, toys, and most other items, are not recommended in the crib. Infant contact with soft materials is associated with a suffocation hazard. The crib bumper forms a soft vertical wall, and together with pillows and other soft items placed in the crib, can form an entrapping space for the head of an infant. The firmness of a crib bumper in any orientation is therefore a concern for safe sleep practices.
- Testing the vertically placed crib bumper using a horizontal test method adds, in effect, a factor of safety. Although in use, a crib bumper is not likely to experience a lateral load similar to that of the test weight in the firmness test, issues such as the security of attachment means and an entrapping space can lead to hazards such as the scenario in which the crib bumper separates from the crib side or otherwise protrudes into the sleep area and gets underneath an infant. Adding additional safety to crib bumper/liners through a firmness test meant for mattresses will tend to reduce the potential suffocation hazard posed by a crib bumper.

Summary of BS 4578:1970 ***Test for Hardness of and for Air Flow Through Infants Pillows***

Hardness

The firmness test method in the British standard BS 4578:1970 is intended to address suffocation on soft infant pillows. The standard does not include a rationale for this test method, including the fixture dimensions, test forces, or the allowable deflection limit. The hardness test method in section 3 reads:

"The overall thickness, and the indentation of the pillow caused by a force of 10 N applied through an indentor of 100 mm diameter applied to the centre of the pillow for 1 min shall be measured with the loaded indentor in place, and recorded."

The test is performed before and after two washings. Figure 3 shows a diagram of the BS 4578:1970 test fixture. The test is paired with the performance requirement in BS 1877-8:1974 that requires "the indentation, when measured in accordance with the method set out in BS 4578:1970, shall not exceed 25%" of the original thickness of the pillow.

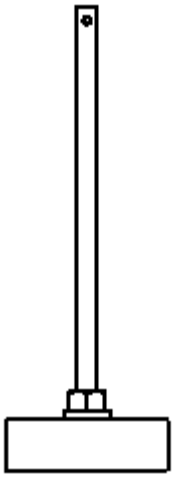


Figure 3. BS 4578:1970 Hardness Test Fixture

Crib bumper/liners could physically be tested according to the BS 4578:1970 test method since crib bumper/liners typically are wider than that of the 100 mm (3.93 in) base of the test apparatus. The firmness test would be applied to a horizontally placed crib bumper, as in AS/NZS 8811.1. The same justifications apply here, summarized as crib bumpers/liners can become part of the sleep environment that includes other bedding products, none of which are recommended in the crib.

C. Summary of Standards with Air Flow Requirements for Bedding Products or Fabrics

Staff is aware of three voluntary standards that contain performance requirements for air flow through bedding products or fabrics that potentially could be applied to crib bumper/liners. One standard is the British standard, BS 4578:1970, *Test for Hardness of and for Air Flow Through Infants Pillows,* with the performance requirements specified in BS 1877-8:1974, *Specification for Domestic bedding -Part 8: Pillows and bolsters for domestic use (excluding cellular rubber pillows and bolsters).* The others are ASTM D737 – 18 *Air Permeability of Textile Fabrics* and ASTM D3574-17 *Standard Test Methods for Flexible Cellular Materials—Slab, Bonded, and Molded Urethane Foams*. The latter two standards measure air flow through fabrics, but these standards do not include requirements that are intended to address a suffocation hazard.

Summary of BS 4578:1970 *Test for Hardness of and for Air Flow Through Infants Pillows*

BS 4578:1970 describes the test apparatus for pillows that measures air pressure differential at a set air flow. The requirements for the air flow test in BS 4578:1970 is in BS 1877-8:1974.

The air permeability test method in section 4 of BS 4578:1970 is intended to address deaths associated with suffocation on soft infant pillows. Air permeability in this standard is defined and measured as the pressure difference that develops in a 36 mm (1.41 in) internal diameter tube that is in contact with a sample pillow when the flow of air is set to 200 ml/sec, which is equivalent to 12 L/min (0.42 ft^3/min). The test method includes the apparatus shown in Figure 4. The tube with a 100 mm (3.93 in) diameter bottom skirt (disk) is placed on the sample pillow

while a 10 N (1.0 kgf or 2.2 lbf) thrust force presses the pillow upward into the skirt. A blower induces air flow in the tube as pressure is monitored.

The performance requirement for this test is in BS 1877-8:1974,[70] which requires, both before and after washing, that the pressure differential shall not exceed 20 mm[71] (0.8 in) water column while the air flow is maintained at 200 ml/sec, or 12 L/min (0.42 ft^3/min).

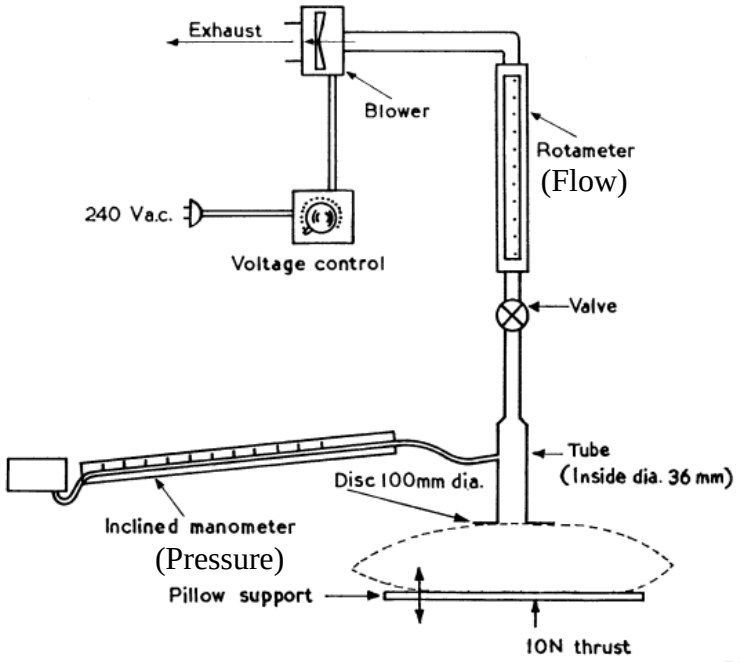


Figure 4. BS 4578:1970 Air Permeability Test Apparatus[72]

The BS 4578:1970 test method draws air under negative pressure from the top of a pillow's surface. It is designed to address hazards associated with restricted airflow such as suffocation. As a low pressure open suction system, a proper seal on the intake "disc" should be possible without overly distorting the pillow. The test method specifies method apparatus that includes a "plane rigid unperforated support" for the pillow. In applying the BS 4578 test to crib bumpers/liners, the specified pillow support approximates a solid crib panel. Since crib bumper/liners are typically installed against crib panels that are either open with rails or solid, a bumper/liner test support could be designed to approximate the restriction to air flow of open rails or solid panels. Test supports could also comprise grating to minimally affect air flow and thus test the air flow characteristics of the crib bumper/liner itself. Accordingly, this test method appears to be adaptable to crib bumpers/liners. Thicker, padded, crib bumpers/liners appear to have characteristics more like pillows than the thinner mesh liners. Accordingly, BS 4578:1970 may not be appropriate for the possibly much higher air flow through the open fabric of mesh crib bumpers/liners. Comparisons among padded crib bumpers, which are present in suffocation

[70] BS 1877-8:1974 Specification for Domestic bedding — Part 8: Pillows and bolsters for domestic use (excluding cellular rubber pillows and bolsters), section 9 Performance Requirement (2).
[71] BS 1877-8 does not give a rationale for the 20 mm performance requirement. Refer to the HS Staff Memorandum for a discussion on infant breathing development.
[72] BS 4578:1970, Figure 1 – Layout for air permeability test on pillows.

deaths, could yield results that would differentiate between products, once an appropriate threshold for sleeping infant breathing is established. A further discussion on this test method and results of testing on products typically found in the infant sleep environment is in the Engineering Sciences Mechanical and Combustion (ESMC) staff memorandum. The breathing threshold issue is addressed in the Health Sciences (HS) staff memorandum.

Summary of ASTM D737 – 18 *Air Permeability of Textile Fabrics*

ASTM's standard test method for air permeability, ASTM D737 – 18, can assign a value of air permeability to a thin fabric. Section 4.1, summary of test method reads:

"The rate of air flow passing perpendicularly through a known area of fabric is adjusted to obtain a prescribed air pressure differential between the two fabric surfaces. From this rate of air flow, the air permeability of the fabric is determined."

This test method is intended for thin fabrics that can be clamped in a test head "without distortion and minimal edge leakage underneath the test specimen." Test apparatus built to ASTM D737 – 18 requirements typically clamps fabric specimens to a wide flat plate with a circular opening through which the air is drawn. Under these conditions, air is drawn perpendicularly through the fabric and into the opening where the air flow is measured. This test method could be applied to thinner crib bumper/liners such as mesh liners, since that material could be clamped with far less distortion than thicker, more padded types. Modifications to the clamping system would be necessary to clamp all samples consistently with a known force that does not distort padded crib bumpers/liners. As will be apparent in the testing section, the minimum measured flow rate for this test (18 L/sec) is higher than that for a sleeping infant[73]. Thus, this test method does not seem appropriate to directly assess a suffocation hazard with crib bumper/liners. However, gross comparisons or rankings of air flows through crib bumpers/liners could be made, *e.g.*, open mesh compared to padded bumpers. Staff tested a sampling of mesh and padded bumpers to ASTM D737 – 18 using modified test apparatus. Test results are presented in the section "Airflow Tests of Crib Bumpers/Liners" of this memorandum.

Summary of ASTM D3574-17 *Standard Test Methods for Flexible Cellular Materials—Slab, Bonded, and Molded Urethane Foams*

ASTM D3574-17 includes several test methods that apply to slab, bonded, and molded flexible cellular products known as urethane foams. One of these test methods is Test G – Air Flow Test. A summary reads:

"The test consists of placing a flexible foam core specimen in a cavity over a chamber and creating a specified constant air pressure differential. The rate of flow of air required to maintain this pressure differential is the air flow value. This test is normally for slab foam products or for the core materials of molded products." The size of the test specimen is set by the dimensions of the test equipment: "The specimen mount cavity shall be 50.0 +/- 0.5 by 50.0 +/- 0.5 by 25.0 +/- 0.5 mm in size." For "molded skins or extremely high air flow products", the scope suggests

[73] Refer to the Heath Science staff memorandum.

using the test method in ASTM D737 – 18 Air Permeability of Textile Fabrics, "although some modification of the D737 equipment could be necessary".

This test method is intended for homogeneous materials and requires the specimen be cut to fit into a small cavity. A small specimen size is not likely to represent the typical crib bumper construction which generally includes layers of fabric and loose padding. Cutting of a crib bumper would introduce fit and air leakage issues within the test cavity. These drawbacks make the test method difficult to apply to crib bumper/liners.

III. FIRMNESS AND THICKNESS TESTS OF CRIB BUMPER/LINERS

A. Assessment of Firmness/Thickness Test Results from Three Test Methods

Staff collected 11 padded crib bumper samples, which when measured, ranged in initial thickness from 0.7 in to 2.5 in (17 mm to 64 mm), in spring 2018. Staff conducted thickness tests to ASTM F1917 – 12 and firmness tests to AS/NZS 8811.1 and BS 4578:1970 on these samples. To summarize, to pass the thickness requirement in ASTM F1917 – 12, the crib bumper must pass completely through a 2-inch (51 mm) slot. To pass the firmness requirement in AS/NZS 8811.1, the crib bumper must support 5.2 kg (11.4 lb) test apparatus with a 203 mm (8.00 in) bottom disk without contacting a 40 mm (1.57 in) projecting feeler gauge located 15 mm above the base or bottom surface of the test apparatus. In BS 4578:1970, the crib bumper must support 1 kg (2.2 lb) test apparatus with a 100 mm (3.93 in) bottom disk and not deflect more than 25 percent into the crib bumper.

Table 1 shows a divergence of results among the two standard firmness tests and the existing thickness test. All samples passed the ASTM F1917 thickness test. All samples failed or borderline-failed the BS 4578:1970 firmness test. The results of the AS/NZS 8811.1 firmness tests show that all tests failed at 1.2 in (31 mm) initial thickness and above and that all tests passed at 0.8 in (20 mm) thickness and below. Of the two samples that were 1 in (25 mm) thick, one exemplar passed and one failed.

Table 1 Comparison of Voluntary Standards – Crib Bumper Test Results

Sample	Length (in.)	Thickness (in.)	AS/NZS 8811.1:2013	ASTM F1917 – 12	BS 4578:1970/ BS 1877-8:1974
18-800-2684	27, 52	0.7	P	P	**F**
18-800-2881	27, 51	0.8	P	P	**F**
18-800-2882	27, 51	0.8	P	P	**F**
18-800-2208	61	1	**F**	P	**F**
18-800-2207	158	1	P	P	P/F
18-800-2438	146	1.2	**F**	P	**F**
18-800-2293	150	1.4	**F**	P	**F**
18-800-2206	158	1.5	**F**	P	**F**
18-800-0455	82	1.9	**F**	P	**F**
18-800-2396	150	2	**F**	P	P/F
18-800-2883	28, 52	2.5	**F**	P	**F**

As noted, the 2-in (51 mm) slot in ASTM F1917 allowed all tested bumpers to pass through. This includes the 2.5 in (64 mm) bumper because the test method pulls bumpers through with the force of a 5 lb (2.27 kg) weight. Since bumpers above 2-in (51 mm) must compress, the test in that range can be seen to indirectly indicate firmness, although friction is also present. But since there is no effective contact with bumpers less than 2 inches, those crib bumper/liners are evaluated only by thickness. A rationale in ASTM F1917 states that the 2-in opening limits the bumper/liner to a thickness that is "not known to present a hazard."

The BS 4578:1970 infant pillow firmness test was applied to bumpers. The deflections of all exemplar bumpers in these firmness tests exceeded 25 percent of the original bumper thicknesses and all tests failed. The 25-percent requirement allows thinner bumpers less deflection than thicker bumpers, because failure is relative to the product's initial thickness. An analysis of test results in Table 1 indicates a relatively small 0.18 in (25% of 0.7 in, 18-800-2684) bumper deflection fails as well as a larger 0.63 in (25% of 2.5 in, 18-800-2883) deflection. The results that thinner crib bumpers/liners fail as well as thicker ones does not agree with the ASTM F1917 or AS/NZS 8811.1 test results. The minimum deflection/thickness limits of the latter two standards would seem consistent with a suffocation hazard. The application of the BS 4578:1970 test method to crib bumper/liners is questionable due to these test results with thin bumpers.

The AS/NZS 8811.1 sleep surfaces firmness test was applied to bumpers. Since the test fixture has a 15 mm (0.59 in) thickness below its feeler gauge, bumper thicknesses around 0.59 in (15 mm) and below should all pass the test. Results in Table 1 indicate all bumpers at or below 0.8

in (20 mm) passed. As the fixture is placed on thicker bumpers, deflection of the top surface still must not exceed the 0.59 in threshold or the feeler will be contacted. Test results show a transition from pass to fail at about 1 in (25 mm) thickness. All sample crib bumper/liners with thicknesses exceeding 1 in. failed. These test results indicated that this test method has differentiated the exemplar bumpers, unlike the BS 4578:1970 and ASTM F1917 methods. The transition from pass to fail at 1-in thickness suggests that a simple change in slot width in the ASTM F1917 test method might improve that assessment. However, including an actual firmness test similar to AS/NZS 8811.1 into ASTM F1917 would serve to assess the soft material hazard directly.

B. **Human Facial Conformance to a Padded Crib Bumper**

The Commission directed staff to consider the development of a test method for the conformance of the crib bumper around an infant's face. As described in the ESMC staff memorandum, staff developed an anatomical model of the infant nose/mouth region and head mass and applied it to the air permeability test method in BS 4578:1970. The anthropometry-based probe developed by staff seemed promising in developing a direct facial conformance test.

To study the viability of an anthropometry-based conformance test, staff modified the BS 4578:1970 hardness test device, which employs an indenter with the same 100 mm (4 in) diameter application area as the metal flange on the air permeability test apparatus, with the addition of the anatomical features developed by ESMC staff. These modifications were represented in two features: a truncated cone representing the nose and mouth added to the bottom of the cylindrical base, and an increase of the fixture weight to 1.8 kg, representing the average head mass for a 6-month-old infants. Figure 5 shows the modified fixture.

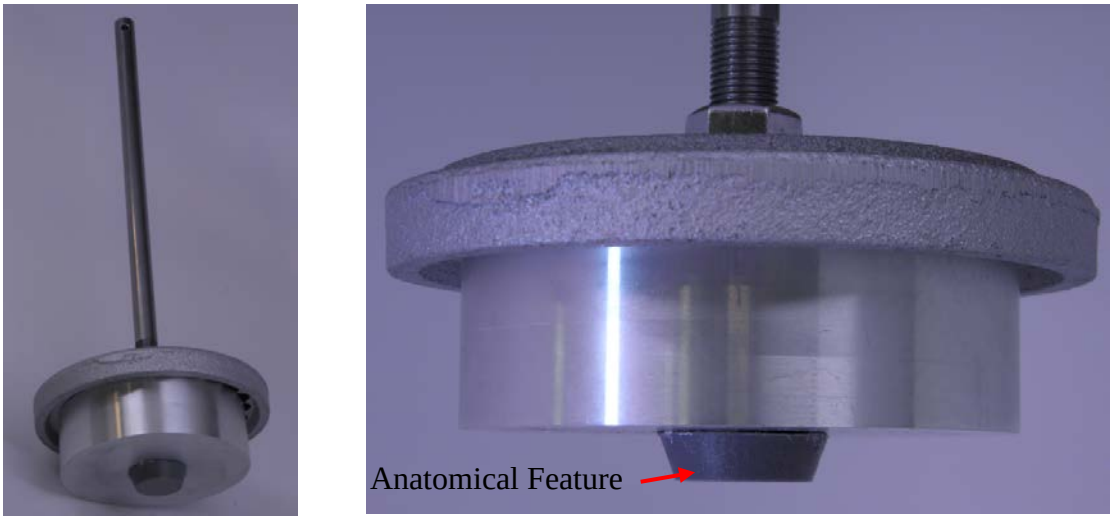


Figure 5. Facial Conformance Test Fixture

Staff chose not to apply the 25-percent deflection criterion in BS 1877-8 in considering facial conformance for the reasons previously discussed. Instead, staff observed conformance of the bumpers around the modified fixture, with the goal of ascertaining what measures of conformance could be observed. As suggested in the ESMC staff memorandum, staff hypothesized that one could assess conformance to the face by applying the anthropometry-based

probe to a crib bumper/liner. A crib bumper/liner that is flush against the entire perimeter of the bottom disk of the probe would be considered a failure, as this presumably would simulate a full submersion of a child's nose and mouth into the bedding.

Staff tested the modified fixture with exemplar crib bumper/liners configured with the anatomical facial features and a weight of 1.8 kg. Figure 6 shows the modified fixture during a typical test on a 0.75 in thick crib bumper. In Figure 6, the perimeter of the base does not fully conform due to two visible voids in the crib bumper fabric. This shows as dark spots at the perimeter. These voids are due to wrinkles caused by the addition of the anatomical features. Voids were not detected in tests with the test fixture without the anatomical features.

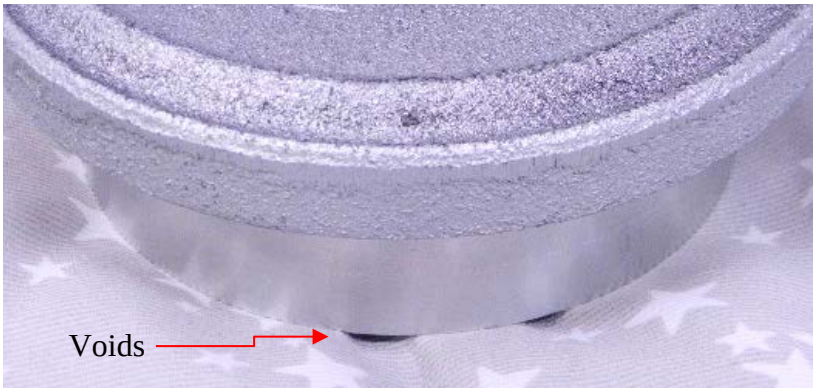


Figure 6. Test of Facial Conformance
Modified Test Fixture With Anatomical Features on Bottom Face

This observation demonstrates that adding features to the modified fixture to account for the infant anatomy has an impact on the results, preventing full contact or conformance of the crib bumper around the entire perimeter of the fixture base. Full conformity around the face will likely present a hazard involved with restricted breathing. However, breathing air flow is also drawn through the crib bumper material. As shown in the ESMC staff memorandum, some crib bumpers/liners can have pressure/flow characteristics similar to mesh liners. Although there may be conformance to the face with a crib bumper/liner, there may still be adequate air flow. As such, no simple test for facial conformance can be recommended. A conformance assessment for crib bumper/liners cannot be determined by any simpler test at this time.

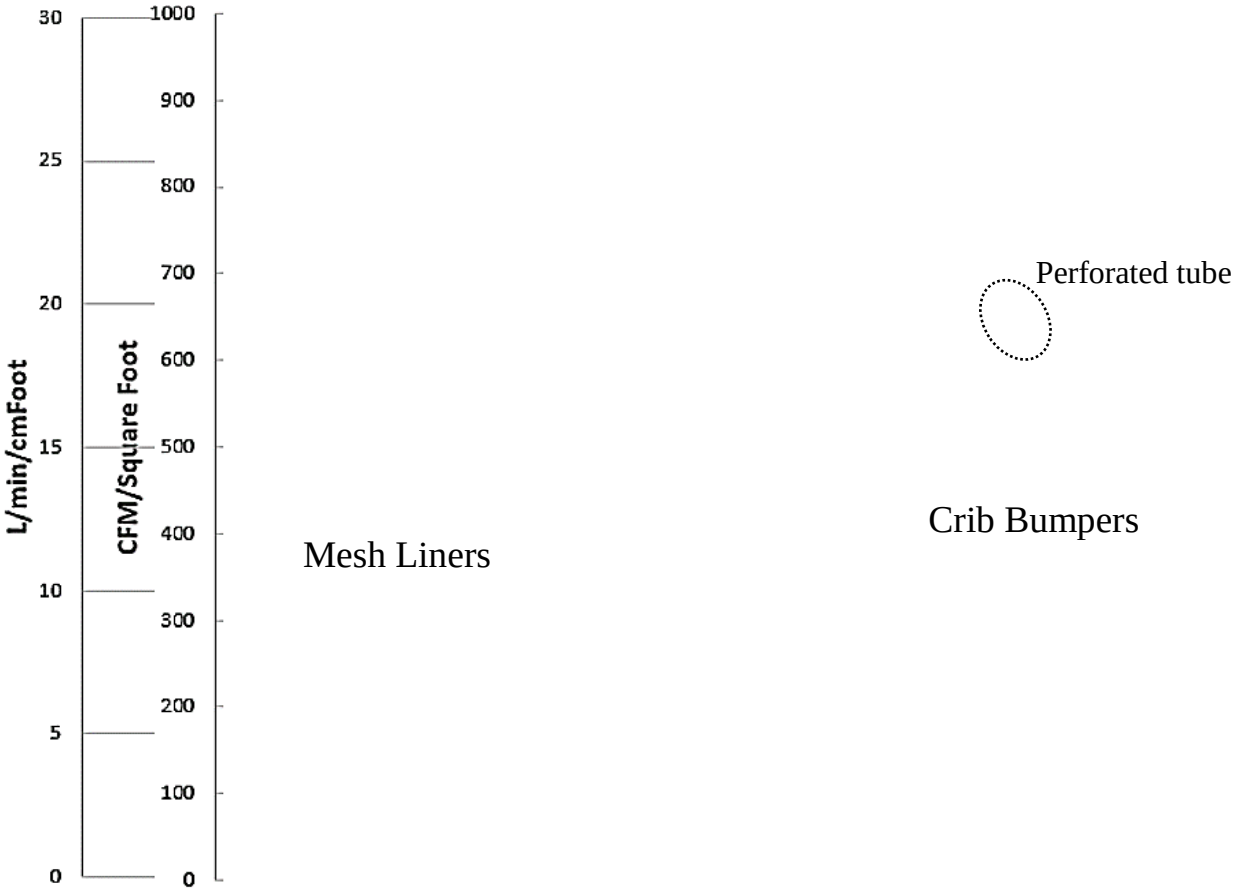
IV. AIRFLOW TESTS OF CRIB BUMPER/LINERS

Staff conducted air flow testing of 16 selected bumper and mesh liner[74] samples using a Frazier Air Permeability 2000, which tests to ASTM D737 – 18. The eight mesh samples and eight bumper samples are described in the Phase II section in the ESMC staff memorandum. The eight bumper samples measured from 0.25 inches (0.65 cm) to 0.73 inches (1.8 cm) thick. Six bumper samples were stuffed with a polyester fiber, one had a closed-cell foam filling, and one

[74] The same products tested in ESMC staff's phase II airflow testing.

contained perforated plastic half tubes. In the Frazier test, fabric is clamped on a table and over a 2.75 in (7.0 cm) diameter, 0.041 ft^2 (38 cm^2) area, open conduit through which air is drawn. In the Frazier test method, air flow is determined from tabulated data using the air pressure measured across the specimen during the test. Air flow is reported as cubic feet per minute per square foot of fabric area. Staff modified the clamping force of the test apparatus to hold all bumpers/liners with equal force. The sample bumpers/liners were held to the test table with weights applied to the Frazier test clamp, instead of using the mechanical leverage part of the clamp. The hold-down force applied was 4.5 lbf (20 N), which was selected to provide a minimally effective seal for the typical bumper or liner.

Test results are grouped into mesh and bumper categories in Figure 7. Mesh samples ranged in air flow from 496 to more than 900 cfm/sf (15 to 27 L/min/cm2). Bumper samples ranged from 15 to 638 cfm/sf (0.5 to 19 L/min/cm2), which includes the perforated plastic tube sample. However, that sample is not a typical padded bumper and also has the open quality of a mesh liner. Considering the perforated plastic tube sample as a distinct or as a mesh-like product, bumper samples would have ranged in air flow from 15 to 292 cfm/sf (0.5 to 9 L/min/cm2). With that concession, Figure 7 indicates a separation of about 200 cfm/sf (6 L/min/cm2) between the lower air flow of traditional mesh, 300 cfm/sf (9 L/min/cm2) and traditional bumper, 500 cfm/sf (15 L/min/cm2) samples.



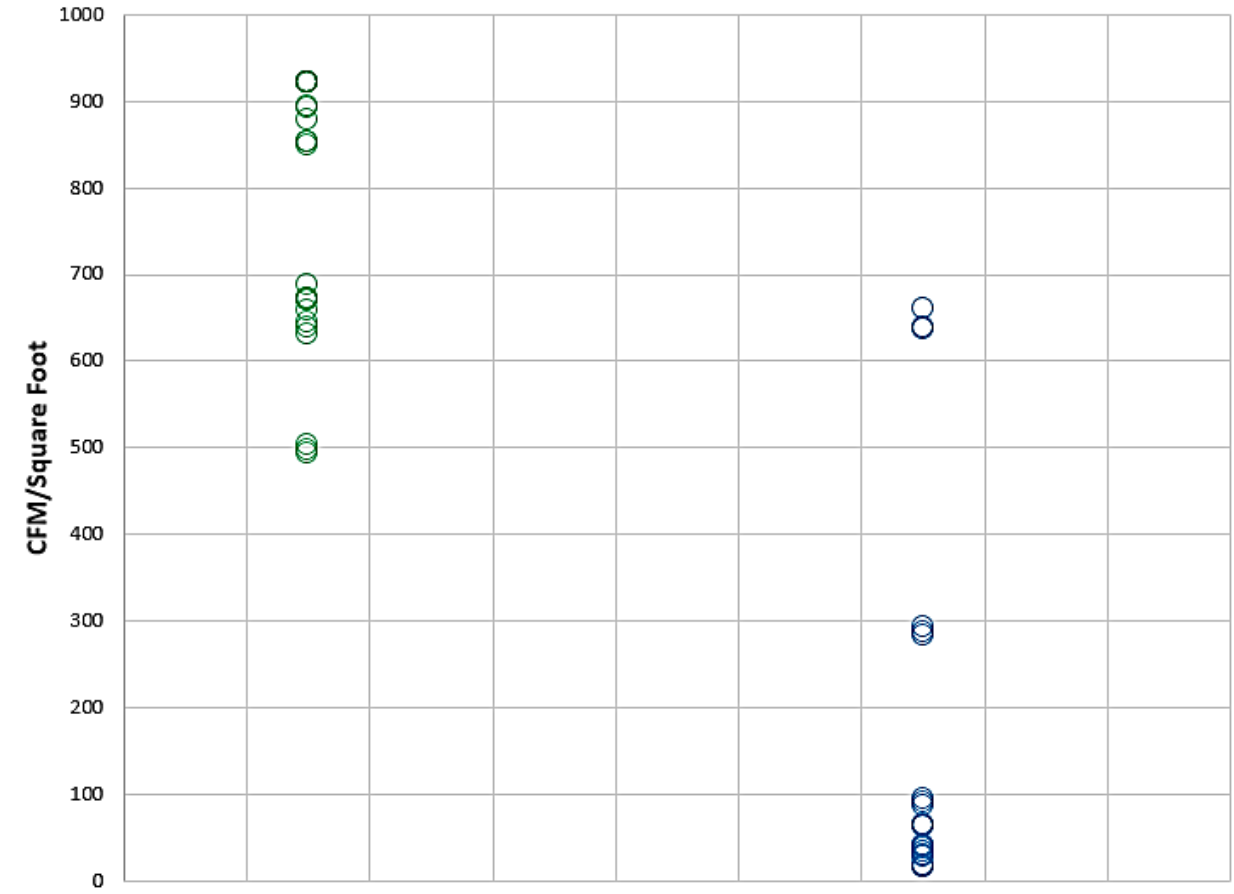


Figure 7. ASTM D737 – 18 Air Flow Tests
Comparison of Mesh Liners to Crib Bumper/Liners

These ASTM D737 – 18 air flow tests are reported as flow per area. To compare these test results to the requirement in BS 4578:1970, the ASTM D737 – 18 results can be reported in the same flow units. Table 2 compares the ASTM D737 – 18 flow rate test results with the BS 4578:1970 requirement. The ASTM D737 – 18 values were obtained by conversion of cfm to L/min and multiplying the result by the area, 0.041 ft^2 (38 cm^2), of the ASTM D737 – 18 test opening. The lowest flow rate calculated was 0.62 cfm (18 L/min) compared to the 200 ml/sec, or 12 L/min (0.42 cfm), BS 4578:1970 requirement. This conversion indicates that the lowest measured test flows from the ASTM D737 – 18 tests are higher than the requirement in BS 4578:1970 both of which exceed breathing rates expected for infants younger than 12 months of age when sleeping or resting in their cribs.[75]

[75] Tab D, HS staff memorandum, Table 3.

Table 2 Comparison of ASTM D737 – 18 Flow Rate
to the BS 4578:1970 Flow Requirement

Standard	Lowest Test Result cfm (L/min)	Highest Test Result cfm (L/min)	Requirement (cfm) L/min
ASTM D737 – 18	0.62 (18)	37 (1050)	--
BS 4578:1970	--	--	(0.42) 12

These ASTM D737 – 18 tests demonstrate that these traditional mesh liners have higher air flows than the padded bumpers when tested at the higher pressures of the Frazier 2000. However, air permeability measurements do not necessarily demonstrate hazardous conditions with crib bumpers/liners. To characterize the restriction on breathing through contact with crib bumpers/liners requires a model for human breathing, including breathing rate and volume, and contributing factors such as facial and airway dimensions and head weight. No simple modifications to ASTM D737 – 18 can accommodate such a human model. In addition, measured air flows in ASTM D737 – 18 for crib bumper/liners are out of the range of the 12 L/min airflow specified in BS 4578:1970, the latter being closer to, but still at least four times higher than expected breathing rates in infants who are sleeping or resting in their cribs. The BS 4578:1970 testing at 2 L/min reported in the ESMC staff memorandum indicates that padded bumpers and mesh liners can be differentiated by measured pressure differentials at an air flow closer to the expected breathing rates of infants who are sleeping or resting in their cribs. However, as explained in the HS staff memorandum, the result is not directly relevant because the differential pressures measured are many times lower than that for breathing infants. Staff made modifications to BS 4578:1970 to add additional anatomical refinements. Test results presented in the ESMC staff memorandum indicate that further work will be necessary to develop a test with those additions. Overall, staff would recommend the study of the restrictions on breathing on contact with crib bumpers/liners using the BS 4578:1970 test method, as further modified and refined by staff, over the ASTM D737 – 18 test method.

V. RECOMMENDATIONS

A. Adequacy of Performance Requirements in ASTM F1917 – 2012

This section discusses how each hazard pattern associated with crib bumper/liners relates to ASTM F1917 – 2012, the voluntary standard that includes crib bumper/liners. The hazard patterns and incident data are taken from the Division of Hazard Analysis memorandum. Fatal incidents occurred between 1990 and 2019. Nonfatal incidents occurred between 2008 and 2019. LSM staff believes that performance requirements in ASTM F1917 – 2012 can be improved to better address the hazard patterns associated with crib bumper/liners.

Entrapment/Wedging

Forty-four (53 percent) of the 83 reported fatalities in which there was crib bumper contact involved entrapment or wedging against the crib bumper. Among them were 25 deaths where the child was entrapped or wedged between a bumper and another object in the crib. The remaining 19 deaths included 13 associated with contact with the crib bumper when the child was entrapped between the crib mattress and the side of the crib, and six that were miscellaneous entrapments or wedgings, including wedging beneath the crib bumper. In addition, 17 reported nonfatal incidents (15 percent) involved contact under or behind the bumper (10 incidents) or entrapments against other objects in the crib (7 incidents), and 39 nonfatal incidents (35 percent) involved slat entrapments of limbs, mostly legs.

The ASTM F1917 standard has requirements for crib bumper/liner thickness and means to attach the crib bumper/liners. The attachment requirement specifies that crib bumpers/liners must "be capable of being secured at or near all corners and at the midpoints of the long sides of the crib." Staff is concerned that some nonfatal cases involved cribs without ties at the bottom, and that current requirements may not adequately keep bumpers against the side of the crib, creating a potential wedging hazard. Additionally, attachment intervals may not adequately prevent sagging, particularly given the range of crib designs (*e.g.*, number and sizes of crib slats) to which bumpers might be attached. Improved requirements to address these hazards, including head entrapment hazard with the crib bumper and slat entrapment, would include a test for an adequate fit of the crib bumper to the crib sides.

The ASTM F1917 thickness requirement does not place limits on the firmness of bumpers that can pass through the 2-inch (51 mm) thickness test fixture. Crib bumper/liners could be produced that are soft and can conform to the face yet still be 2 inches or less in thickness. The current thickness requirement alone also allows for bumpers that are somewhat thicker than 2 inches but are soft and compressible enough to pass through. The standard has no requirement that specifically addresses the hazards associated with soft crib bumper/liners conforming to the face. A firmness requirement for the crib bumper could address this suffocation hazard more directly than the current thickness requirement, since a bumper/liner that does not conform to the face as easily would be less likely to lead to suffocations.

Hazard Patterns Involving Neck/Airway Constriction – Near Strangulation or Entanglements and Choking or Ingestion of Small Parts

Fifteen of the 113 nonfatal incidents were in these two categories. Eight of these incidents involved near strangulation or entanglements in which a crib bumper tie, a piece of the crib bumper, or loose threading entangled with, typically, the head, mouth, or neck. The remaining seven incidents involved choking on or the ingestion of a loose piece of the bumper or stuffing within the crib bumper. There were no fatalities attributed to strangulation or choking. The ASTM F1917 – 12 standard includes a strength test for crib bumper ties. However, that test does not apply to all attachment means. In addition, there are no strength tests for other constructions that can fail, such as decorative components or seams. New requirements for strength of all attachment means, decorative components, and crib bumper/liner seams would address hazards associated with strangulation, entanglements, and choking/ingestion.

B. Staff Recommended Changes to ASTM F1917 – 2012

After analysis and testing, staff developed the following list of recommended changes to ASTM F1917 – 2012. Staff made these recommendations to the Subcommittee Co-Chairman for ASTM F15.19, Infant Bedding in a letter dated April 26, 2018, and in subsequent meetings with ASTM Task Groups. ASTM intends to ballot many of these recommendations, and has already balloted variations of a definition for crib bumpers. These recommendations address the hazard patterns identified with crib bumper/liners, including entrapment, suffocation, strangulation, and choking. Staff is also recommending some revisions and additions to address parts of the voluntary standard that require clarification. Section numbers or names, as appropriate, are included. Detailed tables that show staff's recommended revisions relative to ASTM F1917 – 12 can be seen in Tab F.

Terminology (Section 3)

Staff recommends adding a definition for "crib bumper/liners" (or similar phrase) that encompasses all products intended to be placed against the interior perimeter of a crib to cover the crib slats or spindles. F1917 – 12 currently lacks a definition for crib bumper/liners, and includes terminology, requirements, and test methods that refer to: "bumper pad" (6.3, 7.4, 7.4.1, Note 2); "bumper guards" (3.1.4, 5.1, 5.4); "headboard bumper guards" (3.1.4, 5.1), "headboard/bumper set" (8.2.1), "bumper" (3.1.1, 6.2, Figure 1, 7.3, 8.2.1); and "crib bumper" (6.2). Staff believes changing these various terms to "crib bumpers/liners" will improve consistency in the interpretation of requirements, which would further reduce the risk of injury associated with crib bumpers.

Staff recommends adding a definition for "conspicuous," which is referenced in Product/Package Marking, sections 8.1 and 8.2, and is used to identify the appropriate placement of the on-product warnings. This subject is discussed in the Human Factors memorandum. Staff believes adding the definition for "conspicuous" will help to ensure the labels are displayed where the user is most likely to view them.

Staff recommends that the word "ties" be changed to "attachment means" in all sections that have requirements and test methods that apply to "ties." Staff believes changing "ties" to "attachment means" will better encompass all means that crib bumpers/liners are secured, including those that are not tied.

General Requirements (Section 5)

Staff recommends replacing the requirement for crib bumper/liners to be capable of being secured "at or near all corners" of a crib (5.4), which is vague and open to interpretation. A more defined requirement would clarify what constitutes conformance. Staff recommends a new requirement and test method in sections 6 and 7. This is discussed in detail in the next section.

Staff recommends that requirements for the lengths of bumper ties (5.1) and decorative components (5.2) shall apply both before and after testing. Staff believes both the as-received bumper tie length to the consumer and the length after the pull tests should be determined and

evaluated to ensure that the "ties" are not lengthened due to testing and become a strangulation hazard.

Performance Requirements (Section 6)

Attachment means

Staff recommends a new performance requirement that crib bumpers/liners stay suitably attached to the crib sides, as determined by testing using a head probe on representative crib side panels. This requirement would replace the existing general requirement for bumpers to be capable of being secured at or near all corners (discussed above), and would have a corresponding new test method in section 7.

- Crib Bumper/Liner Entrapment in Openings - When tested in accordance with the entrapment in openings test, no opening shall allow passage of the small head test probe. Passage is defined as admitting the base of the probe.

Staff believes that this alternative attachment requirement and test method would reduce the risk of suffocation associated with infants accessing the spaces under and behind installed crib bumpers. The requirements would also limit the suffocation potential presented by a bumper that can be pulled away from a crib side and can come to lie flat on a mattress surface, either because it only had ties on its upper edge or because ties on either edge became detached.

Thickness Test

Staff recommends not limiting Maximum Bumper Thickness (6.2) to bumpers that are filled with "fibrous material." Because bumpers constructed from other materials still could be soft and pillow-like, and pose the same hazard, staff recommends that all products under the scope of "crib bumper/liner" should be required to pass the thickness test.

Staff recommends setting a lower limit on the rate in which the crib bumper/liner slides through the slot of the bumper thickness test fixture to no less than 0.5 inch per second (12.7 mm/s) to more clearly establish pass-fail criteria. Most bumpers with thicknesses at or below 2 in (51 mm) slide through the fixture very quickly. Friction causes thicker bumpers to slide through more slowly, and staff's prior testing of crib bumper samples identified some bumpers that passed through the bumper test fixture at such a slow rate that staff found it difficult to determine whether the bumper technically passed or failed the test. The rate was selected to differentiate very slow slides from movements maintained by external influences that can affect test results, such as a swinging pull weight that restarts a stopped bumper. Staff also recommends that a smoothness requirement be added to the slot of the bumper thickness test fixture to provide more consistency between test laboratories. The recommended smoothness is a 1.6 Ra "roughness average" surface finish. This is the smoothness specification of staff's test fixture and is practical to achieve. Staff believes that both of these additional requirements—the recommended rate and the recommended surface finish—further reduces the risk of suffocation by improving a test laboratory's ability to identify crib bumpers that would fail the thickness test.

Attachments to Crib Bumpers/Liners

Staff recommends applying the requirement for Bumper Pad Tie Strength (6.3) to "decorative components" which would include many constructions that can be attached to crib bumper/liners. Staff also recommends changing the word "tie" to "attachment means," which is more broadly defined to include all methods of attaching the bumper to a crib, and includes ties. Staff is aware of nonfatal incidents involving detached decorative components and believes adding a strength requirement to those components will tend to reduce incidents.

Staff recommends adding a strength requirement for bumper seams to address incidents involving bumpers "coming apart" or opening at the seams. Staff's recommended test method is based on the tension test for seams in ASTM F963 – 17[76], section 8.9.1. Staff believes adding a strength requirement to seams will tend to reduce choking and strangulation hazards by limiting access to filling materials within the crib bumpers/liners and to any separated materials.

Firmness

Staff recommends adding a firmness requirement to limit the conformance of crib bumper material around an infant's face and reduce the suffocation hazard. Staff's testing indicates that AS/NZS 8811.1 has differentiated between products in a sampling of padded crib bumper/liners, and staff's recommended firmness requirement is based on the test method and test fixture in AS/NZS 8811.1, with modifications. In review of the test method and fixture in AS/NZS 8811.1, staff recommends that crib bumper/liners equal or less than a 0.59 in (15 mm) thickness should not require testing, since the feeler arm and 0.59 in base of the fixture determine a thickness threshold below which crib bumper/liners will not make contact. Staff recommends some modifications to test and fixture specifications. Recommendations include:

- Specifying test locations for crib bumpers/liners for rectangular and circular cribs, as well as for vertical crib bumpers/liners attached to crib rails,
- Adding specifications for test equipment, including for the level indication and the feeler arm,
- Allowing crib bumpers/liners to be attached for testing in a manner that approximates securing the crib bumper/liner to crib rails, as well as on a flat surface.

Test Methods (Section 7)

Staff recommends changes to the test methods in ASTM F1917 – 12 to strengthen the requirements and also to support staff's recommended performance requirements. These are described below.

Crib bumper/liner entrapment in openings test

Staff recommends adding a test method to support staff's recommended requirement for entrapment in openings that replaces the requirement for crib bumpers/liners to be capable of being secured at or near all corners. This test method was developed with the ASTM Bumper

[76] F963 – 17 Standard Consumer Safety Specification for Toy Safety.

Attachment task group. ASTM is developing a similar requirement for consideration by the subcommittee. The recommended test method includes the following:

- Test platforms. Staff recommends standardized crib test platforms that represent typical crib construction. Test laboratories would prefer to use standard platforms to ensure consistency among laboratories. While most cribs are rectangular with consistent dimensions to fit standard crib mattresses, cribs typically vary in construction, including in shapes and numbers of spindles and presence of solid side panels. Staff recommends rectangular test platforms that have dimensions, including inside length and width and slat or spindle spacing that are consistent to those specified in ASTM 1169 Standard Consumer Safety Specification for Full-Size Baby Cribs. Staff recommends a number of test platform configurations to test rectangular cribs, including open and solid panel types and differing numbers and shapes of spindles. Common spindle shapes are round and rectangular. The following recommended rectangular configurations model commonly available cribs. Staff recommends that bumpers/liners intended for circular cribs be tested on commercially available circular cribs.

  Test Platform A. This test platform is composed of two long panels with 16 round spindles each and two short panels with eight round spindles each.

  Test Platform B. This test platform is composed of one long panel with 16 round spindles, one solid long panel, and two short panels with eight round spindles each.

  Test Platform C. This test platform is composed of two long panels with 16 round spindles each and two solid short panels.

  Test Platform D. This test platform is composed of two long panels with 14 rectangular spindles each and two short panels with seven rectangular spindles each.

  Test Platform E. This test platform is composed of one long panel with 14 rectangular spindles, one solid long panel, and two short panels with seven rectangular spindles each.

  Test Platform F. This test platform is composed of two long panels with 14 rectangular spindles each and two solid short panels.

- Head probe. Use of an existing head probe that is used in similar child's products entrapment testing would provide suitable rationale and save development time. Staff recommends the head probe specified in ASTM F963, which is used to test for hazardous loops and cords, and is based on the 5^{th} percentile head length and breadth dimensions of an infant 0 to 3 months old (ASTM F963 – 03, Section A5.7.13).
- Test locations. Specific test sites indicated by the manner of attachment of the crib bumper/liner to the crib will not be addressed. Staff instead recommends testing at any location most likely to fail this new head probe test, including between at the top and bottom edges of the crib bumper/liner and the test platforms.
- Head probe test, accessible openings. As children may create openings by moving or stretching the fabric of the crib bumper/liner, a head probe test should begin by

establishing accessible openings into which the head probe may enter. The ASTM Bumper Attachment task group proposed and staff recommends that an accessible opening be created by exerting a force on the bumper/liner using an appropriate clamping device, equal to 3-lbf (13 N) and be directed horizontally away from, and perpendicular to, the test platform. The force is be applied gradually over a 5 s period and maintained throughout the head probe test.

- Head probe test. Staff recommends to insert the head test probe, tapered end first, into any opening created between the crib bumper/liner and the test platform, and rotate the head test probe to the orientation most likely to fail. The tester would then apply a force of 10 lbf (45 N) at the base of the small head test probe in a direction that is perpendicular to the plane of the opening.
- Testing in multiple configurations. Staff recommends repeating the head probe test at any locations on the crib bumper/liner most likely to fail. Repeat testing on the remaining test platforms.

Crib bumper/liner firmness test

Staff recommends adding a crib bumper/liner firmness test method based on AS/NZS 8811.1 to support the staff's recommended firmness requirement. The following recommended additions and modifications affect test procedures and test fixture dimensions.

- Test locations, rectangular cribs. Recommended test locations are based on the intended installation locations in the crib (long versus short side) and are relative to the length of the crib bumper/liner. Crib bumper/liners for short and long sides of rectangular cribs are to be marked along the bumper center line at the 1/3 and 2/3 length points for short sides and at the ¼, ½, and ¾ length points for long sides. The resulting distant between the 10 test locations is 9 to 14 in (229 to 356 mm) for all crib bumper/liners lengths. Staff believes the specified test locations are generally the most likely to fail the test because all are placed at the typically thickest middle portion of crib bumper/liners and are away from the ends.
- Test locations, circular cribs. Because crib bumpers intended for circular cribs would not be intended for particular "sides" of a crib, crib bumpers for circular cribs are to be marked at the center of 10 equal segments. The resulting distant between test locations will vary depending on the size of the circular crib, but should fall into the same 9- to 14-inch range as bumpers intended for rectangular cribs. Staff believes the required test locations are generally the most likely to fail the test because all are placed at the typically thickest middle part and are away from the ends.
- Test locations on vertical crib bumper/liners. For crib bumper/liners no wider than 8 inches (203 mm), with the long axis intended to be installed vertically on the crib side, mark the centroid of the bumper. Staff recommends this central placement to allow the feeler arm of the test device, which is on the outside of the fixture base, to reach the ends of the crib bumper. When installed, the lower end of the crib bumper will be nearest the crib surface and in close proximity to a resting infant's face.

- Feeler arm orientation. The feeler arm in AS/NZS 8811.1 is aligned with the centerline of the sleep surface for three test locations and in an orientation most likely to fail for the fourth location. Staff recommends that feeler arm orientations for crib bumpers be those most likely to fail for all placements on a crib bumper.
- Horizontal placement of the test fixture. Once placed, a freely supported test fixture on the sleep surface in AS/NZS 8811.1 must remain horizontal or the test must be restarted. Staff recommends modest manual adjustment of the test fixture be allowed to achieve a horizontal orientation. This change will avoid restarting and follow the intent that horizontal placement provides an even support of the test fixture.
- Securing a crib bumper for testing. Staff recommends an option that crib bumper/liners may be secured using the attachment means in a manner that approximates securing the crib bumper to crib rails. This will allow crib bumper/liners to be tested in an installed position that more closely represents use by consumers closer to an assembled state.
- Recommended fixture modifications. Additional specifications were recommended for the feeler arm and the level indicator. Dimensional changes to the test fixture were recommended to make the fixture more compact to facilitate maintaining a horizontal position.

Other Test Recommendations

Staff recommends changing the Bumper Pad Tie Attachment Strength (7.4) test method to apply to all "attachment means," including ties, and to decorative components, and seams. Staff's proposed test method for seam strength includes a criterion that, after testing, there shall not be an opening that permits insertion of a 0.22-inch diameter rod, which is based on the finger entrapment probe that is employed in many children's product tests.

Staff recommends adding a test method for assessing the permanence of product labels. Refer to the Human Factors memorandum for a discussion of this issue and specific recommendations.

Product/Package Marking (Section 8)

Staff recommends making revisions to *Product/Package Marking*. Refer to the Human Factors memorandum for a discussion of this issue and specific recommendations.

Instructional Literature (New)

Staff recommends adding a new section for instructional literature. Refer to the Human Factors memorandum for a discussion of this issue and specific recommendations.

VI. CONCLUSIONS

Staff's testing of a convenience sample of crib bumper/liner products demonstrates that AS/NZS 8811.1-2013 can differentiate between padded crib bumper/liner samples by firmness. In

contrast, all these products passed the thickness test in the current ASTM F1917 – 12 crib bumper standard, which did not differentiate between their firmness. Staff finds that the addition of a firmness test based on AS/NZS 8811.1-2013 to the performance requirements in ASTM F1917 – 12 would tend to reduce the hazard of entrapment/wedging of an infant's face into softer padded crib bumpers. Staff also finds other areas for improvement in ASTM F1917 – 12 that can reduce hazards, including addressing strangulation by expanding tensile testing to include decorative components and seams, and addressing entrapment/wedging by adding a requirement for testing the fit of the crib bumper to the crib. Revised warning requirements and a new instructional literature section are recommended and are discussed in the Human Factors memorandum. Staff was not, however, able to identify a standard to address breathability in a physiologically meaningful way.

TAB D: HS Staff Memorandum, "Crib bumper firmness and airflow, considering infant vulnerability to respiratory compromise"

TAB D

Executive Summary

This Health Sciences (HS) staff memorandum covers several topics that are germane to crib bumper-associated hazard patterns and to potential mandatory performance requirements for bumper firmness and bumper airflow characteristics that take into account "the safety of infants with compromised breathing," in accordance with the Commission's direction.

- Section I summarizes the Commission direction to staff in developing a crib bumper NPR.
- Section II summarizes information on seven new bumper-associated fatalities reported since staff's September 2016 crib bumper-related briefing package.[1] Infants ranged in age from 1 month to almost 8 months and, aside from a 2-month-old infant, whose head reportedly was wedged in a crib corner by a crib toy attached to the crib side, the reported scenarios were similar to those described in staff's previous crib bumper-related briefing packages. Section II also reviews 113 nonfatal bumper-associated incidents reported from January 1, 2008, to March 31, 2019.
- Section III provides more detailed tabular breakdowns of grouped data reported in Tab B (EPHA staff) for 113 fatalities, 113 nonfatal bumper associated no-injury concerns and injury reports, and the subset of 60 nonfatal reports of injury. When broken down by hazard category and individual victim age in months, disparate hazard patterns and infant age distributions are clearly evident for deaths versus nonfatal injuries; the data patterns helped to guide selection of appropriate infant breathing characteristics used in investigations of potential airflow test methods.
- Section IV provides summary information on Sudden Infant Death Syndrome (SIDS), including peak victim age range, which is identical to that of bumper associated infant deaths. An overlap between SIDS cases and suffocation cases is due to inability to clearly distinguish between these causes of death. A lack of uniform approaches and a diagnostic shift in SIDS age distribution can help explain why the same fatality data are frequently interpreted differently both within and outside the forensic community. Recent evidence indicates that most SIDS deaths are not random, with up to 70 percent of victims found to have atypical brainstem anatomy and chemistry at autopsy. This has important implications, because the brainstem is a key area involved in control of autonomic functions such as infant breathing, heart rate, blood pressure, body temperature, and sleep; these control systems gradually adapt to life *ex-utero* during the first 3 to 4 months.
- Section V summarizes the Australian/New Zealand (AS/NZS 8811.1:2013) firmness standard, which staff considered for the draft proposed rule. Occlusion of airway openings clearly can present a suffocation risk. Theoretically, inclusion of an AS/NZS 8811.1-based firmness test in the draft proposed rule could improve the safety of crib bumpers by offering some protection against smothering-type suffocation deaths in situations where the victim's face may be pressed against a bumper so as to partially occlude external airway openings due to an applied force, such as the infant's head weight, or due to wedging by a sibling or large object in the crib. It would also improve safety in situations where, due to initial lack of lower edge ties in some ASTM F1917–12 compliant padded bumpers, or damaged bumpers where ties detached, some bumpers might be able to protrude into the sleep area, and come to lie horizontally on the crib mattress. In this position, a bumper could present a smothering–type suffocation hazard similar to a quilt or any other thick, compressible infant bedding that is able to conform to, and occlude, airway openings of a face down, prone positioned young infant who has inappropriate reflex responses to developing hypoxia.

- Section VI concerns the Commission's direction to staff to develop a mandatory bumper airflow test. Staff provides information needed to understand and assess the permeability-based airflow test method ESMC staff explored, as follows:
    - An overview of fetal and neonatal infant lung development, drawing attention to pertinent physiological factors affecting infant vulnerability to respiratory compromise. Preterm delivery, especially if it occurs prior to completion of 35 weeks gestation, can seriously compromise an infant's acute and long-term lung function. Immediate, dramatic physiological changes to the lungs that begin with an infant's first breath are described, and inspiratory pressures healthy newborns must generate to first aerate their lungs are detailed (from -30 to -70 cm H_2O).
    - Key descriptors of infant age that explain why chronological birth age, as used in CPSC databases, is not necessarily a reliable indicator of infant gestational age at birth.
    - Commission direction to staff for a mandatory bumper airflow test, suggestions for method starting point considerations, and rationale for an airflow test approach
    - Several subsections on lung measures and mechanics, which explain that lung mechanics and different pressures involved during a single breathing cycle are extremely complicated, vary dynamically throughout the cycle, and are also influenced significantly by activity level. Reference data are identified for tidal volumes, respiratory rates, and respiratory minute volumes of healthy, sleeping infants at different ages, and also for healthy preterm infants and more vulnerable preterm infants suffering from bronchopulmonary dysplasia (a complication that can result from a neonatal need for mechanical ventilation and supplemental oxygen treatment).

    The following summarizes HS staff's main recommendations and findings related to ESMC airflow tests:

    - For ESMC staff's phase II airflow tests of bumper and liner products, HS staff recommended a 2 liter per minute (L/min) airflow rate to approximate quiet breathing in a sleeping 3-month-old term infant. This recommendation reflects the fact that the 2 to 4 month age range is common to: a) the majority of the bumper fatal incident data; b) the peak age range for SIDS deaths; and c) the developmental timeframe when an infant's homeostatic systems controlling important autonomic respiratory, cardiovascular, and thermoregulatory functions, as well as sleep organization and arousal, are actively adapting and maturing from their *in utero* fetal set points.
    - Despite intense searching of medical literature and authoritative academic text books, HS staff was unable to identify any reference values for pressures that a healthy sleeping 3 month old infant need generate to maintain a normal air intake rate of 2 L/min. Findings indicate such reference values have not been specifically documented for such healthy populations. As such, although HS staff considers it theoretically possible that an airflow test with appropriate limits might improve bumper safety, presently, staff is unable to identify appropriate, physiologically meaningful reference values for peak inspiratory or mean airway pressures that are relevant to young infants who are capable of breathing spontaneously while sleeping without any respiratory support. Staff reasons that an appropriate range of values, which might eventually form the basis of a differential pressure limit for bedding-related airflow tests, is likely to range from at least 1 cm H_2O (10 mm H_2O; 0.394 inches H_2O) based on resting adult PIP, to no more than 10

to 12 cm H_2O (100 to 120 mm H_2O; 3.937 to 4.724 inches H_2O) as used to wean infants off mechanical ventilation.

- Staff discusses ESMC staff's findings on comparative pressure differentials needed to maintain airflow through eight padded crib bumpers and eight mesh liner products, at flow rates of 2 L/min and 12 L/min, as documented in Tab G. A 200 ml/sec (12 L/min) flow rate is specified for airflow tests of infant pillows in British standard, BS 4578:1970, and (ii) BS 1877-8:1974. HS staff considers the 12 L/min flow rate too high for any sleeping individual, and especially inappropriate for a young infant. Currently, HS staff is unable to conclude whether there is any physiological relevance to the very small mean pressure differentials measured for bumpers at 2 L/min (mean ± standard deviation in the order of 0.014 ±0.013 inches H_2O [0.353 ± 0.333 mm H_2O; 0.035 ± 0.033 cm H_2O]), which are significantly lower than the ranges cited above as likely to be physiologically relevant. Of note, no discernable pressure differentials could be measured for liner products at 2 L/min.

- Section VII summarizes staff's recommended changes to ASTM F1917–12 that it considers can improve safety of crib bumpers and liner products. The ASTM Infant Bedding Subcommittee is taking action on staff's recommendations for a bumper firmness test. HS staff has provided some reasoning to explain why this requirement, and other recommendations for bumper attachment, could further reduce the risk of injury associated with bumpers by reducing the likelihood that bumpers will be able to conform to a vulnerable infant's face to fully or partially occlude airway openings. As noted above, there are still too many uncertainties that prevent HS staff from making recommendations for an appropriate threshold pressure limit for a crib bumper or liner airflow test that is based on the British Pillow standard test methodology for airflow through infant pillows.

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
ROCKVILLE, MD 20850

MEMORANDUM

Date: August 22, 2019

To: Timothy P. Smith, Project Manager, Crib Bumpers Project
Division of Human Factors, Directorate for Engineering Sciences

Through: Alice Thaler, D.V.M., M.S. Bioethics
Associate Executive Director,
Directorate for Health Sciences

Jacqueline Ferrante, Ph.D., Division Director
Division of Pharmacology and Physiology Assessment
Directorate for Health Sciences

From: Sandra E. Inkster, Ph.D. Physiology, Pharmacologist
Division of Pharmacology and Physiology Assessment
Directorate for Health Sciences

Subject: Crib bumper firmness and airflow, considering infant vulnerability to respiratory compromise

I. Introduction

In the FY 2017 operating plan the Commission directed staff to begin rulemaking activities for a crib bumper safety standard, under section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA).[*] As detailed in the briefing memorandum of this current briefing package, the Commission directed staff to develop a mandatory standard for crib bumpers that is more stringent than the current applicable voluntary standard, ASTM F1917 –12, *Standard Consumer Safety Performance Specification for Infant Bedding and Related Accessories.* Two of the additional specific tasks directed staff to "at a minimum (1) develop a performance requirement and test method to show that a crib bumper is firm enough not to conform to the face of an infant, based on known anthropometric parameters; (2) develop a performance requirement and test method based on known infant inhalation and exhalation requirements and anthropometric parameters to demonstrate that a crib bumper matches or exceeds the airflow characteristics of mesh or mesh-like materials, taking into account the safety of infants with compromised breathing."[†]

[*] See CPSC Fiscal Year 2017 Operating Plan, 10/19/16 https://www.cpsc.gov/s3fs-public/CPSCFY2017OpPlan.pdf

[†] Note: as consensus has not yet been reached regarding product terminology to be used in ASTM F1917, unless otherwise stated in this briefing package memorandum (i) the term bumper applies to traditional crib bumper designs consisting of an internal compressible filling/padding (often polyester) enclosed within a woven fabric cover, and (ii) the term liner applies to any "mesh-liner type" product (*i.e.*, a relatively thin product that has a mesh-like external surface rather than a woven fabric cover) regardless of whether the product consists of a single layer of compressible mesh or a separate thin padding contained within a mesh cover.

II. Data Review

Fatal Incidents

In staff's earlier, 2016 briefing package on crib bumpers,[1] a multidisciplinary team applied a consensus approach to assign each fatal case to one of the following hazard pattern categories[*]: *1) Entrapment/Wedging Against Object in Crib; 2) Entrapment/Wedging in Crib Perimeter; 3) Entrapment/Wedging, Other; 4) Contact With Possible Entrapment/Wedging; 5) Contact Without Entrapment/ Wedging; 6) Contact Outside Crib (Not used in a Crib); and 7) Incidental.* Cases where available information did not indicate any evidence of bumper contact or involvement in the death were assigned to the "Incidental" category. In addition, the multidisciplinary team carefully considered information on the reported "as found" position of the victim's face relative to the crib bumper, and HS staff reviewed the reports from a physiological perspective to assess whether the absence of a crib bumper would likely have impacted the fatal outcomes. The 2016 briefing package included detailed reviews of fatal incident data from both Health Sciences (HS) and Human Factors (HF) staffs' perspectives. HS staff has written three prior assessments of available fatal incident information.[2,3,4]

Epidemiology Hazard Analysis (EPHA) staff's memorandum (Tab B)[5] reports a total of 113 fatalities associated with crib bumpers that are known to have occurred from January 1, 1990, through March 31, 2019.[†] Staff updated the previous 2016 fatality data that reported 107 fatal incidents,[‡] to reflect the removal of a duplicate record, updates of 2 cases, amendment of 1 case, and addition of 7 new cases as detailed below:

- 2016 briefing package Tab D records #94 and #95 were identified as duplicates of the same 2013 incident involving a 1 month-old boy. Case records are now consolidated as record *#96, Incidental/ Unlikely* in the 2019 dataset.

- Updates received for two previously reported fatalities consist of color photographs of death scene reenactments; previously, only indistinct black and white photocopies of these images were available. Despite much improved image quality, the photographs do not provide any useful new information. The records for these two cases are the same in the 2016 (Tab D table) and 2019 data sets *(#9, 2MOM (1992) - Contact without Entrapment Wedging/Unlikely; #46, 4MOF (2007) Contact without Entrapment Wedging/Unknown).*

- To avoid confusion, the location of one incident has been amended from a day bed to a toddler bed. As was noted in the 2016 briefing package, the incident report depicts a toddler bed and clearly reports mattress dimensions consistent with a crib mattress/toddler bed,

[*] Details of these hazard pattern categories are found in staff's 2016 briefing package (briefing memorandum; ESHF staff memorandum).
[†] Excel file of crib bumper-associated cases found in CPSC databases as of 03/31/19 (May 2019, A. Suchy, EPHA).
[‡] A. Suchy, EPHA 2016 Crib Bumper package memorandum reported 107 fatal incidents for the period January 1, 1990 - March 31, 2016 (Entered into CPSC databases as of 03/31/16).

rather than a twin mattress that is typically used for a day bed[*] *(case #29 11 MOF, Contact Outside Crib/Likely in 2016 and 2019 datasets).*

- In the seven new incidents, infants ranged in age from 1 month to almost 8 months. The reported scenarios were generally similar to those described in previous staff reviews.
    - Four cases involved *Contact without Entrapment Wedging* (2 month-old female (MOF), 3 MOF, 4-month-old male (MOM), and 6 MOM – all with unclear face position).
    - Two cases involved *Entrapment/Wedging Against Object in Crib* (1 MOF wedged by a-pillow and an unusual case of a 2 MOF whose head reportedly was wedged in a crib corner by a crib toy attached to the crib side).
    - The remaining case involved *Entrapment/Wedging in Crib Perimeter* (7 MOM whose face was pressed into a mattress after his body fell through a gap of a structurally defective crib).

Nonfatal Incident Reports and Complaints

HS staff's 2016 briefing package memorandum did not review nonfatal data. For this memorandum, staff reviewed nonfatal incident scenarios and consumer concerns to help further understanding of actual or purported crib bumper-related safety concerns, in order to help inform whether the Commission's recommended changes to current product performance standards requirements might be expected to further reduce the risk of injury associated with crib bumpers *(see Section V and VI).* HS staff reviewed available information for each of the 113 nonfatal reports to CPSC databases that mention or depict a crib bumper, as reported by EPHA staff for the period January 1, 2008, through March 31, 2019 (Tab B).

The mention or depiction of a crib bumper in these reports does not necessarily mean that the bumper product was the product of concern to the individual submitting the report, or that any bumper-related injury or incident actually occurred. In multiple reports, consumers identified only specific crib products of concern by manufacturer and complained that their cribs experienced structural failures (*e.g.*, drop-side rail detachment, slat detachment) or that the crib design allowed limb entrapments between slats of intact cribs. Sixty of the nonfatal reports did mention that an injury occurred. In the remaining 53 nonfatal reports, there were 3 incidents where injury status was unclear, and 50 reports where either:

(i) a non-injury incident was documented, though injury (not necessarily bumper related) was thought to be possible or narrowly avoided, or

(ii) consumers submitted non-incident complaints expressing mixed concerns, mainly, but not exclusively, directed at bumper/liner products (*i.e.*, insufficient number or detachment of ties, poor quality control of other bumper materials and construction, poor fit in crib, unpleasant odor, or potential suffocation or strangulation hazard).

EPHA staff provides the following information for nonfatal reports: injury status, victim sex and age group, and year of reported incident/complaint; it also provides a breakdown of the

[*] The incident mattress measured 48″ x 24″ (crib size), whereas day bed mattresses typically measure 75″ x 39″ (twin) see http://homeguides.sfgate.com/daybed-mattress-vs-twin-mattress-95642.html

113 nonfatal reports into eight hazard categories that EPHA staff considered most representative of the primary hazard pattern of concern (see Table 7 of Tab B).

Limb entrapments between crib slats* represent the main nonfatal hazard category, but 37 of the 38 reports concerning slat entrapment were submitted as specific safety concerns regarding crib design and slat spacing (36 IPII reports and 1 NEISS† case).

- The specific crib manufacturer or model of concern was identified in all 36 IPII reports, but not in the 2 NEISS reports (both of which involved arm entrapment).
- Although most of the slat entrapment reports indicate that limb entrapment between crib slats occurred despite the presence of a crib bumper, the bumper products were not the subject of the complaint and only 8 IPII cases provided any details of bumper products, specifically mentioning that they were "breathable" or mesh liner-type products that did not prevent limb entrapment.
- In multiple reports a bumper is simply mentioned as being present or shown in an incident photo. Staff took a conservative approach by including these unclear, somewhat nebulous cases in the dataset for nonfatal crib bumper reports.

NEISS Cases: In fourteen nonfatal incidents, injuries of victims, ranging in age from 5 to 17 months, were evaluated in a NEISS hospital emergency room (ER). Injuries resulted from:

- Arm entrapment between crib slats (2 cases: 5 MOM and 6 MOM)
- Ingestion of an unspecified plastic part from a bumper (1 case: 13 MOF).
- Climbing or Climb Out; specifically, these 11 cases, none of which required hospital admission, involved 7 head injuries, 1 facial injury, and 1 lower back injury due to falling out of a crib (9 victims ranging from 7 to 17 months of age); 1 head impact injury due to a fall within a crib (10 MOF), and 1 leg injury likely involving a fall within a crib consequent to slat entrapment of lower limb (13 MOM).

All but one of the nine victims who fell out of a crib were older (between 9 and 17 months of age); in the case of the youngest 7-month-old fall victim, the crib mattress was at its highest setting, which raises the possibility that the short distance between the mattress surface and top of the side rail may have allowed the infant to pull up to stand, lean over the side rail, then overbalance and fall from the crib, as opposed to having climbed out. The NEISS narratives of nine cases of falls from a crib suggest that in eight cases parents witnessed their infant using a crib bumper to help them climb out of the crib. However, additional incident information for six cases was acquired by subsequent computer-assisted telephone interview (CATI) with the parents. Four of the six cases clearly reported the falls were not witnessed and only one case clearly reported the fall was witnessed. The CATI information for the remaining case was contradictory because the mother first reported the fall was witnessed, but later responded that her back was turned when the fall occurred.

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* Note: crib designs vary; side components can be flat slats of varying widths or rounded spindles of varying diameter. For convenience, in this memorandum, HS staff uses *slat* as a generic term for any slat or spindle.

† National Electronic Injury Surveillance System (NEISS) hospital ERs are part of a national, statistically representative, ER network that collects and reports information on consumer product-related injury cases to CPSC's NEISS database.

Injuries in all but one of the fourteen NEISS cases were considered relatively minor and victims were released the same day following examination or treatment (two infants underwent CAT scans to evaluate head injuries). Details are limited for the single NEISS case where the victim was hospitalized for treatment of more serious injuries, which allegedly resulted from crib bumper use. The brief NEISS case narrative states "*DX FX Humerus/FX Multiple Ribs: 6 MOM Father of PT reports PT has been get, arms stuck BTW crib rails, L arm wedged under crib bumper.*"[*]

Several of the nonfatal incident reports described scenarios of particular concern because they appear to be nearly identical to scenarios described in one or more of the fatal case reports. In these "near miss" nonfatal incidents, parents reported finding their infants in compromised positions when responding to unusual noises or simply checking on them. Durations when the infant was unattended ranged from a few minutes to several hours of overnight sleep. For example, infants were reported to be found as follows:

- still harnessed in an inclined infant sleep product (being used to maintain a supine sleep position) but with their body partially out of the recliner and head and neck hyperextended over one side *(case #34 - minor injury reporting a red mark on 4 MOM's head; case #41 reporting no injury to a 3 MOF)*
- wedged against the crib, beside, beneath, or outside of a non-inclined infant sleep positioner that was used to maintain a supine sleep position but that had "flipped" over *(cases #5, no injury to 4 MOF; #13, no injury to 2 MOF; #14, no injury to 3 MOM; injury status not specified in case #16, 1 MOF)*
- with feet touching the floor, torso wedged between the mattress support and a detached crib side, and a bumper around face/neck, consequent to an incomplete fall through a gap in a broken crib that caused a bruised forehead and facial scratches *(case #32, 18 MOM)*
- sitting on the floor between the main body of the crib and a partially detached side panel of a drop-side crib *(case #37, no injury to 12 MOM)*
- with face uncovered and directed toward the crib interior while their head was wedged between the crib mattress and a crib toy attached to the crib side rails (case #89, *no injury to* 7 MOM)

Some complaints noted bumper installation issues. These included complaints about: a complete lack of ties on the lower edge of the bumper *(cases #3, #8, #21, and #31)*; a lack of ties between corner attachments of shorter bumper panels corresponding to the short sides of a crib *(case #60);* and poor fit of a bumper in a crib due to insufficient ties *(case #20),* or insufficient bumper length *(case #23).* There were 12 complaints reporting that bumper ties detached from a bumper (cases #7, #28, #47, #56, #65, #76, #79, #88, #90, #91, #95, and #102). Missing or detached ties raised consumer concerns that

[*] While limb fractures are a possible outcome of limb entrapment between crib slats, fracture of an upper arm bone plus multiple rib fractures is not an expected outcome, so the implication that a crib bumper was involved in this infant's injuries is uncertain. The multiple bone fractures reported in different body sites might be consistent with *osteogenesis imperfecta*, a genetic disorder with varying degrees of severity that causes fragile brittle bones, and can manifest at different ages.

(i) an infant could become entrapped after inserting their head or limbs either under or over a loose-fitting bumper, into the gap between bumper and the crib side, or

(ii) that the bumper could present a potential suffocation issue if it sagged or collapsed onto the mattress surface or if the ties detached .

Although HS staff did not have access to incident bumper samples, it did examine some new exemplar bumper samples purchased by other staff. HS staff considers that, like most fabric items that infants might mouth, bumper ties do not pose a very likely risk of choking, nor does the tie length of products meeting current requirements present a likely strangulation hazard. However, the complaints suggest the possibility that part of an affected bumper could become repositioned from the vertical crib side allowing the bumper to protrude into the sleep area, where it possibly might come to lie on the crib mattress. In a horizontal position, a padded bumper could present a similar suffocation hazard to a quilt, or any other thick compressible infant bedding that is able to conform to, and fully or partially occlude, airway openings of a young infant lying prone with face straight down into underlying soft bedding.

Generally speaking, unless movement is restricted, complete or partial obstruction of airway openings is expected to prompt healthy sleeping infants to begin a sequence of airway defensive behaviors involving increasing levels of arousal (from sighs, grunts, head lifting and turning, limb thrashing, and ultimately to full awakening) until they can move their heads away to free airway openings or vocalize their distress by crying.[6] However, some young infants do not react appropriately to falling oxygen levels in blood (hypoxemia) most likely due to immaturity of autonomic control mechanisms or underlying pathophysiology. While lying supine (*i.e.*, facing up), if an infant gets his or her head underneath an improperly secured bumper, the overlying bumper probably would not be firmly pressed against the infant's face and likely would not cause complete occlusion of nose and mouth. However, a partial obstruction of airway openings could possibly result in increased airway resistance requiring increased breathing effort, which could also cause difficulties for subsets of infants having very immature or compromised respiratory systems (see section VI).

III. Fatal and Nonfatal Data as a Function of Hazard Pattern and Victim Age

Although section 104 rules generally do not discuss incidents in detail, this section addresses the Commission's direction to staff to develop an airflow performance test taking into account the safety of infants with compromised breathing. Given the significant physiological and developmental changes that occur by month as an infant ages, it is important to better understand each hazard pattern as a function of victim age in months. This was needed to help identify the appropriate age for infant breathing characteristics to be used in Directorate for Engineering, Division of Mechanical and Combustion Engineering staff's (ESMC) bumper and liner air flow tests (see TAB G).

Table 1A provides HS staff's detailed breakdowns of fatal incident data hazard patterns by each victim's post-natal age in months for all 113 fatal incidents. Tables 1B and 1C, respectively, provide similar breakdowns of all 113 nonfatal bumper associated reports and concerns, and of the 50 nonfatal reports involving injury as grouped by the hazard pattern categories reported by EPHA staff (Tab B).

For the fatality data, the majority of all deaths, including those the team considered *Incidental*, involve victims aged 6 months or less (82 of 113, 73 percent), with 71 of 113 (63 percent) aged 4 months or less. In contrast, the subset of 13 deaths due to entrapment/wedging in the crib perimeter mostly involves older, more mobile infants ranging from 8 months to 15 months of age (12 of 13 victims). Younger infants, with immature lung function, are inherently more vulnerable to respiratory compromise. (See sections IV and V.)

In contrast to fatality data, the nonfatal injury data are skewed towards older infants. No injuries are reported for infants aged 3 months or less (although some near misses are reported) and only 9 of 60 reported injuries involved infants aged 4 to 6 months. Limb entrapment between crib slats is the predominant hazard pattern accounting for 27 of the 60 cases of reported injury. Climb outs and climbing in the crib is the second leading cause of injury and 10 of 11 reports involved older infants aged 9 to 17 months; the other incident involved a 7 month-old infant.

Regarding limb entrapment, several consumers noted that installation of a traditional bumper or mesh liner did not prevent leg entrapment incidents. When viewed in terms of victim ages and the specific limb entrapped *(see table 1C),* the data suggests that bumpers are generally very effective at preventing arm and leg entrapments of younger infants when they begin to move around (younger than 7 months old), but, as would be expected, are less effective at preventing leg entrapments of older infants (at least 9 months old) who can stand up in a crib and so are able to insert a leg/knee between crib slats at a height above most traditional bumpers and mesh-type liner designs.

Table 1A. Breakdown of 113 reports of fatal injury (01/01/90 -03/31/19) by hazard pattern and victim age.

	Age (months)	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	≥24	Totals
Hazard Pattern	*Entrapment/Wedging Against Object in Crib*	7	4	5	4	1	1	1	1														1			25
	Entrapment/Wedging in Perimeter		1						1	1	5	1	2	1		1										13
	Entrapment/Wedging, Other		2		2	2																				6
	Contact With Possible Entrapment/Wedging		4		1															1					1	7
	Contact Without Entrapment/Wedging	1	9	3	6	2	2	1	1						1										1	27
	Incidental	3	10	6	1	2	1	3	1		1	1													1	30
	*Not Used in a Crib**		1		1							1										1			1	5
	Monthly Age Totals	**11**	**31**	**14**	**15**	**7**	**4**	**5**	**4**	**1**	**6**	**3**	**2**	**1**	**1**	**1**	**0**	**0**	**0**	**1**	**0**	**1**	**1**	**0**	**4**	**113**

Table 1B. Breakdown of 113 reports of nonfatal injuries, no-injury concerns, and/or other complaints (01/01/08-03/31/19) by hazard pattern and victim age.

	Age (months)	*1*	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*11*	*12*	*13*	*14*	*15*	*16*	*17*	*18*	*19*	*20*	*21*	*22*	*23*	*24*	*Age?*	*Totals*
Hazard Pattern	Slat Entrapment			1		1	3	1	1	3	1	2	7	1		2	1	1	1	1	1		2		2	6	**38**
	Slat entrapment-leg						*2*	*1*	*1*	*3*	*1*	*2*	*6*	*1*		*1*	*1*		*1*	*1*	*1*		*2*		*2*	*5*	***(31)***
	Slat entrapment-arm					*1*	*1*																				***(2)***
	Slat entrapment-both limbs			*1*									*1*					*1*								*1*	***(4)***
	Slat entrapment-other															*1*											***(1)***
	Climbing or Climb-Outs							2		3	1	1	2	1	1			1									**12**
	Under or Behind Bumper				2		1	2		1	1								1							2	**10**
	Near Strangulation/Entanglements					1	1					1	1	1					1							2	**8**
	Entrapped Against Object in Crib	1	1	2	3																						**7**
	Choking or Ingestion of Small Parts				1		1	1	1			1		1												1	**7**
	Other				1		1	1			1		1					1								8	**14**
	Concerns		1																							16	**17**
	Monthy age totals	**1**	**2**	**3**	**7**	**2**	**7**	**7**	**2**	**7**	**4**	**5**	**11**	**4**	**1**	**2**	**1**	**3**	**3**	**1**	**1**	**0**	**2**	**0**	**2**	**35**	**113**

Table 1C. Breakdown of 60 reports relating a nonfatal injury (01/01/08-03/31/19) by hazard pattern and victim age.

	Age (months)	*1*	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*11*	*12*	*13*	*14*	*15*	*16*	*17*	*18*	*19*	*20*	*21*	*22*	*23*	*24*	*Age?*	*Totals*
Hazard Pattern	Slat Entrapment					1	2		1	2	1	2	5	1		1	1	1	1	1	1		1		1	4	**27**
	Slat entrapment-leg						*1*		*1*	*2*	*1*	*2*	*5*	*1*		*1*	*1*		*1*	*1*	*1*		*1*		*1*	*4*	***(24)***
	Slat entrapment-arm					*1*	*1*																				***(2)***
	Slat entrapment-both limbs																	*1*									***(1)***
	Slat entrapment-other																										***(0)***
	Climbing or Climb-Outs							1		3	1	1	2	1	1			1									**11**
	Under or Behind Bumper						1	1		1									1							1	**5**
	Near Strangulation/Entanglements						1						1	1					1							1	**5**
	Entrapped Against Object in Crib				2																						**2**
	Choking or Ingestion of Small Parts				1			1	1					1													**4**
	Other				1						1															3	**5**
	Concerns																									1	**1**
	Monthy age totals	**0**	**0**	**0**	**4**	**1**	**4**	**3**	**2**	**6**	**3**	**3**	**8**	**4**	**1**	**1**	**1**	**2**	**3**	**1**	**1**	**0**	**1**	**0**	**1**	**10**	**60**

IV. Overlap Between SIDS and Asphyxia-Related Deaths

There are many similarities between the circumstances of SIDS deaths in infants under 6 months old and bumper-associated deaths of infants in the same age range that are attributed to suffocation; arguably, some might not differ. The definition and understanding of SIDS has evolved since it was first defined in 1969 as: "The sudden death of any infant or young child, which is unexpected by history, and in which a thorough post-mortem examination fails to demonstrate an adequate cause for death." During the 1990s, investigation of SIDs cases began to include examination of death scenes and review of clinical history. By 2004, concern about the changing patterns seen in the diagnosis of SIDS deaths led to an expert panel meeting in San Diego and a new general definition of SIDS as: "The sudden unexpected death of an infant < 1 year of age, with onset of the fatal episode occurring during sleep, which remains unexplained after a thorough investigation, including performance of a completed autopsy and review of the circumstances of death and the clinical history."[7] The "San Diego" SIDS definition included four additional subcategories intended to facilitate research and better understanding of SIDS. Of note, the circumstances of death for its "SIDS category II" states "Mechanical asphyxia or suffocation caused by overlaying not determined with certainty," which could apply to purported bumper suffocation cases. Risk of SIDS is recognized to be greatest when three factors, a vulnerable infant, a critical developmental period in homeostatic control, and an exogenous stressor(s), are present.[8] Historically, most SIDS deaths involved infants between 1 and 6 months of age, with a peak age range from 2 to 4 months.[9]

Over the last 15 to 20 years, an emphasis on the results of more complete autopsies, and greater reliance by child death review teams on death scene investigations and the use of doll reenactments, has led to identification of additional potential SIDS risk factors.[10] The changing patterns of deaths diagnosed as SIDS, in part reflects changes in coding systems, policies and preferences applied to cause-of-death determinations. In the United States, the resulting diagnostic coding shift, apparent for at least 15 years, has moved a significant proportion of the 2- to 4-month-old infant SIDS deaths to a non-SIDS diagnosis of accidental suffocation.[11] This is not altogether surprising since SIDS studies have identified various environmental risk factors as being potential asphyxiating (*e.g.*, prone position, hyperthermia, bed sharing, and soft bedding). As noted by Hunt, Darnall and McEntire (2015):[12]

> In reality, however, in many cases when such risk factors are present, there is no clear physical evidence of fatal airway compromise. Moreover, there are no objective criteria for fatal suffocation unless the scene investigation indicates obvious wedging or strangulation such that an underlying vulnerability would have been unnecessary to cause death. Otherwise, the conclusion is based on circumstantial evidence of varying degrees of certainty.

These authors include a figure that effectively illustrates the continuum of possible interactions between the extremes for inherent infant vulnerability and potentially asphyxiating environmental factors, which helps explain why identical scenarios can be interpreted differently by many reasoned, objective, individuals (Figure 1).

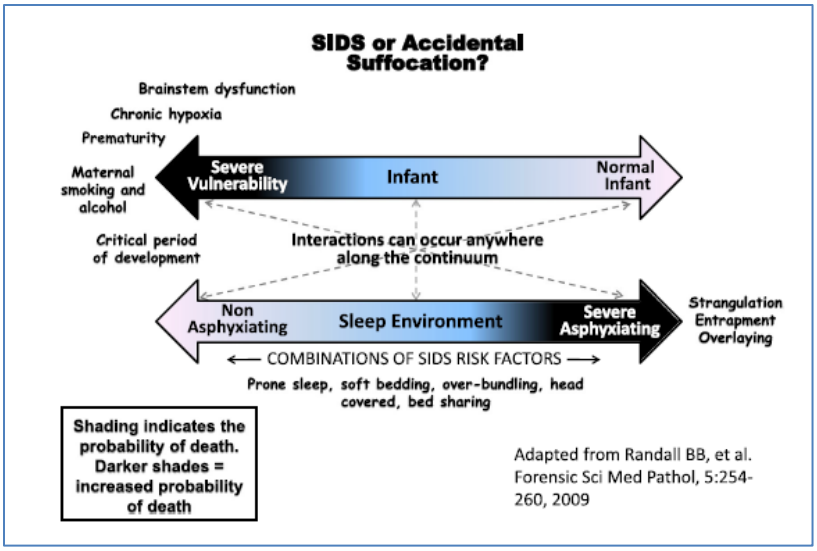

Figure 1. Schematic illustration of the spectrum of variability in risk for sudden unexpected infant death and the spectrum of variability in the degree of risk of the sleep-related environment, ranging from completely safe (non-asphyxiating) to potentially severe asphyxiating.
(copied from *Hunt, Darnall, McEntire, Forensic Sci Med Pathol (2015) 11: 283-288*)

The effects of classifying infant deaths in sleep settings using inconsistently applied diagnostic criteria is captured by the following conclusion of a recent 2017 paper reporting findings of a nationally representative survey study of U.S. medical examiners (MEs) and coroners, which aimed to quantify and describe variations in cause-of-death certification of Sudden Unexpected Infant Deaths (SUID)[*] cases[†]:

> US medical examiners and coroners apply variable practices to classify and investigate SUID, and thus, they certify the same deaths differently. This variability influences surveillance and research, impacts true understanding of infant mortality causes, and inhibits our ability to accurately monitor and ultimately prevent future deaths.[13]

Growing evidence indicates that most SIDS infants have preexisting vulnerabilities. In particular, studies show that up to 70 percent of SIDS victims have atypical brainstem anatomy and chemistry, which could be due to immaturity (SIDS risk is higher in preterm infants) or an underlying pathology, and is possibly affected by a mother's smoking habit during pregnancy. The brainstem regulates many important autonomic functions including respiration, heart rate,

[*] SUID cases include infant deaths certified as SIDS, accidental suffocation and strangulation in bed, and unknown cause.

[†] Death certificates are usually signed by MEs, forensic pathologists, and/or coroners. In the U.S., coroners are often elected officials, and, depending on the requirements of their office type (local county, regional, or state level) their expertise can range from little or no formal forensic training to that of an ME (some coroners are also MEs). Instructions for completing death certificates note: "The cause-of-death section consists of two parts. **Part I** is for reporting a chain of events leading directly to death, with the **immediate cause** of death (the final disease, injury, or complication directly causing death) on Line a and the **underlying cause** of death (the disease or injury that initiated the chain of morbid events that led directly and inevitably to death) on the lowest used line. **Part II** is for reporting all other significant diseases, conditions, or injuries that contributed to death but which did not result in the underlying cause of death given in **Part I**." http://www.cdc.gov/nchs/data/dvs/blue_form.pdf

body temperature, sleep state, and arousal; thus, brainstem dysfunction can have far-reaching effects. Aberrations in the brainstem neurotransmitter systems and higher brain areas have been found.[9,10]

V. Firmness Test – Assessment of Potential Safety Benefits

The current voluntary standard, ASTM F1917 – 12, *Standard Consumer Safety Performance Specification for Infant Bedding and Related Accessories,* does not include a bumper firmness requirement. After the Commission directed staff to begin rulemaking activities for a mandatory crib bumper standard that would include a performance requirement for firmness, and in response to CPSC staff's request, the ASTM Infant Bedding subcommittee formed a Bumper Firmness task group (TG) in April 2017.

The ASTM Bumper Firmness TG is working to refine a draft requirement and test method for crib bumper/liner firmness that is based on a proposal initially suggested by CPSC staff[14] and based on a modified version of the test method in the AS/NZS 8811.1:2013 standard. In Tab C of this briefing package, Directorate for Laboratory Sciences, Division of Mechanical Engineering staff (LSM) provides background and analyses of existing voluntary standards that address, or potentially could be adapted to address, the suffocation hazard associated with crib bumpers.[15]

Based on methods used in some existing standards that could be appropriate for assessing the relative hazard potential of bumpers being able to "conform to the face of an infant," LSM staff conducted some firmness tests of exemplar bumper samples. LSM staff's current test findings show that a firmness test methodology based on the AS/NZS 8811.1:2013 standard fails 7 of 11 exemplar bumper samples tested so is able to differentiate between 11 exemplar sample products that all pass the current ASTM F1917–12 performance requirement, which limits bumper thickness based on ability to pass through a 2 inch slot under a 5 lb applied force. In essence, the AS/NZS 8811.1:2013-based firmness test method would fail any bumper that can compress more than 15 mm under a 5200 g (11.46 lb) weight applied over a 203 mm (8 inch) diameter circle; equivalent to 16 g/cm^2 (0.2276 lb/sq. inch). LSM staff reports that the firmness test fixture design described in AS/NZS 8811.1:2013 was derived from a related test fixture described in a German research study by Schlaud *et al., 2010*[16]; LSM staff reports that neither standard indicates an anthropomorphic basis for its test fixture.

Potential Effectiveness of a Firmness Requirement

Occlusion of airway openings clearly presents a suffocation risk. Theoretically, inclusion of an AS/NZS 8811.1-based firmness test in staff's proposed rule could improve the safety of crib bumpers by offering some protection against smothering-type suffocation deaths in situations where the victim's face may be pressed against a bumper so as to partially occlude external airway openings due to an applied force, such as the infant's head weight, or due to wedging by a sibling or large object in the crib. From review of the nonfatal incident data and complaints, HS staff understands that it is possible for a bumper that meets current requirements of ASTM F1917–12 to have ties only on the upper edge of the bumper. As was mentioned in section II's review of nonfatal data, this leads staff to believe that it is possible for the bottom part of some ASTM F1917–12 compliant padded bumpers to protrude into the sleep area, and lie

horizontally on the crib mattress. Such protrusion can also occur if bumper ties are loosened or detach from the upper or lower edges of an installed bumper, as is reported to have occurred in some nonfatal incidents. In this position, a bumper could present a smothering–type suffocation hazard similar to a quilt or any other thick, compressible infant bedding that is able to conform to, and occlude, airway openings of a face down, prone positioned young infant who has inappropriate reflex responses to developing hypoxia due either to immaturity of homeostatic control systems (for infants up to about 3 to 4 months old) or otherwise compromised neurological and/or physiological systems.

Additionally, when examining exemplar bumper samples, staff observed that it is possible to install continuous four-sided traditional bumpers incorrectly, if one starts by installing a bumper end section intended for the short side of a standard crib at one end of a long crib side, and continues until the bumper is attached to all crib sides.[*] Such incorrect installation is not necessarily obvious to consumers because the two bumper sections intended for the short section of the crib are only slightly overlong when installed against each long crib side, and two of bumper section intended for half of the long crib side are only slightly too short when located along the short crib sides. However, when installed in this manner, the excess length of the short end bumper panels installed incorrectly against the long crib side allows these two bumper segments to sag into the crib sleeping area, even when ties are tightly secured to the crib frame. As with insufficient or detached ties, this might present a smothering–type suffocation hazard similar to an underlying quilt or other thick infant bedding that is able to conform to, and occlude, airway openings of certain especially vulnerable prone positioned infants. At least two cases in the fatality dataset include incident photos showing a sagging bumper and it is possible that these bumpers were installed incorrectly as described. There are also multiple deaths reported in CPSC's data where reported details of the position of the infant's face relative to the crib bumper, are missing, vague, ambiguous, or conflicting. One or more of these fatal incidents might have involved a bumper that came to lie horizontally under the infant's face because the bumper was lacking lower ties, missing previously attached ties, or incorrectly installed. Thus, HS staff believes that the addition of a firmness test to ensure that bumpers are less likely to conform to an infant's face, plus requirements to ensure crib bumpers have sufficient attachment means to keep both top and bottom edges flush against the interior side of the crib, could reduce the likelihood of suffocation injury or death associated with crib bumpers when an infant's face is pressed against a bumper.

For scenarios where an infant's face is turned to one side, and is just contacting a vertically positioned bumper (rather than having airway openings forced against the bumper by another object), it is not clear how limiting compression of a soft bumper to no more than 15 mm thickness would reduce any putative suffocation risk.

VI. Airflow Test – Assessment of Potential Safety Benefits

The Commission directed staff to "develop a performance requirement and test method based on known infant inhalation and exhalation requirements and anthropometric parameters to

[*] Interior dimensions of standard size cribs must be 28 ± 5/8" (71 ± 1.6 cm) in width x 52 3/8 ± 5/8" (133 ± 1.6 cm) in length; thus, half of a long crib side (~26.5" or 67 cm) is only slightly shorter than the short crib sides (see https://www.cpsc.gov/Business--Manufacturing/Business-Education/Business-Guidance/Full-Size-Baby-Cribs/)

demonstrate that a crib bumper matches or exceeds the airflow characteristics of mesh or mesh-like materials, taking into account the safety of infants with compromised breathing." Infant inhalation and exhalation requirements, and the underlying causes of compromised breathing, vary substantially with circumstances of birth, age, general health, and activity level. Respiratory pressure levels are particularly relevant to airflow test methods investigated by staff.

The period of rapid growth and development of the respiratory system, from late pregnancy through early infancy, greatly influences respiratory function in childhood and beyond. This section provides some fundamental information on developmental changes in fetal and infant anatomy and physiology, particularly those that occur in the weeks just prior to and following birth that are considered particularly relevant to normal and compromised respiratory function. This information is highly relevant to infant deaths in sleep settings where airways are occluded and airflow is compromised.

Fetal and Neonatal Lung Development

The third trimester is a critical period for major development of components essential for air exchange. The aveoli (lung air sacs) begin to produce lung fluid and a very specialized essential lipoprotein, surfactant. Surfactant reduces surface tension at the lung-air interface and so greatly reduces the work effort to first inflate the lungs, *i.e.,* reduces the lung pressures the newborn must generate. Generally, fetal surfactant production is inadequate to prevent lung collapse *ex-utero* until about week 35 of gestation (lung pressures are related to the pressure differentials assessed in ESMC air flow tests -TAB G). As the fetus grows in size, the caliber of all airway levels increases, resulting in a decrease in airway resistance (upper airway resistance is inversely related to the fourth power of airway diameter). Note that airway resistance, pressure and airflow are interdependent factors, as is explained further below in *Lung Measures* sub-section.[17,18,19]

A neonate's first breath is a unique event that requires the lungs to generate a very large negative inspiratory pressure in order to clear lung fluid and aerate the lungs for the first time. Normally this requires an alveolar pressure level of about -40 centimeters of water (cm H_2O) relative to atmospheric pressure,[*] which is generated as the newborn starts to cry vigorously; as much as -70 cm H_2O in might be needed in more extreme cases. Deflation of the lungs during the first exhalation requires positive expiratory pressures of about +40 cm H_2O, due to presence of remaining viscous lung fluid in the bronchioles. Provided sufficient surfactant is present, a neonate's lungs normally begin to function as an air driven oxygen uptake and carbon dioxide excretion system within the first minute or so of delivery. By reducing surface tension, adequate surfactant reduces the negative inspiratory pressure needed to inflate the lungs and also helps alveoli retain some air, which prevents them from collapsing completely. Retention of part of the first breath after exhalation is of critical importance because it allows the lungs to develop a volume of air known as the functional residual capacity (FRC), which decreases airway

[*] Note: Respiratory pressures are customarily expressed as centimeters water column (cm H_2O); 1 cm H_2O is equal 10 mm H_2O or to 0.395 inches of H_2O. In spontaneously breathing individuals, inspiratory pressures are expressed as negative values representing suction pressures that must be generated to draw air into the lungs; when individuals require external assisted ventilation, air is forced into the lungs using positive pressure levels equivalent to the amount of negative pressure the individual would need to generate to breathe without assistance.

resistance and also forms a crucial oxygen reserve. Establishment of an FRC means that the second breath requires significantly lower inspiratory and expiratory forces (about -30 cm H_2O to about +18 cm H_2O, respectively.)[20,21,22] By about 60-90 minutes post-delivery, healthy neonates have established relatively stable breathing patterns and much less pressure is needed to inflate their lungs. Breaths become more regular, slower, and deeper in the first few days following birth, and pressures measured during the first 100 milliseconds of inspiration (not the same as peak alveolar pressure) were found to drop from about 6.1 ± 2.7 cm H_2O (mean ± standard deviation) at 10 minutes after delivery, to about 4 ± 2.0 cm H_2O, by 90 minutes; furthermore, they remained near the 90 minute level a few days after birth.[23] In premature infants lacking sufficient surfactant, a FRC cannot be established because the lungs collapse after each expiration. Each breath requires high negative inspiratory pressures to inflate the lungs and this greatly increases the work effort of breathing, which typically leads to oxygen deficiency, respiratory distress, and need for supported ventilation.

Infant Age and Respiratory Vulnerability

Terms and methods of measuring an infant's age vary.[24] Differences between chronological age and gestational age influence the likelihood of respiratory compromise in young infants.

Gestational (or menstrual) age is the preferred measure for expressing a newborn infant's age. It was long defined as the interval between the first day of the mother's last normal menstrual period (LMP) and the date of birth, rounded to the nearest full week. However, in 2014, the U.S. Centers for Disease Control and Prevention (CDC) transitioned to an improved measure of gestational age, "obstetric estimate" (OE). The OE is defined as "*the best estimate of the infant's gestation in completed weeks based on the birth attendant's final estimate of gestation.*"[25]

In contrast, chronological age refers to an infant's age from the date of birth and can be expressed as days, weeks, and/or months. Thus, two infants who are born on the same day are the same chronological age, but can have gestational ages that can differ considerably if one is a full term or post term infant and the other an extremely preterm infant.

<u>*CPSC Age Data:*</u> For children under 2 years old, CPSC databases use a three digit age code. The first digit is always a 2 and the last two digits represent the child's chronological age, in months, rounded to the nearest complete month for all infants ranging from 2 months and 0 days to 23 months and 30 days (*i.e.,* these age codes increase from 202 through 223). However, all infants with a chronological age younger than 2 complete months (approximately < 8 weeks) are assigned the same age code, 201, which results in all infants under 8 weeks of age being viewed as 1 month-old infants, unless any birthdate details that might be included in the full database record are considered. Above 8 weeks of age, two healthy term infants can have the same CPSC age classification even if born as many as 30 days apart (*e.g.,* full term infants born on July 1, 2017 and July 31, 2017 would both be considered 3 months old on October 31, 2017). Furthermore, in this example, if the baby born on July 31 was a preterm baby born at 28 weeks gestation (12 weeks preterm), although both infants would have the same CPSC age code, their corrected ages would differ by almost 4 months. This difference has significant impact on lung maturity and vulnerability to compromised respiratory function, and on other anatomical,

physiological, and behavioral aspects of infant development. Few bumper-associated fatalities have any hospital records. CPSC database ages are based on chronological age as captured by the IDI investigator or documented in a death certificate. If included in an IDI, the actual birthdate is based on information from parents, first responder records, and/or autopsy reports. Cases in the CSPC deaths database, usually capture the victim's birthdate in the corresponding death certificate.

Permeability Test Rationale

A policy paper on the hazards of padded crib bumpers, released by CPSC Commissioner Elliot Kaye on May 17, 2017,[*] suggested some starting points to be used as the basis of a recommended airflow test. These suggestions were taken from information and citations found in a comment submitted to CPSC, in August 2016, as part of a comment response to the request for information (RFI) regarding crib bumpers issued on February 16, 2016 (81 *Federal Register* 7765).[26] The starting points suggested were:

- The pressures for breathing in and out range between <10 – 100 cm H_2O.
- The time to take a breath is 0.65±0.14 seconds.
- The time to exhale is 0.98±0.24 seconds.
- The cross-sectional area of the nose is 21 mm^2.
- The diameter of the nasal airway is 5.2–6.7 mm.

The current voluntary standard, ASTM F1917 –12, *Standard Consumer Safety Performance Specification for Infant Bedding and Related Accessories,* does not include a bumper airflow requirement. An ASTM Bumper Airflow Test task group that was formed in April 2017, at CPSC staff's request, could not make any progress in coming up with a recommended airflow test, and efforts stalled in late 2017/early 2018, as detailed in the Briefing Memorandum of this package.

At face value the above recommended starting points could appear reasonable; however, as explained below, they greatly oversimplify the very complex mechanisms involved in infant respiratory function. Infant respiratory measures differ significantly by gestational age and activity level, as well as health status. Although reference values for infant tidal volumes (volume of air inhaled or exhaled in one breathing cycle), respiratory rates, and airflow rates can be found, normative values for "the pressures for breathing in and out" are not readily available for spontaneously breathing infants.

It is logical to conclude that materials that are difficult to breathe through will pose an increased risk of suffocation if they are pressed against airway openings. If materials can simultaneously cover the openings of both nostrils and mouth to form a seal, the relative ease with which air can pass through the material will impact the work of breathing. Quiet breathing during sleep or rest will not be impacted by materials that allow free passage of air, but as the permeability of a material decreases, the respiratory muscles must generate greater inspiratory

[*] https://www.cpsc.gov/s3fs-public/CBStatement.pdf?dhFXWQNHUqQ2yV4xuY654JrJ3K0Towc
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and expiratory pressures to overcome the external resistance to airflow and move the same amount of air in and out of the lungs, and this will increase the work of breathing. The increased muscle activity will increase the oxygen demand and can lead to respiratory distress and failure. If a low permeability material covers the external airways of a normal infant, the increase in resistance to air flow is expected to change baseline measures of airflow rate, and inspiratory and expiratory pressures during quiet sleep, and will likely fully rouse a healthy infant who cannot turn away from the material or remove it themselves.[6] It is known that some immature infants at increased risk of SIDS do not have these appropriate responses to situations that reduce blood oxygen levels (hypoxia) and increase carbon dioxide levels (hypercapnia); instead they respond by ceasing breathing actions, which is an appropriate response for a fetus *in utero* to conserve oxygen by limiting non-functional breathing movements.[27] A reasonable, but simplistic, approach to assess the relative permeability of different materials, in terms of the pressure differential needed to maintain physiologically relevant airflow rate(s), might serve as an index of a material's relative "suffocation potential," provided any pressure differential is likely to be physiologically relevant. HS staff was asked to provide guidance on reference values for different infant respiratory measures, including breathing volumes, flow rates, and pressures.

Overview of Lung Mechanics

Airflow in and out of the lungs is governed by gas law principles, which dictate that,

- pressure gradients drive passive bulk flow of gas from high to low pressure areas and airflow rates increase with increasing pressure differential
- gas pressure is inversely related to volume
- gas pressure is positively related to temperature

Put simply, during each inspiration-expiration cycle, bulk flow of air in and out of the lungs results from dynamic differences in pressure inside the lungs relative to atmospheric pressure. Quiet (eupneic) breathing at sleep or rest is controlled by the autonomic nervous system and does not involve conscious effort. During inspiration, chest volume increases primarily due to contraction and downward movement of the diaphragm. Additional contraction of the external intercostal muscles, raises the ribs and pulls the chest wall outwards to increase the anterior-posterior chest diameter. As chest volume increases, pressure inside the lungs decreases, setting up a negative pressure gradient that draws external atmospheric air into the lungs. As inspiratory muscle contraction stops, there is a brief moment of zero airflow when lung and atmospheric pressures are equal, then passive expiration begins as the stretched rib cage, chest muscles, and lungs tissues begin to recoil to their pre-inspiration positions. Recoil reduces chest volume and increases lung pressure, and therefore, reverses the pressure gradient with atmospheric air, forcing air out of the lungs.[*] At the end of a quiet exhalation, just prior to onset of the next inspiration, lung and atmospheric air pressures are again equal (pressure differential = 0) resulting in another momentary pause in lung airflow. At this time of no air flow after exhalation, lung volume is equal to the functional residual capacity (FRC), and in older infants, children and adults, the elastic lung recoil forces that would favor lung collapse are

[*] In contrast to quiet (eupneic) breathing, deeper breathing requires increased effort and higher energy demands as the diaphragm and external intercostal muscles contract more forcefully, and recruitment of accessory inspiratory muscles further raise the ribs and sternum to achieve larger chest volumes. The larger pressure gradient, between atmospheric and alveolar air pressures, moves more air into the lungs, at faster flow rates.

equal, but opposite in sign, to the elastic recoil forces pulling the compliant chest wall outward and away from the lungs.

A newborn infant's highly compliant cartilaginous rib cage favors passage through the birth canal, but is less able to oppose the elastic recoil forces of the lungs once air breathing commences. This tends to pull the chest inward at the end of exhalation, reducing the lung volume and FRC. While awake, these young infants typically use different respiratory braking actions to prolong the exhalation phase (contracting the diaphragm to slow its passive recoil; closing of vocal chords and glottis to slow expiratory airflow; and taking sighing and gasping breaths). These actions help to maintain an adequate FRC and protect against lung collapse. However, infants spend most of their day sleeping and so their reduced muscle tone and typical horizontal sleep position reduces the FRC, and particularly for young preterm infants, increases the potential for lung collapse that then necessitates a need to generate higher inspiratory pressures to reinflate the lungs (as discussed in section IV).

Lung Measures

Measurement of respiratory system parameters is complex. The interrelated air flow rates, resistance, and pressure relative to atmospheric pressure, normally vary dynamically throughout the course of a breathing cycle (inspiration and exhalation) according to the simplified relationship:

Resistance = Change in Pressure/Airflow Rate ($R=\Delta P/Flow$)

A given airflow rate is affected by different respiratory pressure and resistance measurements that pertain to different respiratory components (lungs, chest wall, pleural space, conducting airways, and upper airways). These measurements will change depending on their timing during a breathing cycle. Air flow rate, pressure, and timing during exhalation is not simply a mirror image of flow during inspiration (*i.e.,* airflow does not follow a sinusoidal wave pattern.) Furthermore, the measurement technique and equipment used can influence the measure. Therefore, when interpreting any respiratory measurement it is important to understand exactly what, how, and when the measurement was taken. Adults and older children can perform many basic pulmonary function tests in a general practitioner's office, but reliable measurements in infants typically require them to be sleeping or sedated. Obtaining infant measurements can involve more complicated techniques and equipment that is not usually found in general practitioner settings. Much information on infant respiratory measures comes from individual studies of hospitalized neonates; frequently, their measures are compared with healthy newborns prior to discharge from hospital. Reported study values can differ widely, and aside from tidal volumes and respiratory rates, reliable normative infant reference data for several respiratory measures are not well established as a function of age. As recently as 2016, the American Thoracic Society (ATS) and European Respiratory Society (ERS) issued an official workshop report on respiratory mechanics and function in infants that concluded "There is a requirement to develop standardized procedures/protocols, minimum standards for equipment, and ideally normative data to differentiate normal from disease states before incorporation of a technique into our daily clinical practice."[28]

Respiratory Minute Volumes, Tidal Volumes, and Respiration Rates

The volume of air that moves in and out of the lungs during a breathing cycle is defined as the tidal volume (V_T), which is significantly affected by an individual's activity level; thus, the measurement conditions for reported V_T values are important. The breathing frequency, or respiratory rate (RR), is the number of breaths taken per minute. Typically, expiration time is slightly longer than inspiration time. The respiratory minute volume (RMV) is the product of V_T x RR, and is the amount of air entering (or leaving) the lungs each minute; conventionally, it is expressed as a volume per minute, (usually in milliliters per minute (ml/min) or liters per minute (L/min)), or as a volume per kilogram of body weight per minute (ml/kg/min or L/kg/min). As with V_T, an individual's activity level significantly affects RMV because it changes both V_T volume and RR.

Table 2 shows reference short-term ventilation rates in liters per minute (L/min) for infants and toddlers up to 2 years of age, as influenced by activity level; these were developed by HS staff from exposure modeling reference values published by the U.S. EPA (2009).[29] While useful for understanding comparative effects of activity level on minute volumes (see shaded cells of interest to infants), EPA's L/min data for young infants has only one age category that spans the first year of life (from birth until 12 months);[*] as such, it cannot adequately reflect the marked changes in lung maturation that occur from the second half of pregnancy through the first year of life.

[*] Note: EPA's Child-specific exposure factors handbook (2008) includes a further breakdown of infant age groups and average inhalation rates (m^3/day) recommended for use in modelling long term exposures ≥30 days.

Table 2.

Average Ventilation Rate (L/min) - Males & Females, Unadjusted for Body Weight*									
Age Category	**Mean**	**Percentiles**							**Max**
		5th	**10th**	**25th**	**50th**	**75th**	**90th**	**95th**	
	Sleep or nap								
Birth to <1 year	3.00	1.60	1.82	2.36	2.94	3.59	4.20	4.59	7.94
1 year	4.55	3.07	3.28	3.77	4.46	5.14	5.93	6.41	9.81
2 years	4.59	3.01	3.33	3.96	4.51	5.21	5.91	6.44	9.22
	Sedentary & Passive Activities (Includes Sleep or Nap)								
Birth to <1 year	3.09	1.67	1.90	2.41	3.04	3.69	4.26	4.66	8.34
1 year	4.67	3.22	3.47	3.95	4.61	5.17	5.95	6.54	9.71
2 years	4.76	3.30	3.60	4.15	4.68	5.30	5.90	6.47	9.26
	Light Intensity Activities								
Birth to <1 year	7.63	3.97	4.85	5.95	7.57	9.15	10.29	11.35	16.24
1 year	11.59	8.63	8.90	9.96	11.31	12.93	14.78	15.78	20.67
2 years	11.83	8.63	9.27	10.12	11.53	13.10	15.15	15.83	21.30
	Moderate Intensity Activities								
Birth to <1 year	14.24	7.66	8.91	11.31	13.94	16.64	19.75	22.40	35.71
1 year	21.17	15.05	16.09	17.98	20.38	23.79	27.02	29.08	37.20
2 years	21.44	14.79	16.14	18.30	21.14	24.00	27.24	29.22	44.26
	High Intensity								
Birth to <1 year	25.83	13.72	15.26	18.89	25.12	30.87	37.00	41.46	66.23
1 year	38.37	27.14	28.96	32.54	37.96	43.16	49.45	52.28	68.82
2 years	39.02	28.57	30.13	33.39	38.50	43.49	49.99	53.21	82.51

* Derived by HS staff from gender-specific ventilation rates (L/min) US EPA (2009) Tables C4. Sex has minimal impact up to 2 years
Note: the 12 L/min flow rate used in BS 4578:1970 is closer to the "light activity" average 50th percentile values for 1 to 2 year-olds (shown above) and average adults, 16-70 years (~12.25 L/min; *males 13.51 L/min; females 11.0 L/min*) derived from EPA 2009).

A 1993 review article from ATS and ERS provides a more useful source of some respiratory reference values for infants from birth to 12 months of age;[30] it recommends respiratory rates, tidal volumes and respiratory minute volumes that are still cited in the most recent (2017) edition of the authoritative textbook *Smith's Anesthesia for Infants and Children*.[31] Table 3 provides summary data for respiratory minute volumes and other relevant measures that staff obtained from this ATS/ERS source.

Table 3. Reference Respiratory Rates, Tidal Volumes, and Respiratory Minute Volumes During Quiet Sleep, in Healthy Infants by Age*

	Age (months)				
	Birth	3	6	9	12
	Weight (kg)				
	3.2	5.5	7.5	9.0	10.0
Predicted Respiratory Rate (breaths/min) weighted mean of three studies (n = 203)	47	38	33	29	26
Predicted Values of Tidal Volume (ml) weighted mean of four studies (n = 364)	23.8	49.1	67.8	81.1	89.1
Predicted Values of Tidal Volume (ml/kg) weighted mean of four studies	7.4	8.9	9.0	9.0	8.9
Calculated Respiratory Minute Volume (ml/min)	**1119**	**1866**	**2237**	**2352**	**2317**
Calculated Respiratory Minute Volume (ml/min/kg)	349.6	339.2	298.3	261.3	231.7

**Based on values reported in American Thoracic Society/European Respiratory Society (ATS/ERS) Respiratory mechanics in infants: physiologic evaluation in health and disease. Am Rev Respir Dis (1993) 147:474-496*

As reported by ESMC staff in TAB G,[32] staff previously conducted some preliminary permeability tests using 12 L/min and 0.6 L/min airflow rates. Based on the respiratory rates for infants shown in Table 3, HS staff advised ESMC staff to use a 2 L/min airflow rate for additional airflow tests, to approximate quiet breathing in a sleeping 3 month-old term infant (calculated in Table 3 to be 1866 ml/min (1.866 L/min), assuming 40 x 50 ml breaths per minute[*]). This recommendation is based on the respiratory information shown in Table 3 for a sleeping 3 month old. Staff believes using the information for a 3 month old is appropriate because the 2 to 4 month age range is common to:

- the majority of the bumper fatal incident data;
- the peak age range for SIDS deaths; and
- the developmental timeframe when homeostatic systems controlling important autonomic respiratory, cardiovascular, and thermoregulatory functions, as well as sleep organization and arousal, are actively adapting and maturing from their *in utero* fetal set points. In particular maturation of brainstem anatomy, function, and communication with higher brain areas occurs during this time frame.

[*] Note 1 liter (L) is equal to 1000 milliliters (ml).

The Commission's instructions to staff regarding an airflow test method included direction to consider infants with compromised breathing. Preterm and low birth weight infants represent the largest "most vulnerable" infant population that has compromised breathing, due to their high oxygen demand, poorly developed chest muscles, and small, stiff, immature lungs that are prone to collapse. As noted previously, the number of small infants who require assisted ventilation and/or supplemental oxygen for prolonged periods has increased with improved survival of premature infants. These small infants typically suffer from respiratory conditions including apnea of prematurity[*] and hyaline membrane disease/respiratory distress syndrome,[†] which can lead to chronic lung impairment such as bronchopulmonary dysplasia (BPD).[‡] Key lung function data were extracted from a large study[33] that compared healthy term and healthy preterm infants with those of preterm infants suffering from BPD of varying severity (Table 4). For all infants, the study was conducted at an average postconceptional age of about 44 weeks. At this age, it is evident that BPD infants have smaller tidal volumes than term infants, but infants with moderate to severe BPD actually have slightly higher respiratory minute volumes than healthy term infants, due to high their respiratory rates. In these smaller compromised infants, the volume of airway dead space (where no gas exchange take place) relative to tidal volume, is larger than that of term infants, so they must take extra breaths to meet their higher oxygen requirements. Moreover, compared to healthy term infants, lung inflation in these compromised infants requires much higher inspiratory pressures due the higher respiratory resistance resulting from smaller airways, stiffer, and often surfactant deficient lungs, and highly compliant chest wall. In the most severe cases, the inspiratory pressures required to inflate (or re-inflate) their lungs can approach the highest pressures needed to inflate a newborn infant's amniotic fluid-filled lungs for the first time, which, as previously noted in section IV, usually requires around 30 to 40 cm H_2O (300 to 400 mm H_2O; 11.811 to 15.748 inches H_2O), but can be as much 70 to 80 cm H_2O (700 to 800 mm H_2O; 27.559 to 31.496 inches H_2O).

[*] "Apnea of prematurity" is generally defined as cessation of breathing for 20 seconds or longer.

[†] Hyaline membrane disease, now called respiratory distress syndrome, occurs in immature surfactant-deficient lungs and is characterized by a glassy looking "hyaline" membrane composed of dead cells and proteins, that lines the alveoli and seriously impairs air exchange.

[‡] Bronchopulmonary dysplasia, a chronic lung condition that is caused by tissue damage to the lungs, is marked by inflammation, exudate, scarring, fibrosis, and emphysema; it is a recognized hazard related to use of mechanical ventilation and supplemental oxygen for treatment of acute respiratory distress syndrome that occurs frequently in premature infants.

Table 4

Age, Weights, and Measures of Lung Function During Quiet Sleep in Healthy Term and Preterm Infants, and Preterm Infants Afflicted by Bronchopulmonary Dysplasia (BPD)*					
	Healthy		Bronchopulmonary Dysplasia (BPD)		
	Term	Preterm	*Mild*	*Moderate*	*Severe*
Number of Subjects	239	58	44	53	30
Post-conceptional age at birth, wks	39.8	32	28.1	27.9	27.4
Birth Weight, kg	3.4	1.66	1.1	1.02	0.87
Post-conceptional age at study date, wks	44.8	44.3	44.3	44.8	44.8
Weight at study date, kg	4.4	4.1	3.9	3.8	3.7
Respiratory rate, per minute	45	48	50	53	58
Tidal Volume, ml/kg	7.5	7.6	7.5	7.5	7.3
Tidal Volume, ml	**33.0**	**31.2**	**29.3**	**28.5**	**27.0**
Respiratory minute volume (ml/min/kg)	338	365	375	398	423
Respiratory minute volume (ml/min)	**1485**	**1496**	**1463**	**1511**	**1567**

* data extracted and/or derived from Latzin P, Roth S, et al., (2009)

Respiratory Pressures[*]

Very preterm infants and those with moderate to severe BPD or other respiratory conditions require assisted ventilation until well enough for discharge from hospital. HS staff examined clinical studies to obtain information on appropriate pressure ranges used to treat and to wean infants off of assisted ventilation; these values can help to guide estimated pressure ranges appropriate for any airflow tests of bumpers and liners (and sleep surfaces of other infant products).

Assisted ventilation is accomplished by administration of an oxygen-enriched air supply delivered either by invasive mechanical ventilators requiring placement of an endotracheal tube or by non-invasive continuous positive airway pressure (CPAP) devices. While spontaneous breathing draws atmospheric air into the lungs by creating a negative inspiratory lung pressure gradient due to muscular contractions of the diaphragm and chest wall, assisted ventilation uses positive pressures to force air into the lungs, in order to open the alveoli, prevent lung collapse, and reduce the work of breathing. The positive inspiratory pressure level required for mechanical ventilation is therefore equivalent in magnitude to the negative inspiratory pressure the individual would need to generate, in order to breathe without assistance.

Modern mechanical ventilators use microprocessors to deliver cyclical air flows that can be closely monitored, controlled, and tailored to each patient's changing needs; *i.e.,* air flow rates, pressures and cyclical patterns can be customized using limits dictated by tidal volumes, flow rate, or pressure (mean airway pressure (MAP), positive end expiration pressure (PEEP), and peak inspiratory pressure (PIP)). Current practice indicates that to avoid lung damage,

[*] Conventionally, physiological respiratory pressures are expressed as centimeters of water column, *i.e.,* cm H_2O; 1 cm H_2O is equivalent to 10 mm H_2O, and 0.394 inches H_2O.

whenever possible, it is best to limit pressures, by keeping MAP under 12 cm H_2O (120 mm H_2O; 4.724 inches H_2O) and PEEP in the range of 4 to 7 cm H_2O (40 to 70 mm H_2O; 1.575 to 2.756 inches H_2O).* Initial PIP settings should be set as low as necessary to inflate lungs; about 20 to 25 cm H_2O (200 to 250 mm H_2O; 7.874 to 9.843 inches H_2O) is a general starting level and higher PIP settings around (30 to 40 cm H_2O) (300 to 400 mm H_2O; 11.811 to 15.748 inches H_2O) are appropriate for short term treatment of infants with reduced lung compliance. Even higher PIP can be used in more extreme cases, but it is important to monitor infants closely, and reduce PIP (and MAP and PEEP) as soon as possible to avoid over-pressuring and over-distending an infant's fragile lungs.† According to one review, for most infants, mechanical ventilation can be removed when infants are able to maintain a reliable breathing rate and target V_T at a PIP less than about 10 to 12 cm H_2O (100 to 120 mm H_2O; 3.937 to 4.724 inches H_2O).[34]

Noninvasive CPAP is used to prevent lung collapse in infants who are capable of spontaneous breathing by delivering a continuous high air flow rate. (*i.e.,* PEEP is kept above 0 cm H_2O so airway pressures do not become negative as normally occurs during unsupported inspiration). The ideal starting level for CPAP is not clearly established and reportedly:

> is based more on anecdotal experience, opinion and conventional wisdom than on actual scientific evidence, and these practices vary greatly from one institution to another. There is no consensus regarding the proper initial CPAP level, weaning strategies, or appropriated timing for implementation and weaning during the course of lung disease.[35]

An initial CPAP setting of 5 cm H_2O is most common in the United States, with most values ranging from 4 to 7 cm H_2O (300 to 400 mm H_2O; 11.811 to 15.748 inches H_2O); stiffer premature lungs could require up to 12 cm H_2O (120 mm H_2O; 4.724 inches H_2O), but CPAP levels exceeding 10 to 12 cm H_2O (100 to 120 mm H_2O; 3.937 to 4.724 inches H_2O) have an increased risk of adverse effects and air leaks. A recent European review indicates that most studies used initial CPAP levels of at least 6 cm H_2O, (60 mm H_2O; 2.362 inches H_2O) with some as high as 9 cm H_2O (90 mm H_2O; 3.543 inches H_2O).[36]

Approaches to wean infants from mechanical ventilators and CPAP devices also vary based on institutional guidelines and individual clinical judgement. However, they generally proceed by gradual reductions in the level of oxygen enrichment, with gradual decreases in pressure. Infants on mechanical ventilators are frequently transitioned to CPAP support, which is subsequently removed when an infant's vital functions (blood gases, heart rate, and respiration rate, *etc.*,) remain stable for time frames ranging from 8 to 48 hours, at a low CPAP pressure of about 3 cm H_2O (30 mm H_2O; 1.181 inches H_2O),‡ at normal atmospheric oxygen level (~21 percent).[37, §]

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* AARC Clinical Practice Guideline Neonatal Time-Triggered, Pressure-Limited, Time-Cycled Mechanical Ventilation (1994) http://www.rcjournal.com/cpgs/tptvcpg.html

† https://www.respiratorytherapyzone.com/neonatal-pediatric-mechanical-ventilation/

‡ https://www.networks.nhs.uk/nhs-networks/staffordshire-shropshire-and-black-country-newborn/documents/CPAP%202009-11.pdf

§ Queensland Clinical Guideline: Neonatal respiratory distress including CPAP (2014) https://www.health.qld.gov.au/__data/assets/pdf_file/0012/141150/g-cpap.pdf

Once an infant is successfully removed from a mechanical ventilator or CPAP device, their respiration will revert to normal breathing patterns, meaning that PEEP will fall to 0 cm H_2O, and they will generate negative lung pressures during inspiration. For spontaneously breathing infants in residential settings, it is not entirely clear to HS staff whether MAP or PIP is the most appropriate measurement to guide an airflow test pressure limit. Compared to healthy infants, higher pressures will be needed to inflate smaller, stiffer lungs of more premature infants, but if an infant has a condition with overly compliant lungs, lower pressures will be needed. Despite intensive searching, staff has not been able to find specific reference values for these pressures in spontaneously breathing infants. Staff's unsuccessful search efforts to date, are corroborated by the authors of a recent study of low birth weight infants who required mechanical ventilation while suffering from acute respiratory distress due to bronchiolitis. They reported pressure values for 16 young infants with median age 2.5 months (range 1.5 to 5.8 months) during mechanical ventilation (PIP median 29, (290 mm H_2O; 11.417 inches H_2O;) range 18 to 33 cm H_2O (180 to 330 mm H_2O; 7.087 to 12.992 inches H_2O); PEEP median 7.5 (75 mm H_2O; 2.953 inches H_2O), range 7 to 12 cm H_2O 70 to 120 mm H_2O; 2.756 to 4.724 inches H_2O) but also noted that *"Reference values for healthy children in this age group has not been specifically reported."*[38] Therefore, though an authoritative physiology text informs that a negative inspiratory pressure of -1 cm H_2O is sufficient to draw 500 ml of air into a healthy adult's lungs during quiet breathing (12 to 15 breaths per minute),[39] at this time, HS staff is unable to recommend a reliable (healthy or compromised) infant based, pressure limit for airflow tests of bumpers and mesh liners.

Potential Effectiveness of an Airflow Requirement

In HS staff's most recent memorandum on bumpers (Tab E in 2016 briefing package), staff identified four infant deaths where the victim's face was reported to be in contact with a bumper, without evidence of wedging or entrapment. Although these cases also included confounders, based on the victim's "as found" position, HS staff concluded that removal of the bumper, and replacement with a mesh liner (or individual slat vertical bumper), likely could have prevented death. Staff considers these four cases to represent the best evidence supporting the view that inclusion of an airflow test requirement to match airflow allowed by mesh liner-type products could improve bumper safety. While HS staff still considers it theoretically possible that an airflow test with appropriate limits could improve bumper safety, at present, staff is unable to identify appropriate reference inspiratory or mean airway pressure limits for young infants who are able to breathe spontaneously without respiratory support while asleep, aside from saying it is likely to be at least 1 cm H_2O (10 mm H_2O; 0.394 inches H_2O) based on resting adult PIP,[*] and less than 10 to 12 cm H_2O (100 to 120 mm H_2O; 3.937 to 4.724 inches H_2O) as used to wean infants off mechanical ventilation.

ESMC staff's efforts related to possible test fixtures and airflow test methods are discussed in Tab G. Staff's early tests were based on British standards BS 4578:1970 (methodology) and BS 1877-8:1974 (performance criteria) for testing permeability of infant pillows (*see HS staff review of this standard and a related research study by Emery, Johnson,*

[*] During quiet eupneic breathing in adults, the magnitude of the peak pressure differential between the lung and the atmosphere during both inspiration and expiration phases is equal to 1 cm H_2O, regardless of whether air is sucked into, or blown out of the lungs.

1968,[40] *in Appendix*). As explained above, although in initial tests, ESMC staff could demonstrate some pressure differentials between traditional bumpers and mesh-like liners when tested at the 12 L/min airflow rate specified in BS 4578:1970, but, as noted in Tables 2, 3 and 4, this rate is considered much too high for a sleeping infant. Also, ESMC staff could not make any findings that distinguished between these different bumper designs at a lower 0.6 L/min airflow rate, which based on HS staff's findings is more physiologically relevant to a very small sleeping newborn infant.

Recently, ESMC staff conducted more airflow tests using higher resolution equipment* and airflow rates of 2 L/min, which HS staff considers physiologically representative of a sleeping 3 month-old infant, and 12 L/min airflow rate, as specified in BS 4578:1970. These tests have detected some very small but significant measureable pressure differences between convenience samples of eight different traditional bumper products and eight mesh liner-type products. At 2 L/min, reported pressure differentials related to padded bumpers were 0.0139 ±0.0131 inches H_2O (0.353 ± 0.333 mm H_2O; 0.035 ± 0.033 cm H_2O) (mean ± standard deviation) and one sample had a pressure differential of 0.041 inches H_2O (1.041 mm H_2O; 0.104 cm H_2O); in contrast, no discernable pressure differentials could be measured for liner products. At 12 L/min, pressure differentials of bumper samples ranged from undetectable to 0.585 inches H_2O (14.859 mm H_2O; 1.486 cm H_2O); with a mean and standard deviation of 0.110 ±0.150 inches H_2O (2.794 ± 3.810 mm H_2O; 0.279 ± 0.381 cm H_2O,); pressure differentials of liner products ranged from undetectable to 0.003 inches H_2O (0.076 mm H_2O; 0.008 cm H_2O) with a mean and standard deviation of 0.002 ±0.001 inches H_2O (0.051 ± 0.025 mm H_2O; 0.005 ± 0.003 cm H_2O).

Although ESMC staff's airflow tests are able to distinguish significant differences between measured pressure differentials of bumper and liner products, the measured differences are considered very small (though still within the test equipment's limit of resolution; *i.e.,* 0.001 inches H_2O (0.0254 mm H_2O; 0.003 cm H_2O)). Aside from estimating that a critical upper inspiratory pressure limit for spontaneously breathing sleeping infants should probably be below about 10 to 12 cm H_2O (100 to 120 mm H_2O; 3.937 to 4.724 inches H_2O) (as used to help assess whether infants can be weaned off mechanical ventilation) and is likely above a 1 cm H_2O (10 mm H_2O; 0.394 inches H_2O) pressure level in resting adults, HS staff is not able to identify a more precise critical pressure limit for airflow rates of sleeping infants. This estimated range of relevant inspiratory pressures for young infants while sleeping is orders of magnitude above pressure differentials reported in ESMC staff's airflow tests of bumpers and mesh liners at airflow rates of sleeping infants. Therefore, it is currently unclear the degree to which ESMC staff's measured pressure differentials of 0.0139 ±0.0131 inches H_2O (0.353 ± 0.333 mm H_2O; 0.035 ± 0.033 cm H_2O) (mean ± standard deviation) might represent a physiologically relevant concern. ESMC staff's data suggest that very small pressure threshold limits might distinguish between mesh liners and padded bumpers, *i.e.,* a pressure limit of no more than 0.003 inches H_2O (0.076 mm H_2O; 0.008 cm H_2O) at 2 L/min or no more than 0.005 inches H_2O (12.700 mm

* Note: Digital pressure gauges used by ESMC staff to measure pressure differentials report data in inches of water column (inches H_2O); metric units are used in BS 4578:1970 and BS 1877-8:1974 (mm H_2O) and for physiological respiratory pressures (cm H_2O). To facilitate data comparison, imperial and metric units are reported in this section using the original reported value as the lead unit and parentheses to identify values that were converted from their original reported format.

H_2O; 1.270 cm H_2O at 12 L/min). Considering the uncertainty regarding physiological significance of low pressure differentials and the extremely low rates of bumper-associated deaths where a bumper reportedly was simply in contact with the victim's face, plus questions regarding the underlying cause and mechanisms involved in these deaths, it is unknown whether any effective safety gains would result from an airflow performance test requirement based on pressure levels that are orders of magnitude below the expected range of PIP values in sleeping 3 month-old infants.

VII. Summary and Conclusions

Staff has reviewed new fatal and nonfatal data related to crib bumpers, which has furthered its understanding of potentially hazardous crib bumper scenarios. Staff recommendations for a bumper firmness test are being acted on by the ASTM firmness TG, and HS staff has provided some reasoning as to why it thinks this (and other recommendations for bumper attachment) will reduce the risk of injury or death associated with bumpers by reducing the likelihood that bumpers will be able to conform to an infant's face to fully or partially occlude airway openings.

HS staff has provided information on fetal and infant lung development to help explain the inherent difficulties in trying to devise a physiologically relevant airflow test for bumpers that takes *"into account the safety of infants with compromised breathing."* ESMC staff's recent permeability tests of padded bumpers and mesh liners have shown some very small significant differences between these product variants at two airflow rates: the 2 L/min rate is relevant to a 3 month-old sleeping infant and the 12 L/min rate is relevant to an infant under 12 months old at a moderate activity level, or a toddler aged 1 to 2 years at a light activity level. The 2 L/min airflow rate is considered representative of the majority of bumper-associated fatalities, but it is not clear if small pressure differentials measured in padded bumpers at this low flow rate are meaningful, physiologically. Staff has been unable to identify critical lower limits for inspiratory alveolar pressure in spontaneously breathing infants, and several reports in the medical literature indicate such normative reference values are not established. As such, HS staff cannot recommend a minimum pressure differential to use in airflow tests as a threshold limit to distinguish between a safe versus unsafe product. However, this differential appears to be greater than the differences between the mesh and padded bumpers in the testing done to date. Although an effective airflow performance test requirement might appear to be an additional measure of safety for crib bumpers, for the reasons discussed above, staff cannot assess its effectiveness at this time.

VIII. Appendix: Summary Review of Firmness and Airflow Standard Test Methods
(Note: measures in bolded text are the units specified in the standard or citation)

A) Australian/New Zealand standard, AS/NZS 8811.1:2013, Methods of testing infant products Method 1: sleep surfaces-test for firmness

The scope of AS/NZS 8881.1:2013 states "*This standard sets out the method for assessing whether a horizontal or nearly horizontal infant sleep surface exhibits excessive compression when subjected to a constant force applied thorough a standard load pad."* The firmness test described in the AS/NZS 8811.1:2013 standard uses the custom designed test device, shown in Figure A, to assess the firmness of sleep surfaces.

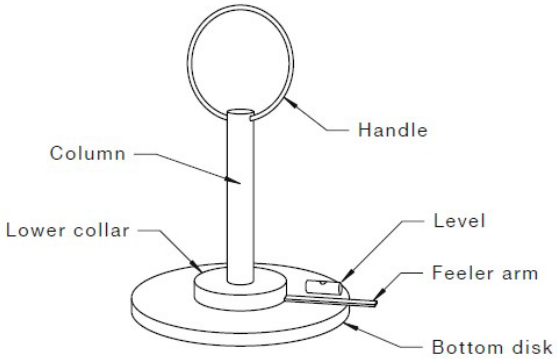

Figure A. Firmness Test Device Used in AS/NZS 8811.1:2013

In essence, the firmness test device is used to apply a force of **5,200 g** to a sleep surface via the rigid circular bottom disk **(208 mm diameter)** (340 cm^2 area; 15.3 g/cm^2 pressure**).** The bottom disk is **15 mm thick** and must account for at least **70 percent** (3,640 g) of the test device's total weight. Located immediately above the bottom disc is a lightweight, flexible bar or feeler arm **(12 mm wide)**; the feeler arm extends **40 mm** beyond the bottom disc's perimeter and can be rotated freely above the bottom disc. When the test device is placed on a sleep surface, if the feeler arm makes contact with the sleep surface, the surface is considered too soft and fails the test. The product is meant to be tested in a dry state, and preferably in a conditioned environment (23 ± 2°C; 50 ± 5% RH) after 48 hours preconditioning. The basis of the specified weights and dimensions are not provided; however, the standard's Foreword section cites four papers as examples of good quality research indicating an association between infant mortality and overly soft sleep surfaces.[*] It describes one of these studies as follows: "*Schlaud et al (Int J Legal Med 2010: 124) working in Germany utilized a purpose-built instrument to assess surface firmness, and suggested a performance criterion by which to identify sleep surfaces with an average three-fold excess risk of death."* The AS/NZS 8811.12013 standard indicates that the test method gave rise to a less formal method for use by consumers to assess firmness of infant sleep surfaces.[41]

[*] Ponsonby et al., (N Engl J Med 1993; 329); Kemp et al., (Pediatr Res 1994; 36); Hauck et al., Pediatrics 2003;111); Schlaud et al., (Int J Legal Med 2010; 124).

B) British standard, BS 4578:1970, Test for Hardness of and for Air Flow Through Infants Pillows, and applicable performance requirements specified in *BS 1877-8:1974, Specification for Domestic bedding-Part 8: Pillows and bolsters for domestic use (excluding cellular rubber pillows and bolsters). (Referred to as BS 4578 and BS 1877-8)*

BS 4578 describes performance test methods and BS 1877-8 details relevant performance requirements for hardness (equivalent to firmness) and permeability (airflow) characteristics of infant pillows. Both tests are intended to address the suffocation hazard associated with use of infant pillow products, before and after two washes. Essentially, both test methods apply a **10 N force**[*] to a pillow surface via a **100 mm diameter** metal disc (78.54 cm^2). For the firmness test, the solid 100 mm diameter disc is applied for 1 minute and the resulting pillow indentation with the test fixture in place is not allowed to exceed **25 percent of the overall pillow thickness**. For the airflow test, the **100 mm diameter** disc is modified to have a central **36 mm diameter opening** (10.18 cm^2), which is formed by a tube (**150 mm tall**) that connects to the disc and a flowmeter, which then connects to the suction side of a blower that draws air through the pillow. The blower-flowmeter airflow system is equipped with controls allowing for fine adjustment of airflow to achieve the intended test airflow rate of **200 ml/s**, (equivalent to an RMV of 12,000 ml/min or 12 L/min). When the pillow is being tested under the **10 N force/thrust** (~1.02 kgf; 2.2 lbf), any additional pressure required to maintain the **200 ml/sec** airflow rate cannot exceed **20 mm H_2O** (2 cm H_2O). According to the relationship Resistance = ΔPressure/Flow, at a 200 ml/sec (12 L/min) flow rate and 20 mm (2 cm) H_2O pressure limit, the upper limit for resistance allowed by the standard cannot exceed 100 mm H_2O/L/sec (*i.e.,* 10 cm H_2O/L/sec).

The British standards do not explain the basis of the disc dimensions and force applied to the pillow, pillow compression limit, or the specified airflow rate and differential pressure limit used in the British standards. According to publication histories included in each standard, three editions of BS 1877-8 1974 have been published (1952, 1963, 1974) and the current version was amended in April 1976 without a new edition being published; BS 4578:1970 was first published in March 1970, and was amended in March 1972, again without a new edition being released. (Standard amendments can be made without necessarily issuing a new edition.) Both standards were developed and published well before there was widespread recognition that the prone sleep position significantly increased the risk of SIDS. The Foreword section of BS 4578:1970 reports that it was developed due to increasing concern about the possible contribution of pillows to unexplained cot deaths (*i.e.*, SIDS). It also specifies that "*The committee has therefore tried to consult anyone who may be able to contribute to the solution of the problem of a British Standard for a safe pillow, and the inquiries have included consultation with physiologists about the breathing of young children (quantity and rate of flow, psychological and other effects if air flow becomes restricted, etc.).*" This section also mentions concerns that the suffocation risk could be increased if a pillow's porosity properties were reduced due to fluid accumulation on its surface or cover (*e.g.*, from regurgitation or spillage). HS staff identified the authors of the following citation as the likely advisors on infant physiology, during development of BS 4578:1970.

[*] 10 N is equivalent to 1 kgf or 2.248 pounds force (lbf), so when applied to 78.54 cm2 = 12.7g/cm^2 pressure.

Emery JL,[*] Johnson JA (1968) Effects of obstruction in respiration in infants, with particular reference to mattresses, pillows and their coverings, *BMJ 3:209-213*

Based on the opening line of this paper, "*This investigation was stimulated by inquiries for guidance on the advisability of having different types of pillows for children,"* it is highly likely that some, possibly all, of the physiologically based requirements in BS 4578 and BS 1877-8 were guided by information obtained from these authors. Their research study used cadavers of six infant cot death victims, ranging from 6 weeks to 9 months of age. They aimed to simulate normal breathing patterns by pumping air upwards from below the larynx, to exit through the nose and mouth, using sinusoidal flow rate patterns. The authors stated: "*The rate and tidal volume were determined from a knowledge of the subject's weight, Radford's Nomogram (1955)[42] being used, and this setting remained constant throughout the investigation"*; however, no specific values are reported. Effects of airflow obstruction resulting from movement of the tongue or neck, obstruction of nostril(s) or mouth, and changes in head position when placed prone with face straight down on different pillow and mattress products, or with face rotated to either side, were assessed by noting any pressure changes seen in continuous pressure recordings.[†] In this cadaver system, near-complete airway obstruction of inspiration versus expiration was observed when the tongue was able to fall back into the nasopharynx. Without the tongue blocking the nasopharynx, closure of one or two airway openings did not affect pressure, and free passage of air occurred if only one airway opening remained patent (either a nostril or the mouth). When placed prone with face straight down, the degree of airway obstruction varied by pillow type; turning the face/head to either side negated any obstruction-related pressure changes. To simulate regurgitation, 30 ml of milk was allowed to accumulate on pillow surfaces in the depression left by a cadaver face; subsequent tests with cadavers replaced face down in the depression showed higher pressures were needed to maintain pump driven tidal airflow rate (indicative of increased airway resistance). The authors observed that when face down on a marble slab, with the cadaver head weight resting on the tip of its nose, a small rise in pressure (airway obstruction) was seen in the youngest infant cadaver, which was not seen in cadavers of older children that they had studied previously; the authors considered that this was likely due to deformation of the young infant's relatively softer nasal tissues. Although considered somewhat crude by today's standards, the study did find that softer pillows and mattresses caused a greater degree of airway obstruction in prone, face straight down position, compared to firmer products.

Although not specified, after reviewing Emery and Johnson's study, HS staff considers it is probable that in *BS 4578 and BS 1877-8*:

- The **36 mm diameter** (10.18 cm^2) air flow opening contacting the test pillow is likely intended to represent the combined airway openings of an infant's nose and mouth.
- The 10 N thrust (1.02 kgf; 2.2 lb force) applied to the pillow is likely intended to represent an infant's head. Crash test infant dummy head weights are 2.2 kg (4.65 lb) for a 6 month CRABI (27.0% of 7.8 kg total weight) and 2.64 kg (5.82 lb) for a 12 month CRABI

[*] John Emery, a pediatric pathologist, became a recognized authority on SUID/SIDS, and published extensively before his death in 2000.

[†] The authors acknowledge that changes in resistance were not measured directly, but reasoned that with constant volume and respiratory rate, observed pressure changes would reflect altered resistance ($R = \Delta P/\text{flow rate}$).

(26.4% of 10.0 kg total weight) (see *https://www.humaneticsatd.com/crash-test-dummies/children*); a 1 kg (2.2 lb) head weight was used for a 1.5 month anthropomorphic infant surrogate (23% of 4.4 kg (9.7 lb) body weight) developed by *Coats and Margulies, 2008[59]; per ESMC staff (Tab G), an average head mass of 1.8 kilograms (4 lb), for 6-month-old infants is suggested by the regression equation for average infant head mass developed by Sun and Jensen (1994).*

- The differential pressure limit of **20 mm H_2O** (2 cm H_2O) is likely related to the largest pressure differential between lung alveolar pressure (P_{alv}) and atmospheric pressure (P_{atm}) during an infant's normal quiet breathing cycle and related to resistance levels, although no specifics are provided in the standard. As explained above, staff could not identify specific pressure measures for infants during normal quiet breathing but for adult quiet breathing found that an average negative peak inspiratory alveolar pressure of -1 cm H_2O draws ~ 0.5 liters of air into the lungs over 2 seconds, whereas a positive peak expiratory alveolar pressure of +1 cm H_2O forces 0.5 liters from the lungs over about 3 seconds.[*]
- The specified test airflow rate of 200 ml/sec (12 L/min) was likely informed by the same source identified in Emery and Radford's study, namely Radford's nomogram 1955 relating body weight, respiratory rate (breathing frequency), and basal tidal volumes; it is unclear whether the specified rate was selected to represent breathing rates of infants under 12 months or older infants. Regardless, HS staff considers this flow rate is too high to be representative of quiet (eupneic) breathing in any infant, child, or adult while sleeping or resting.

[*] Changes in P_{alv} are related to, but are not directly correlated with, pressure changes in the thin, fluid filled, pleural space between the chest wall and lungs, *i.e.*, pleural pressure (P_{pl}). In healthy adults, P_{pl} is always negative and during quiet breathing, ranges from -5 cm H_2O at the beginning of inspiration (when P_{alv} = 0 cm H_2O), then decreases to -7.5 cm H_2O at the beginning of expiration (when P_{alv} also = 0). In contrast, P_{alv} is lowest during the first third of inspiration (-1 cm H_2O) and highest during the first quarter of expiration (1 cm H_2O). The transpulmonary pressure or recoil pressure of the lung (P_L) is the difference between the P_{alv}-Ppl, and unlike these measures, is always positive, ranging from 5 to 7.5 cm H_2O, *i.e.*, [0 P_{alv} –(-5 P_{pl})] to [0 P_{alv}-(-7.5 P_{pl})] cm H_2O.

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TAB E: ESHF Staff Memorandum, "Human Factors Assessment of ASTM F1917 Requirements for Crib Bumpers (CPSIA Section 104)"

TAB E

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
ROCKVILLE, MD 20850

MEMORANDUM

DATE: August 21, 2019

TO: The Crib Bumpers Rulemaking Project File

THROUGH: Joel R. Recht, Ph.D., Associate Executive Director,
Directorate for Engineering Sciences

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

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

SUBJECT: Human Factors Assessment of ASTM F1917 Requirements for Crib Bumpers (CPSIA Section 104)

I. BACKGROUND

In the fiscal year 2017 (FY 2017) Operating Plan of the U.S. Consumer Product Safety Commission (CPSC),[109] the Commission directed CPSC staff to develop a proposed mandatory consumer product safety standard for crib bumpers under section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA). The Commission stated that this standard must be more stringent than the current ASTM International (ASTM) voluntary standard and must further reduce the risk of injury associated with these products. The Commission also identified three tasks that staff must do, at a minimum, when developing the standard. One task was to "compose warnings and instructions on the product that explain all of the types of cribs on which the product can and cannot be installed, clear advice about how to install the product and at what age of the child to stop using the product."

ASTM F1917, *Standard Consumer Safety Performance Specification for Infant Bedding and Related Accessories*, contains requirements for infant bedding and accessories, including crib bumpers, in the United States. The current, published version of this voluntary standard is ASTM F1917 – 12. Section 8 of ASTM F1917 – 12 specifies product and packaging marking requirements, which include requirements for warnings that must appear on certain infant bedding and accessories covered by the standard; section 8.2.1 identifies warning content that is specific to crib bumpers. The voluntary standard does not include requirements for instructional literature to accompany products covered by the standard.

[109] The final, approved FY17 Operating Plan can be found here: https://www.cpsc.gov/s3fs-public/CPSCFY2017OpPlan.pdf. The Commission reaffirmed this decision in the FY18 Operating Plan, which can be found here: https://www.cpsc.gov/s3fs-public/FY_2018_Operating_Plan_August302017.pdf.

This memorandum, prepared by staff of CPSC's Directorate for Engineering Sciences, Division of Human Factors (ESHF), assesses the adequacy of the ASTM F1917 – 12 warning and instructional requirements in addressing the risk of injury and death associated with the use of crib bumpers. This memorandum also recommends revised requirements that research suggests are likely to reduce this risk and that meet the Commission's stated minimum requirements for warnings and instructions.

II. DISCUSSION

A. ESHF Staff Review of Incident Data

As staff of CPSC's Directorate for Epidemiology, Division of Hazard Analysis (EPHA), discusses in Tab B, staff has identified 113 fatal incidents, reported to CPSC over the more than 29-year period of January 1, 1990, to March 31, 2019, for which staff could confirm that a crib bumper was in the sleep environment. Generally, the reports identified the causes of these deaths as asphyxia, suffocation, or sudden infant death syndrome (SIDS). All but eight of the fatalities involved a crib bumper inside a crib; the eight cases outside a crib involved the following locations: a toddler bed (3 cases), a bassinet (3), a play pen (1), and a mattress on the floor (1).

CPSC staff classified the 113 fatalities into the following hazard patterns, or scenarios:

- Incidental (30 fatalities)
- Entrapment/Wedging (44 fatalities)
    - Against Object in Crib (25)
    - In Perimeter of Crib (13)
    - Other (6)
- Contact Without Entrapment/Wedging (27)
- Contact With Possible Entrapment/Wedging (7)
- Contact Outside Crib (5)

Staff classified 30 reported fatalities as "Incidental" because staff could find no evidence of bumper contact or of bumper involvement in the fatality. Thus, the remaining analysis is limited to the 83 remaining fatalities involving contact between the victim and the crib bumper.

Most (61 percent) of the 83 fatalities were to infants 4 months old or younger, and 90 percent of fatalities were to infants younger than 12 months. Some infants were born prematurely; for these victims, the reported chronological ages likely overestimate the baby's developmental stage (see American Academy of Pediatrics, 2004).

Detailed descriptions and discussions of the hazard patterns above can be found in the EPHA staff memorandum and in staff's 2016 briefing package to the Commission (Smith, 2016a). Some details surrounding these incidents are notable. As shown above, more than half (44) of the 83 reported fatalities involve entrapment or wedging against the bumper, and more than half of *those* cases, or 25 fatalities, involved entrapment between the bumper and something else in the crib. In one case, the victim was sharing the crib with a sibling, who functioned as the other

entrapping surface. The objects involved in the remaining 24 fatalities in this hazard pattern were:

- a bed pillow (10);
- an infant recliner (5);
- a cushion (3), which in one instance was used to prop up the end of an infant bouncer;
- an infant nursing or positioning pillow (2);
- an infant sleep positioner (2);
- a hand-held infant carrier (1); and
- a crib toy (1).

Many of these objects are intended for napping or sleeping, or are products that consumers are likely to use to aid the infant in this activity. Caregivers choosing to use these products within infant cribs is reasonably foreseeable, because cribs are commonly designated sleeping environments and the sides of a crib provide a barrier from older siblings or pets, for example. Although incidents in this hazard pattern are unwitnessed, they appear to involve the infant turning, arching, or rolling over the side of the product and becoming wedged or entrapped between the side of the product and a bumper that is installed on the interior side of the crib.

ESHF staff is aware of 12 reported fatalities associated with crib bumpers that involved crib-integrity issues or failures that directly led to the entrapment:

- Nine cases were entrapments "in the perimeter" of the crib, meaning that the child was found entrapped between the mattress and the side of the crib. In most, possibly all, of these nine cases, the bumper was used in an already-broken crib.
    - Six cases involved detached side rails.
    - Three cases involved missing or detached crib slats.
    - Two cases involved additional crib integrity problems. One case also involved a loose mattress support. Another case involved a crib that was missing hardware and had been assembled from components of different crib manufacturers, with the side rail assembled upside down and mounted with corner braces, or "L" brackets.
- One other entrapment-related fatality involved a mattress support failure.
- Two non-entrapment fatalities involved a bumper that was installed on an already-broken crib. In one case, the crib reportedly was missing "most" of its hardware. In the other case, the crib had makeshift mattress supports of the wrong size that had been installed by the owner.

Thus, as many as 11 of the bumper-related fatalities involving crib-integrity issues involved a crib that was already broken.

EPHA staff also identified 113 crib bumper-related nonfatal incidents and concerns, reported to CPSC over the more than 11-year period of January 1, 2008, to March 31, 2019. "Slat entrapments," defined as entrapment of a limb between crib slats that occurred even though a crib bumper was present, account for about one-third of these incidents (38 incidents, or 34

percent).[110] Although these incidents are useful at demonstrating that bumpers are only partially effective at preventing such entrapments, the incidents also might be related only indirectly to the crib bumper itself. Thus, the total number of nonfatal incidents reported above might overstate the true number of nonfatal incidents that can be ascribed to crib bumpers. Some nonfatal incidents involved entrapment scenarios that are similar to those in the reported fatalities. For example, seven nonfatal incidents involved entrapment between the bumper and an object in the crib, such as a sleep positioner or infant recliner. Twelve nonfatal incidents (nine percent) reportedly involved a child using the bumper to climb, typically by using the bumper as a step. Most cases reportedly involved the child climbing over the crib side. All children involved in these climbing incidents were at least 7 months old.[111]

Eight nonfatal incidents involved near-strangulations or entanglements, where parts of the crib bumper, such as the ties, threads, or stitched-on decorative patterns, wrapped around the neck, limb, or digit of the child. However, none of these cases involved a crib bumper tie wrapping around a child's neck. Furthermore, none of the 113 reported fatalities since 1990 involved strangulation on bumper ties.

B. Current ASTM Warning and Instructional Requirements

Section 8 of ASTM F1917 – 12 specifies product and packaging marking requirements for infant bedding and related accessories, and includes warnings that must appear on certain products covered by the standard. The voluntary standard requires the warnings to be "permanent" and "conspicuous," but neither defines these terms, nor specifies performance requirements for assessing conformance to those requirements.

Section 8.2.1 specifies that each crib bumper, or crib bumper panel if the bumper consists of multiple panels that can be used separately, must include the following warning statements:

> ⚠ **WARNING**
>
> To reduce the risk of suffocation, keep top of bumper up and in position. DO NOT allow bumper to sag down or in toward the sleeping surface. DO NOT use bumper if sagging cannot be corrected.
>
> To prevent entanglement or strangulation, position ties to outside of crib and be sure they are secure.
>
> Remove bumper when child can sit up unaided or can pull to a standing position.

Section 8 also includes two main design or format requirements that apply to all warnings in the voluntary standard:

[110] One of the climbing-related incidents also might have involved a slat entrapment with a crib liner in place.
[111] One of the two cases involving a 7-month-old did not involve the child stepping onto the bumper, but rather, involved the child using the bumper to pull herself up. ESHF staff also is aware of two "incidental" fatalities, one involving an 8-month-old and one involving a 10-month-old, the investigator speculated that the victim might have stood on the bumper to climb over the crib side; however, there is no evidence that the victim used the bumper in this way (Smith, 2016b).

1. *ANSI Z535.4 Formatting*. Section 8.2 states: "The label(s) shall be in the ANSI format, which would include a delineated signal word panel containing the safety alert symbol before the signal word and a contrasting background." Section 2, *Referenced Documents*, clarifies the reference to "ANSI" by referring the reader to ANSI Z535.4, *American National Standard for Product Safety Signs and Labels*. The appendix to ASTM F1917 – 12 also references ANSI Z535.4 when discussing the rationale behind the section 8 requirements (see section X1.3). However, none of these references specify the year of publication for ANSI Z535.4, so warning labels presumably would have to conform to the version of ANSI Z535.4 that is current when the product is manufactured.

2. *Minimum Letter Heights for Warning Text*. Section 8.2 of ASTM F1917 – 12 specifies that the required signal word, "WARNING," must be in letters at least 0.2 inches (5 mm) high. The remaining warning text must be in letters whose uppercase is at least 0.1 inches (2.5 mm) high. The standard does not specify a minimum-height requirement for the safety alert symbol (⚠)[112] that immediately precedes the signal word "WARNING."

The voluntary standard does not include any requirements for instructional literature to accompany crib bumpers.

C. ESHF Staff Assessment of Warning and Instructional Requirements

i. On-Product Warning Requirements

Safety and warnings literature consistently identify a classic hierarchy of approaches that should be followed to control hazards. Warning about hazards is viewed universally as less effective at eliminating or reducing exposure to hazards than either designing the hazard out of a product or guarding the consumer from the hazard; therefore, the use of warnings is lower in the hazard-control hierarchy than the other two approaches (Laughery & Wogalter, 2011; Vredenburgh & Zackowitz, 2005; Wogalter, 2006; Wogalter & Laughery, 2005). Warnings are less effective 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 "last resort" measure that supplements, rather than replaces, redesign or guarding efforts, unless these higher-level, hazard-control efforts are not feasible.

As discussed below, ESHF staff concludes that the on-product warning requirements of ASTM F1917 – 12 are not adequate. Staff recommends that the proposed rule replace or revise these requirements with ones that would further reduce the risk of injury associated with crib bumpers. Specifically, staff recommends a warning with the following content and general format:

[112] The version of the safety alert symbol shown here is based on the default symbol used in the ANSI Z535 series of standards. For consistency, ESHF staff uses this version throughout the memorandum for all instances of the safety alert symbol.

⚠WARNING

To reduce the risk of **SUFFOCATION**:

- **Keep tight against side of crib.** Do not use if product is loose or sags down toward sleeping surface.
- **Never put pillows or anything else in crib** that could trap baby against this product.
- **Only use in a crib without broken parts or missing slats.** This product will not fix a broken crib or prevent baby from falling out. **Never use in a toddler bed or bassinet.**

To help prevent **ENTANGLEMENT** or **STRANGULATION**, position ties to outside of crib and secure tightly.

Remove this product when baby can pull to a stand using crib side (starting about 6 months). Older babies can use product to climb out of crib.

ESHF staff also recommends that the proposed rule include:

- a definition of "conspicuous," to clarify 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.

Tab F of staff's briefing package outlines staff's recommended revisions to the relevant requirements in ASTM F1917 – 12, and the following subsections describe the rationale behind these revisions.

1. Warning Content

The primary U.S. voluntary consensus standard for product safety signs and labels, ANSI Z535.4, *American National Standard for 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:[113]

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

[113] 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 crib bumpers warning specified in ASTM F1917 – 12 does not adequately address these warning elements.

1a. Hazard Description and Consequences

Current crib bumper warnings include a statement that instructs consumers to remove the bumper when the child can sit up unaided or can pull themselves to a standing position;[114] however, the warnings fail to describe why this action is necessary. Staff has learned that this statement is intended to prevent children from using bumpers to climb out of the crib (Smith, 2016b). Although ESHF staff cannot confirm that any of the reported fatalities involved this scenario,[109] 12 nonfatal incidents reportedly involved a child using the crib bumper to climb (*e.g.*, treating the bumper as a step). Most of the 12 incidents were unwitnessed; the caregiver merely speculated that the child might have used the bumper to aid in getting out of the crib. However, a caregiver witnessed a child using the bumper to climb in at least one incident.[115] Thus, ESHF staff recommends that the required warning include language that describes how a child who reaches the stated developmental milestones would be at risk if the bumper stays in the crib. Without this information, consumers may struggle to understand how these two items relate, which may inhibit or delay compliance with the recommendation to remove the bumper. However, given the intended function of the "remove bumper" statement, ESHF staff questions the need for, and relevance of, *both* stated developmental milestones in the warning. The ability to sit up unaided may precede the ability of the child to climb, but this milestone is not the immediate precursor to this skill. The more relevant developmental milestone is the ability of the child to pull to a standing position, and an even more relevant milestone is the ability of a child to pull to a standing position using a chair, rail, or other convenient object. Identifying the milestone in this latter way would be more accurate, and limiting the description to this milestone alone would have the added benefit of reducing the total amount of text dedicated to this issue. This change will increase the likelihood that consumers will read the text, thereby further reducing the risk of injury associated with crib bumpers.

ESHF staff also believes that listing the age at when the developmental milestone is likely to occur will help raise consumers' awareness of when they should look out for this behavior, further improving the safety of crib bumpers. Bayley (1969) estimates the 5th percentile age for children to pull to a standing position using a chair, rail, or other convenient object to be 6 months (also see Atun-Einy, Berger, & Sher, 2011).[116] This age is consistent with the available incident data, because the youngest children involved in the nonfatal climbing incidents were 7 months old.

In recent years, ASTM juvenile products standards have started using the term "baby," and its variants, in place of "infant" within required warnings. ESHF staff initially recommended this change for sling carrier warnings in 2012, making the point that "babies" is a more common and less clinical term than "infants," and therefore, would be more suitable for consumer-directed

[114] The European Standard, EN 16780:2018, *Textile child care articles – Safety requirements and test methods for children's cot bumpers*, also includes a requirement for bumpers to be marked with a warning that tells consumers to "Remove cot bumper when child can sit unaided."
[115] A second incident was reported to have been "witnessed"; however, the incident report stated that the caregiver's back was turned to the child when the child climbed out of the crib.
[116] Bayley classifies this milestone as "stands up by furniture."

warnings that address risks to infants. Staff incorporated this change into the final warnings of the ASTM voluntary standard and CPSC mandatory rule for sling carriers. Then, in 2014, ESHF staff became a member of the ASTM Ad Hoc Language Task Group (Ad Hoc TG). This task group consists of members of the various voluntary standards affected by CPSIA section 104 mandatory standards for durable nursery products, and ASTM formed this group to develop standardized language across ASTM juvenile products standards. One task of this group was to develop standardized warning language for the suffocation hazard associated with infant sleep products. During the development of this language, ESHF staff recommended the use of "babies" rather than "infants" for the same reasons previously stated, and the Ad Hoc TG agreed to the use of this term in the standardized warning. This change is reflected in the Ad Hoc TG's recommendation document, the latest version of which is published in the "Committee Documents" section of the Committee F15 ASTM website.[117] ASTM juvenile products standards have begun using the term "babies" in place of "infants" or similar terms whenever appropriate. Given that crib bumpers are intended for use with infants only, using "babies" in crib bumper warnings to reflect the children most at risk is appropriate.

The crib bumper warning specified in ASTM F1917 – 12 includes a statement that tells consumers to prevent entanglements and strangulations by positioning bumper ties to the outside of the crib and making sure they are secure. Staff notes that there have been no reported fatalities involving a crib bumper tie since the 1980s. In addition, although staff is aware of eight nonfatal incidents involving near-strangulations or entanglements, none of these cases involved a crib bumper tie wrapping around a child's neck. The voluntary standard has included a maximum tie-length requirement of 9 inches since the year 1999, and this requirement is the most likely reason for the lack of fatal and nonfatal incidents involving strangulations or near-strangulations on bumper ties. The apparent effectiveness of this requirement suggests that the warning statement about positioning and securing ties to the outside of the crib is no longer needed, because warnings should be used only when a significant hazard exists. In addition, reducing the length of the required warning could improve its overall effectiveness by reducing consumer efforts to read and retain the warning content. Yet, the lack of relevant incidents could be due partially to the presence of the warning statement and consumers' compliance with the recommended action, at least for those products with attachment means that, in principle, could pose a strangulation risk. Thus, staff does not recommend removing the warning statement for all crib bumpers.

Nevertheless, staff believes that this warning statement does not apply to crib bumpers with attachment means other than ties or ribbons, and does not apply to bumpers with ties or ribbons 7 inches in length or less. ASTM F1917 – 12 (section 5.2) already requires that all decorative components shall not exceed 7 inches, and that decorative components that can tangle to form a loop shall not result in a loop perimeter greater than 14 inches. Anthropometric data show that the 5th percentile neck circumference of infants 0 to 3 months old is 7.2 inches (Schneider, Lehman, Pflug, & Owings, 1986), which is greater than the 7-inch requirement. The data also show that the 5th percentile head circumference of infants from birth to 2 months old is at least 14.1 inches (see Fryar, Gu, Ogden, & Flegal, 2016), which is greater than the 14-inch

[117] This document, "Recommended Language Approved by Ad Hoc Task Group, Revision E," is dated May 28, 2019, and can be found here: https://myastm.astm.org/KEY_DOCUMENTS/PDF_FILES/f150000adhoc7.pdf. This link is accessible to Committee F15 members only.

circumference requirement in F1917. Thus, although the voluntary standard states that a maximum length of 9 inches for bumper ties was chosen to allow bumpers to be "sufficiently secured to the crib rails" (section X1.2), the available anthropometric data suggests that crib bumpers with attachment means, such as ties or ribbons, up to 7 inches in length would not pose a strangulation hazard. For this reason, and to improve the safety of crib bumpers by focusing caregivers on hazards that require their attention, staff recommends that the entanglement and strangulation warning statement not be required to appear on these products.

On the basis of the discussion above, staff recommends the following changes to the hazard and consequence descriptions in the crib bumpers warning to further reduce the risk of injury associated with crib bumpers:

- Revise the warning language to reference "babies" and its variants, rather than less specific terms, such as "child."

- Revise the language about removing of the bumper to focus on the ability of the child to pull to a standing position using the crib side. In addition, include language that identifies the approximate age at which the child will reach this developmental milestone ("starting about 6 months") and explains why removing the bumper is necessary ("Older babies can use product to climb out of crib").

- Revise the warning requirement to specify that the entanglement and strangulation statement need be included only on products with attachment means greater than 7 inches in length.

1b. Hazard Avoidance

Currently, the portion of the ASTM crib bumper warning dedicated to the suffocation hazard limits its recommendations for avoiding this hazard to: (1) keeping the top of the bumper up and in position so it does not sag into the crib, and (2) not using the bumper if sagging cannot be corrected. Staff disagrees that *only* the "top" of a bumper need be kept "up and in position." In some reported fatalities and nonfatal incidents, the child reportedly slipped beneath the bottom of the bumper.[118] A better approach, which staff concludes should improve the safety of crib bumpers, would be to communicate how the bumper, as a whole, should fit when properly installed (*e.g.*, "Keep tight against side of crib"), to help reduce the frequency of loose or sagging bumpers. The extra space that would be needed in the warning to accommodate this sentence can be offset by merging the two "DO NOT" sentences; that is, replace "DO NOT allow bumper to sag down or in toward the sleeping surface. DO NOT use bumper if sagging cannot be corrected," with "Do not use if bumper is loose or sags down toward sleeping surface."

The reported fatalities suggest additional actions that consumers can take to avoid the suffocation hazard. Staff is aware of 25 reported fatalities since 1990 in which the victim was found wedged or entrapped between the bumper and another object, such as a pillow, infant recliner, or sleep positioner. In addition, staff is aware of seven nonfatal incidents since 2008 in which the victim

[118] CPSC staff classified 10 nonfatal incidents as "Under or Behind Bumper," cases in which the child, or some part of the child, was found under or behind the crib bumper.

was found entrapped between the bumper and another object, such as a sleep positioner or infant recliner. Adding language that warns against placing anything into a crib that could trap an infant against the bumper would improve the safety of crib bumpers by alerting consumers to this potential, and would be especially beneficial in cases where a consumer installs a new crib bumper in an old crib that lacks warnings about the suffocation risk that pillows and other soft bedding pose. Staff's proposed language is: "Never put pillows or anything else in crib that could trap baby against this product." The language identifies pillows explicitly because they are the most common object involved in fatal entrapment scenarios against crib sides.

As many as 11 fatalities involved a bumper that was installed in a crib that was already broken, and the integrity of the crib directly caused or likely led to the fatality. Crib integrity issues varied and some cases involved multiple failures. However, six cases involved detached side rails and three cases involved missing or detached crib slats. Although the incident reports are ambiguous on this point, in some cases the bumper might have been installed with the intention of blocking the infant's access to missing slats or a detached side. In addition, in eight reported fatalities, the crib bumper was used in a toddler bed, bassinet, or otherwise outside an infant crib. Crib bumpers are not intended to be used in these sleep environments. Thus, adding warning language that tells consumers only to use bumpers in cribs that are not broken or missing slats, and warns consumers that the bumper will not keep the baby in the crib, should reduce the risk of injury and death with these products. Staff also recommends adding language that explicitly warns consumers against using crib bumpers in toddler beds and bassinets. Staff's recommended warning statements are: "Only use in a crib without broken parts or missing slats. This product will not fix a broken crib or prevent baby from falling out. Never use in a toddler bed or bassinet."

Staff also recommends minor changes to the language of the entanglement and strangulation warning statement to clarify the message and to present the message in more clear, active voice. For example, staff recommends changing the original phrase, "position ties to outside of crib and be sure they are secure," to "position ties to outside of crib and secure tightly." These improvements to the readability of the message should improve the safety of crib bumpers. The ASTM Infant Bedding subcommittee intends to ballot staff's recommended changes to this warning statement.

In CPSC's FY 2017 Operating Plan,[31] the Commission stated that staff shall, at a minimum:

> ". . . compose warnings and instructions on the product that explain all of the types of cribs on which the product can and cannot be installed, clear advice about how to install the product and at what age of the child to stop using the product" (p. 16)

ESHF staff believes that the proposed revisions discussed in this section address the Commission's direction. Staff's proposal includes:

- more explicit descriptions of how the bumper should fit when properly installed;
- new warning statements related to never using crib bumpers in broken cribs;

- new warning statements about only using crib bumpers in cribs, and not using bumpers in toddler beds or bassinets; and

- more details about when and why consumers should remove crib bumpers from a crib.

ESHF staff also recommends that crib bumpers include permanent markings that indicate the portions of the bumper intended for the long and short sides of the crib. This requirement is discussed later in the memorandum.

2. 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). ASTM F1917 – 12 requires the warning labels specified in the standard to conform to ANSI Z535.4, *American National Standard for Product Safety Signs and Labels*. ESHF staff consistently uses this standard—the primary U.S. voluntary consensus standard for the design, application, use, and placement of on-product warning labels—when developing or assessing the adequacy of warning labels. Literature on the design and evaluation of on-product warnings frequently cites ANSI Z535.4 as the minimum set of requirements that products containing such labels that are sold in the United States should meet (*e.g.*, Vredenburgh & Zackowitz, 2005; Wogalter & Laughery, 2005). Hellier and Edworthy (2006) and Peckham (2006) report that this conclusion has been reaffirmed by the U.S. courts, who have accepted the ANSI Z535 series of standards in general, and the ANSI Z535.4 standard in particular, as the benchmark against which warning labels are evaluated for adequacy, because these standards are seen as the state of the art (also see Laughery & Wogalter, 2006).[119] 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).

The information above suggests that the current ASTM F1917 requirement for crib bumper warnings to conform to ANSI Z535.4 should be adequate. However, staff previously examined crib bumper samples and discovered that none of the samples fully conformed to the ANSI standard, even in those cases in which the warning language met the content requirements of ASTM F1917 – 12 (Smith, 2016b). Although this failure to conform could be a result of manufacturers being less diligent about meeting the warning format requirements relative to the content requirements,[120] the current wording of ASTM F1917 – 12 also could be partially to blame. Section 8.2 of the voluntary standard states, in part:

> "The label(s) shall be in the ANSI format, which would include a delineated signal word panel containing the safety alert symbol before the signal word and a contrasting background."

Manufacturers might be misinterpreting this requirement to mean that the warning labels are required *only* to include a delineated signal word panel containing the safety alert symbol before

[119] Also, per G. Peckham, personal communication, June 12, 2015.
[120] For example, many of the warnings failed to meet the text size requirements as well.

the signal word and a contrasting background, rather than those requirements merely being part of what is included in, and required by, ANSI Z535.4.

Since 2016, ASTM juvenile products standards have begun adopting warning format requirements that are consistent with the recommendations of the ASTM Ad Hoc TG. As ESHF staff noted earlier in this memorandum, ASTM formed the Ad Hoc TG to develop standardized language across ASTM juvenile products standards, and has developed recommendations for warning format to be applied to these products. The author 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. ESHF staff collaborated with the other members of the Ad Hoc TG to develop recommendations for warning format that are based primarily on the requirements of ANSI Z535.4, *American National Standard for 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, *American National Standard: 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.[115]

Replacing the current ASTM F1917 – 12 requirements related to warning format with requirements based on the recommendations of the Ad Hoc TG will result in permanent, conspicuous, and consistently formatted on-product warning labels that address many warning format issues related to capturing consumer attention, improving readability, and increasing hazard perception and avoidance behavior. The ASTM Infant Bedding subcommittee has already expressed interest in adopting revised warning format requirements that are consistent with the Ad Hoc TG recommendations. Staff's specific recommended revisions to the warning format requirements of ASTM F1917 – 12, based on the Ad Hoc recommendations, can be seen in Tab F.

Staff also recommends formatting key words and phrases in the warning in boldface to emphasize the most important messages of the text. Warnings in ASTM voluntary standards often use all-uppercase text to emphasize individual words; however, literature on the design of warnings, instructions, and other documents consistently recommends against the use of all-uppercase lettering for long texts (*i.e.*, longer than a few words), because the block-like appearance of such lettering is less legible and readable than mixed-case text (*e.g.*, Frascara, 2006; Robinson, 2009; Schriver, 1997; Wogalter & Vigilante, 2006; also see Singer, Balliro, & Lerner, 2003). In addition, Coles and Foster (1975) have found boldface to be a better cue than all-uppercase lettering when extra emphasis is needed (as cited in Schriver, 1997). Thus, ESHF staff recommends highlighting key phrases in boldface, and only emphasizing the one-word hazard identifiers (*i.e.*, SUFFOCATION, ENTANGLEMENT, STRANGULATION) in both boldface and all-uppercase.

3. Warning Placement

ASTM F1917 – 12 requires the warning labels for crib bumpers and other infant bedding and related accessories to be "conspicuous," but fails to define this term. Numerous ASTM juvenile products standards include a requirement for warnings to be "conspicuous," and define this term in a way that enables one to assess conformance. Typically, the term is defined in terms of when the label must be visible; for example: "visible, when the [product] is in all manufacturer's recommended use positions . . . to a person standing near the [product] at any one position around the [product] but not necessarily visible from all positions."[121] Including a similar definition in the proposed rule would clarify when the warning on crib bumpers must be visible to the consumer, thereby improving crib bumper safety by making sure warnings are visible when needed. Including this definition also will enable a test lab to assess conformance to this element of ASTM F1917 – 12.

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).[122] This guidance is consistent with the guidance typically offered in human factors and warnings literature. Many of the hazard-avoidance behaviors included in staff's revised warning are associated with the initial installation of the bumper (*e.g.*, keeping the bumper tight against the crib side, limiting use to cribs). Thus, these warning messages ought to be visible to consumers during installation. However, some actions require the consumer to respond at some future time. For example, children generally can pull themselves to a standing position using a chair, rail, or other convenient object for support at about 6 to 12 months of age (Bayley, 1969; also see Atun-Einy, Berger, & Scher, 2011). Thus, consumers who install crib bumpers when the child is a newborn might have to wait 6 months or longer after installation before having to follow the recommendation in the warning to remove the bumper. One cannot depend on the consumer to remember what is stated in a warning for that length of time, so to enable consumers to notice, read, and comply with the message, this statement must be visible to consumers after the bumper has been installed, or when in the "manufacturer's recommended use position." Thus, ESHF staff recommends the

[121] From ASTM F404 – 18, *Standard Consumer Safety Specification for High Chairs*.
[122] However, warnings must not be presented so far ahead that the consumer might forget the message when exposed to the hazard.

following definition for "conspicuous" in the proposed rule: "visible, when the product is in all manufacturer's recommended use positions, to a person standing near the product at any one position around the product, but not necessarily visible from all positions."

4. Warning Permanence

ASTM F1917 – 12 requires warning labels for infant bedding and related accessories to be "permanent"; however, the standard neither defines "permanent" nor specifies how one would assess conformance to this requirement. Adding specific permanence requirements and test methods would further reduce the risk of injury associated with crib bumpers by increasing the likelihood that warnings will be available to consumers when consumers need them. ASTM juvenile products standards commonly address this issue with warning label permanence requirements that appear in the *General Requirements* section of the voluntary standard (section 5, in the case of ASTM F1917 – 12), and specify that warning labels must be permanent when tested in accordance with specific test methods that appear in *Test Methods* (section 7). ESHF staff's suggested general requirements and test methods, which are consistent with the general approach taken across ASTM juvenile products standards, follows.

Within the *General Requirements* section:

5.4 *Labeling*—Warning labels (whether paper or non-paper) shall be permanent when tested in accordance with 7.5.

5.4.1 Warning statements applied directly onto the surface of the product by hot stamping, heat transfer, printing, wood burning, and so forth shall be permanent when tested in accordance with 7.6.

5.4.2 Non-paper labels shall not liberate small parts when tested in accordance with 7.6.

Within the *Test Methods* section:

7.5 *Permanency of Labels and Warnings*:

7.5.1 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.

7.5.2 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.

7.5.3 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 most likely to cause failure using a 0.75 in. (19 mm) diameter clamp surface. Gradually apply the force over 5 s and maintain for an additional 10 s.

7.6 *Adhesion Test for Warnings Applied Directly onto the Surface of the Product*:

7.6.1 Apply the tape test defined in Test Methods D3359, Test Method B—Cross-Cut Tape Test of Test Methods, eliminating parallel cuts.

7.6.2 Perform this test once in each different location where warnings are applied.

7.6.3 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.

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

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 that the required warnings are the only way in which many of the hazards associated with crib bumpers are addressed, the warnings must be as permanent as possible and discourage easy removal. Thus, staff recommends that the proposed rule include the following additional requirement:

5.4.3 Crib bumper/liner warning labels that are attached to the fabric 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 7.5.3.

Staff included the same requirement in the 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.

ii. Instructional Requirements

ASTM F1917 – 12 lacks any requirements for instructional literature to accompany crib bumpers. Given the importance of proper installation, staff concludes that instructional literature about installation is essential to adequately address the risk of injury and death associated with crib bumpers. In addition, staff recommends that crib bumpers be required to include permanent markings that identify the intended crib side onto which each portion of the bumper is to be installed. Staff discusses these issues below.

1. Instructional Literature

Numerous ASTM juvenile products standards include an "Instructional Literature" section that requires manufacturers to provide instructions with the product. The ASTM Ad Hoc TG has published recommended requirements for instructional literature and for the formatting of warnings in instructional literature. These requirements can be found in the latest revision to the "Ad Hoc Approved Language" document, referenced earlier.[115] The requirements generally specify that these instructions shall

- be easy to read and understand;
- include information regarding specific tasks associated with the product such as assembly, installation, adjustment, maintenance, cleaning, and use; and
- 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.

ESHF staff's recommended requirements, which can be seen as a new Section 9 in the tables in Tab F, are based on the Ad Hoc TG recommended requirements.

2. Additional Product Markings

ESHF staff also believes that bumpers should be required to include permanent on-product markings that indicate which portions of the bumper are intended for the long and short sides of the crib. ASTM F1917 – 12 requires bumpers to be capable of being secured "at or near all corners and at the midpoints of the long sides of the crib" (section 5.4). For a standard full-size crib, whose interior dimensions measure 28 inches wide and 52 3/8 inches long,[123] this requirement would result in ties separated by about 28 inches on the short crib sides and about 26 inches on the long crib sides. During its examination of crib bumper samples, members of the CPSC crib bumpers rulemaking team discovered that these differing interval lengths were not immediately obvious when installing a long continuous bumper on a crib, and that staff could easily install the portions intended for the short sides onto the long sides, and vice versa. Incorrectly installing the bumper in this way resulted in a somewhat loose fit, but did not seem obviously wrong, and staff was able to determine that the original installation was incorrect only after reinstalling the bumper correctly, via trial and error.

To reduce the likelihood of consumers installing the bumper incorrectly, and the potential for loose or sagging bumpers, ESHF staff recommends that crib bumpers at least 28 inches in length (*i.e.*, the length of the short side of a standard full-size crib) be required to include permanent markings to indicate the intended crib sides. Although the potential for incorrect installation might be addressable somewhat through the instructional literature that would accompany crib bumpers, ESHF staff doubts that many consumers would keep written instructions for bumpers long-term. Requiring markings on the bumpers themselves would improve the safety of crib bumpers by avoiding the potential problems associated with lost or discarded instructions. This requirement also partially addresses the Commission's direction for staff to:

> ". . . compose warnings and instructions on the product that explain all of the types of cribs on which the product can and cannot be installed, clear advice about how to install the product and at what age of the child to stop using the product" (FY17 Operating Plan, p. 16)

ESHF staff does not have specific recommendations for how these markings should appear or what they should say. Rather, at this time, staff recommends that this requirement be worded in a way that provides manufacturers with maximum flexibility to address the markings in a way that is most suited to their products. Thus, staff recommends the following general marking and labeling requirement:

> 8.4 Crib bumpers/liners shall be marked or labeled clearly and legibly, in the English language at a minimum, to identify which segments of the bumper are intended for the short and long sides of the crib, unless the bumper/liner is intended for a circular crib or is less than 28 inches in length, not including attachment means.

III. CONCLUSIONS

ESHF staff concludes that the warning and instructional requirements specified in ASTM F1917 – 12, do not adequately address the risk of injury and death associated with crib bumpers. Staff

[123] From ASTM F1169 – 13, *Standard Consumer Safety Specification for Full-Size Baby Cribs*.

recommends that the Commission adopt ESHF staff's revised requirements for the proposed rule for crib bumpers to further reduce the risk of injury. These requirements include improved requirements for on-product warning content, format, placement, and permanence for crib bumpers; new requirements for instructional literature that would accompany these products; and permanent markings on crib bumpers that identify the portions of the bumper intended for the long and short sides of a crib.

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TAB F: Tables of CPSC Staff's Draft Proposed Rule Relative to ASTM F1917 – 12

TAB F

TABLES OF CPSC STAFF'S RECOMMENDED REVISIONS TO ASTM F1917 – 12[124]

ASTM F1917 – 12, Section 3. Terminology

ASTM F1917 – 12	Staff's Recommended Revisions	Rationale Summary
3.1.1 *attachment means, n*—flexible ribbons, strings, hook and loop straps, ties, and similar devices attached to a bumper for the purpose of attaching to a crib.	3.1.1 *attachment means, n*—flexible ribbons, strings, hook and loop straps, ties, and similar devices attached to a crib bumper/liner for the purpose of attaching to a crib.	Revised existing definitions to account for the new "crib bumper/liner" definition, below.
3.1.4 *infant bedding and related accessories, n*—includes the following items intended for use in a nursery: fitted sheets, blankets, dust ruffles, covers and drapes for canopies, pillows, mattress covers, diaper stackers, fabric wall hangings, bumper guards, headboard bumper guards, and comforters.	3.1.4 *infant bedding and related accessories, n*—includes the following items intended for use in a nursery: fitted sheets, blankets, dust ruffles, covers and drapes for canopies, pillows, mattress covers, diaper stackers, fabric wall hangings, crib bumpers/liners, ~~guards, headboard bumper guards,~~ and comforters.	Revised existing definitions to account for the new "crib bumper/liner" definition, below.
(No requirement)	3.1.X *conspicuous, adj*— visible, when the product is in all manufacturer's recommended use positions, to a person standing near the product at any one position around the product, but not necessarily visible from all positions. 3.1.X *crib bumper/liner, n*—any product intended to be placed against any portion of the interior perimeter of a crib, and that reduces or eliminates an infant's access to the crib sides, slats, spindles, or the spaces between these components. *Discussion*—Such products are commonly referred to as crib bumpers, crib liners, mesh liners, bumper pads, bumper guards, and headboard panels, but do not include products intended to cover only the top horizontal rail of a crib.	New definitions added to clarify requirements and to improve consistency throughout the standard. The "conspicuous" definition was adapted from other ASTM standards, such as ASTM F404 – 18, *Standard Consumer Safety Specification for High Chairs*, and ASTM F2613 – 17a, *Standard Consumer Safety Specification for Children's Chairs and Stools*. The ASTM Infant Bedding subcommittee has balloted two earlier variations of the crib bumper/liner definition.

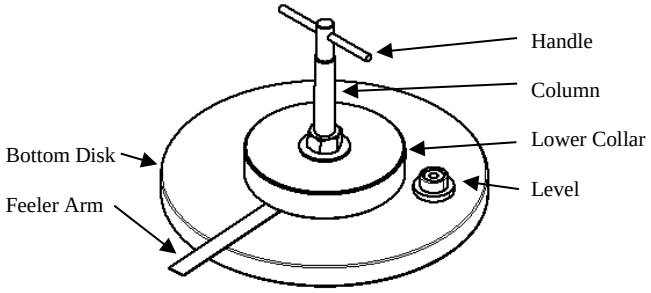
[124] Recommended additions are underlined, and recommended deletions are single struck-through.

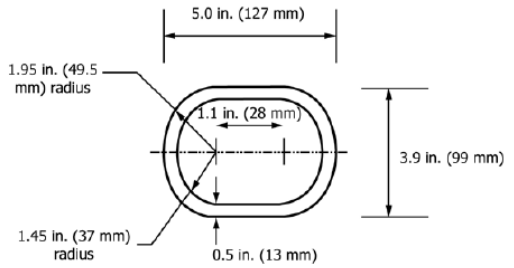
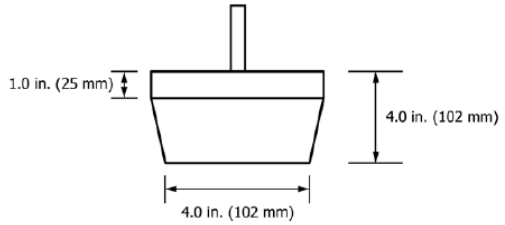
ASTM F1917 – 12, Section 5. General Requirements

ASTM F1917 – 12	Staff's Recommended Revisions	Rationale Summary
5.1 Attachment means on bumper guards and headboard bumper guards shall not exceed 9.0 in. (230 mm) when measured in accordance with 7.1.	5.1 Attachment means on crib bumpers/liners ~~guards and headboard bumper guards~~ shall not exceed 9.0 in. (230 mm) both before and after 7.4.1 testing when measured in accordance with 7.1.	Revised attachment means requirement based on new definition for crib bumpers. Also, the length requirement should apply after testing as well, because otherwise the partial detachment of a tie, which is permitted by the standard, could cause the tie to exceed the 9-inch limit.
5.2 Decorative components as defined in 3.1.2 shall not exceed 7 in. (180 mm) when measured in accordance with 7.1. If any decorative components can tangle to form a loop, then the perimeter of the loop shall not exceed 14 in. (360 mm) when measured in accordance with 7.1.	5.2 Decorative components as defined in 3.1.2 shall not exceed 7 in. (180 mm) when measured in accordance with 7.1. If any decorative components can tangle to form a loop, then the perimeter of the loop shall not exceed 14 in. (360 mm) when ~~measured~~ tested in accordance with 7.1. These requirements shall apply both before and after 7.4.3 testing.	Clarified the requirement to address the fact that section 7.1 measures the extended line length, not a loop perimeter. Also required the requirement to be met both before and after testing.
5.4 Bumper guards shall be capable of being secured at or near all corners and at the midpoints of the long sides of the crib. Bumper guards intended for circular cribs shall be capable of being secured at intervals not exceeding 26 in. (660 mm).	~~5.4 Bumper guards shall be capable of being secured at or near all corners and at the midpoints of the long sides of the crib. Bumper guards intended for circular cribs shall be capable of being secured at intervals not exceeding 26 in. (660 mm).~~	Replaced with new Crib Bumper/Liner Entrapment in Openings requirement (6.5).
(No requirement)	5.4 *Labeling*—Warning labels (whether paper or non-paper) shall be permanent when tested in accordance with 7.5. 5.4.1 Warning statements applied directly onto the surface of the product by hot stamping, heat transfer, printing, wood burning, and so forth shall be permanent when tested in accordance with 7.6. 5.4.2 Non-paper labels shall not liberate small parts when tested in accordance with 7.6. 5.4.3 Crib bumper/liner warning labels that are attached to the fabric 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 7.5.3.	Added missing permanence requirements for warnings that are consistent with analogous requirements in other juvenile products standards. The additional section 5.4.3 requirement is based on a requirement that was added to the final rule for sling carriers to avoid free-hanging labels.

ASTM F1917 – 12, Section 6. Performance Requirements

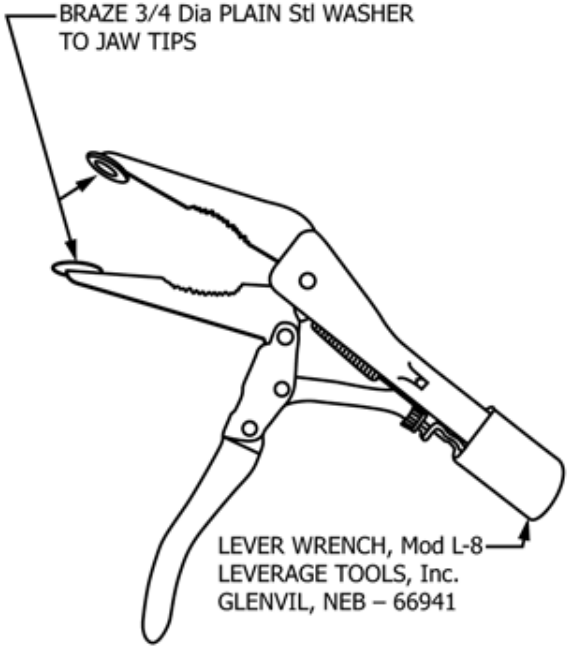
ASTM F1917 – 12	Staff's Recommended Revisions	Rationale Summary
6.2 *Maximum Bumper Thickness*—For crib bumpers manufactured of fabric and filled with a natural or manmade fibrous material, each bumper section shall slide through the bumper thickness test fixture (see Fig. 1) over its entire length when tested in accordance with 7.3. The bumper shall be tested in its pre-washed state and also after three wash/dry cycles performed according to the manufacturer's care instructions.	6.2 *Maximum Crib Bumper/Liner Thickness*—For all crib bumpers/liners ~~manufactured of fabric and filled with a natural or manmade fibrous material~~, each bumper/liner section shall slide through the crib bumper/liner thickness test fixture (see Fig. 1) over its entire length at a rate no less than 0.5 inch per second when tested in accordance with 7.3. The bumper shall be tested in its pre-washed state and also after three wash/dry cycles performed according to the manufacturer's care instructions.	Revised to require that all bumpers meet the thickness requirement, regardless of filling material, and to add a rate at which bumpers must pass through to more clearly delineate a pass from a fail. The rate was selected to avoid bumpers that stop from restarting due to external influences, such as vibration or how the tester feeds the bumper into the fixture. This rate seems reasonable based on how very quickly most bumpers slide through the fixture. Some thick bumpers technically will continue to pass through the fixture, just at an extremely slow rate.
Note: Test fixture shall be fabricated from aluminum and have a smooth finish. **FIG. 1 Bumper Thickness Test Fixture**	Note: Test fixture shall be fabricated from aluminum and have a smooth finish. The test fixture slot and fillet finish shall be 1.6 Ra. **FIG. 1 Crib Bumper/Liner Thickness Test Fixture**	Added a finish requirement, because of its possible effect on how quickly a bumper can slide through the test fixture and the potential for variation among test labs and fixtures. Ra, or roughness average, is a mean measure of surface roughness left by cutting tools, in micrometers. A 1.6 Ra surface finish is approximately the finish of the CPSC test fixture, is a common "smooth" specification, and is practical to achieve. In addition, at a very slow speed of 0.5 in/sec (see above), friction is critical to motion. For comparison, cotton fabric is about 20 Ra.
6.3 *Bumper Pad Tie Strength*—Following the testing specified in 7.4, a bumper pad tie shall not fully detach from the bumper pad. Partial detachment or tearing is allowed.	6.3 *Strength of Crib Bumper/Liner Attachments and Seams* 6.3.1 ~~*Bumper Pad Tie Strength*~~ *Attachment Means*—Following the testing specified in 7.4.1, ~~a bumper pad tie~~ the attachment means for a crib bumper/liner shall not fully detach from the crib bumper/liner ~~pad~~. Partial detachment or tearing is allowed. 6.3.2 *Seams*—Following the testing specified in 7.4,2, no seam shall have an opening that allows a 0.22-inch diameter steel rod to enter. 6.3.3 *Decorative Components*—Following the testing specified in 7.4.3 the decorative component shall not fully detach from the crib bumper/liner. Partial detachment or tearing is allowed.	Revised to clarify that the strength requirements apply to all attachment means, not just bumper ties, and to add strength requirements for seams and decorative components. The seam strength requirement includes a criterion of 0.22 inches, based on the finger entrapment probe that is in many children's product tests.

ASTM F1917 – 12	Staff's Recommended Revisions	Rationale Summary
(No requirement)	6.4 *Crib Bumper/Liner Firmness*—For crib bumpers/liners with an installed thickness of 0.59 in. (15 mm) or greater, no part of the bumper shall contact the feeler arm of the firmness test fixture (see Fig. 2), when tested in accordance with 7.7.	Added a new firmness requirement for crib bumpers, based on the Firmness task group recommendations. The requirement to only test bumpers at least 0.59 in. (15 mm) thick is based on the thickness of the bottom disk of the test device, which is the same dimension.
(No figure)	 **FIG. 2 Firmness Test Fixture**	Added a figure that illustrates the new firmness test fixture, based on AS/NZS 8811.1:2013, referenced in 6.4.
(No requirement)	6.5 Crib Bumper/Liner Entrapment in Openings—When tested in accordance with the head probe test specified in 7.8, no opening shall allow passage of the small head test probe (Fig. 3). Passage is defined as admitting the base of the probe.	Added a new entrapment requirement for crib bumpers, based on the Attachment task group recommendations, to limit the ability of the bumper to pull away from the side of the crib. This would replace the current general requirement in 5.4.

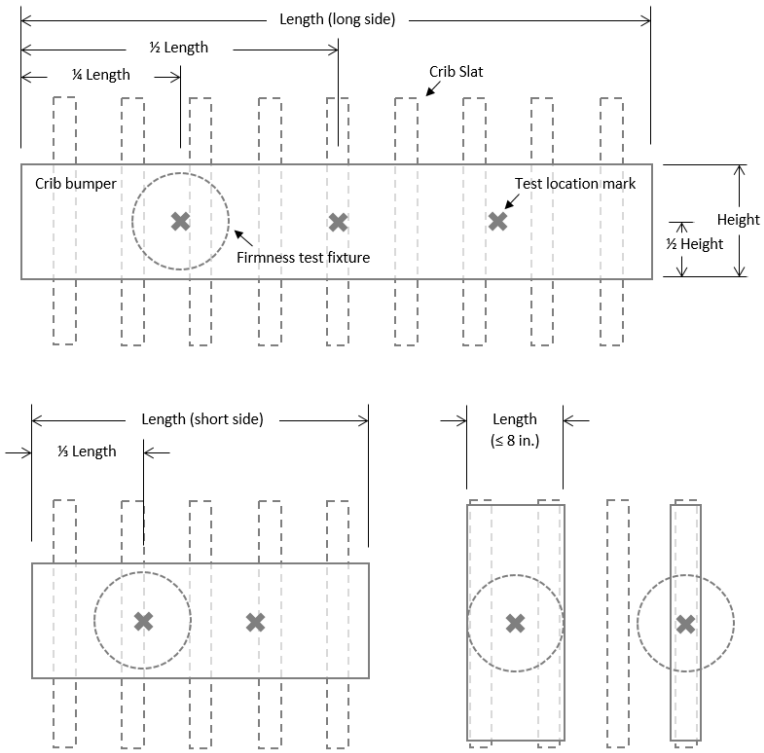
ASTM F1917 – 12	Staff's Recommended Revisions	Rationale Summary
(No figure)	 **End View**  **Side View** **FIG. 3 Head Probe for Entrapment in Openings Testing**	Added a figure of the small head probe from ASTM F963, referenced in 6.5 and as agreed upon by the Attachment task group.

ASTM F1917 – 12, Section 7. Test Methods

ASTM F1917 – 12	Staff's Recommended Revisions	Rationale Summary
7.3 *Bumper Thickness Test*—Align the bumper thickness test fixture so that the surface of the fixture with the opening is horizontal. Insert a bumper end into the opening so that the bumper end protrudes just beyond the lower surface of the test fixture and attach a 5-lb static weight to the midpoint of the protruding bumper end. Keeping the bumper positioned vertically, allow the weight to slowly draw the bumper through the opening. NOTE 1—If bumper ties or other localized means provided to secure the bumper to the crib interfere with the bumper sliding through the bumper thickness test fixture, ease the ties or fasteners through the fixture and then continue the test. 7.4 *Bumper Pad Tie Attachment Strength*—Apply a tensile force of 20 lb on the bumper pad tie(s) in a perpendicular direction away from the attachment point of the ties to the bumper pad. The force shall be applied evenly within a period of 5 s, and maintained for additional 10 s. The loading device shall be a self-indicating force gauge or other appropriate means having an accuracy of 60.5 lb (62 N). 7.4.1 Bumper pad ties that share a common attachment shall be tested together, as if one tie. NOTE 2—There is no single clamp or attachment means specified for the bumper pad tie attachment strength test. Any suitable means may be used to apply the force specified in 7.4.	7.3 *Crib Bumper/Liner Thickness Test*—Align the crib bumper/liner thickness test fixture so that the surface of the fixture with the opening is horizontal. Insert a bumper end into the opening so that the bumper end protrudes just beyond the lower surface of the test fixture and attach a 5-lb static weight to the midpoint of the protruding bumper end. Keeping the bumper positioned vertically, allow the weight to slowly draw the bumper through the opening. NOTE 1—If ~~bumper ties~~ the attachment means or other localized means provided to secure the bumper to the crib interfere with the bumper sliding through the bumper thickness test fixture, ease the ties or ~~fasteners~~ other attachment means through the fixture and then continue the test. 7.4 *Crib Bumper/Liner Strength Tests*—Tensile tests of attachment means, decorative components, and seams shall be conducted using clamps as described in 7.4.1, 7.4.2, 7.4.3. The force in each test shall be applied evenly within a period of 5 s, and maintained for additional 10 s. The loading device shall be a self-indicating gauge or other appropriate means having an accuracy of +/-0.5 lb (+/-2 N). 7.4.1 ~~*Bumper Pad Tie*~~ *Attachment Means Strength*—Apply a tensile force of 20 lb on the bumper ~~pad tie(s)~~ attachment means by clamping the free end in a perpendicular direction away from the attachment point ~~of the ties~~ to the bumper ~~pad. The force shall be applied evenly within a period of 5 s, and maintained for additional 10 s. The loading device shall be a self-indicating force gauge or other appropriate means having an accuracy of 60.5 lb (62 N).~~ 7.4.1.1 ~~Bumper pad ties~~Attachment means that share a common attachment point shall be tested together, as if one ~~tie~~ attachment means. NOTE 2—There is no single clamp or method of attachment ~~means~~ specified for the crib bumper/liner ~~pad tie~~ attachment means strength test. Any suitable means may be used to apply the force specified in 7.4.1.	Added new test methods for the various strength requirements added to section 6. The attachment means strength test was also revised to test the strength of a tie filament along its length.

ASTM F1917 – 12	Staff's Recommended Revisions	Rationale Summary
(No requirement)	7.4.2 *Seams Strength*—Apply a tensile force of 20 lb in a direction most likely to pull the seam apart. The clamps used to grip the material on either side of the seam to be tested shall have jaws to which are attached 3⁄4-in. (19-mm) diameter washers (see Fig. 4). The clamps shall be attached to the cover material of a completely assembled crib liner in a manner such that the outside diameter of the 3⁄4-in. (19-mm) washers at a point nearest the seam shall be close to, but no closer than 1⁄2 in. (13 mm) from the edge of the seam stitching thread. 7.4.3 *Decorative Components*, *Attachment Strength*—Apply a tensile force of 20 lb on the decorative component in a perpendicular direction away from the attachment point of the decorative component to the crib liner. With the crib liner held in a convenient position, an appropriate clamp shall be attached to the decorative component. The clamp shall be applied in a manner that will not affect the structural integrity of the attachment between the decorative component and the crib bumper/liner.	Continuation of Crib Bumper/Liner Strength test methods.
(No requirement)	 **FIG. 4 Seam Clamp**	Added figure showing seam clamp referenced in 7.4.2. This figure is from ASTM F963.

ASTM F1917 – 12	Staff's Recommended Revisions	Rationale Summary
(No requirement)	7.5 *Permanency of Labels and Warnings*: 7.5.1 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. 7.5.2 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. 7.5.3 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 most likely to cause failure using a 0.75 in. (19 mm) diameter clamp surface. Gradually apply the force over 5 s and maintain for an additional 10 s. 7.6 *Adhesion Test for Warnings Applied Directly onto the Surface of the Product*: 7.6.1 Apply the tape test defined in Test Methods D3359, Test Method B—Cross-Cut Tape Test of Test Methods, eliminating parallel cuts. 7.6.2 Perform this test once in each different location where warnings are applied. 7.6.3 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. 7.6.4 A non-paper label, during an attempt to remove it without the aid of tools or solvents, shall not fit entirely within the small parts cylinder defined in 16 CFR 1501 if it can be removed.	Added missing warning permanence test methods that are consistent with analogous requirements in other ASTM juvenile products standards.
(No requirement)	7.7 *Crib Bumper/Liner Firmness Test*—Select one side of the crib bumper/liner. All marks described in this section shall be made at mid-bumper/liner height. For each crib bumper/liner intended for a short side of a crib, or segments of a crib bumper/liner intended for a short side of a crib, mark two points along the bumper/liner length: one at 1/3 of the total length, and one at 2/3 of the total length (see Figure 5). For each crib bumper/liner intended for a long side of a crib, or segments of a crib bumper/liner intended for a long side of a crib, mark three points along the bumper/liner length: 1/4, 1/2, and 3/4 of the total length (see Figure 5). There will be 10 marks in total for a single continuous bumper/liner intended to cover all four sides of a standard full-size rectangular crib. For each crib bumper/liner intended for a circular crib, divide the total bumper/liner length into 10 equal segments and mark the centroid of each segment. For crib bumpers/liners no wider than 8 inches (203 mm), with the long axis intended to be installed vertically on the crib side, mark the centroid of the bumper/liner (see Figure 5). Place the center of the firmness test fixture (Figure 2) on each mark with the feeler arm oriented in a way that is most likely to contact the bumper/liner surface when the fixture is set down, such as over a plush construction. The firmness test fixture may be rotated such that the feeler arm is in any orientation that is completely over the crib bumper/liner.	Added crib bumper firmness test methods, largely based on AS/NZS 8811.1 and the Firmness task group recommendations. Also, added specific test requirements for vertical bumpers and bumpers intended for circular cribs. A new section 8.4 includes a requirement for bumpers to be marked to indicate which portions are intended for the long or short sides of a crib.

ASTM F1917 – 12	Staff's Recommended Revisions	Rationale Summary
(No figure)	 **FIG. 5 Firmness Test Locations**	Added figure to clarify firmness test locations on various crib bumpers, as described in section 7.7.

(No requirement)	7.7.1 Test Equipment – The Firmness Test Fixture of Figure 2 shall be constructed with the following components: 7.7.1.1 A Bottom Disk with a diameter of 203 mm (7.99 in.), thickness of 15 mm (0.59 in.) with a bottom radius of 1 mm (0.039 in.). 7.7.1.2 A Feeler Arm of high speed steel comprising a flat bar, 12 mm (0.47 in.) wide, 0.51 mm to 0.76 mm (0.02 to 0.03 in.) thick, with square-cut ends that is positioned over a radial axis of the Bottom Disk and attached to the Bottom Disk such that the Feeler Arm overhangs the edge of the Bottom Disk by 40 mm (1.57 in.). 7.7.1.3 A Level Indicator attached to the Bottom Disk near the Feeler Arm, without touching, and such that it indicates level with minimum accuracy of.11.7 mm/m (0.14 in./ft) parallel to the feeler arm and does not overhang the edge of the Bottom Disk in a way that interferes with testing. 7.7.1.4 A Vertical Column with Handle and Collar attached to the center of the Bottom Disk. 7.7.1.5 Total mass of the Apparatus shall be 5.2 kg (11.5 lb) including all components and fasteners. 7.7.1.6 Mass of the Bottom Disk shall be not less than 70% of the total mass. 7.7.1.7 Vertical height of assembled apparatus shall not exceed 203.2 mm (8 in.) and the height of the collar shall not exceed 50.8 mm (2 in.) to minimize the bias to the Bottom Disk. 7.7.2 Test Procedure 7.7.2.1 Preconditioning of Sample—The crib bumper/liner shall be tested in its pre-washed state and also after three wash/dry cycles performed according to the manufacturer's care instructions. The crib bumper/liner shall be conditioned for 48 hours prior to testing in an environment of 23 +/- 2 Celsius (73.4 +/- 3.6 Fahrenheit) and a relative humidity of 50 +/- 5%. The crib bumper/liner shall be fully assembled and dry prior to testing. 7.7.2.2 Shake the crib bumper/liner to aerate and distribute any filling materials evenly. Allow the crib bumper/liner to settle for 5 minutes. 7.7.2.3 Place the side to test face up on a horizontal, flat, rigid surface for testing. The crib bumper/liner may be secured to the horizontal surface using the attachment means in a manner that approximates securing the crib bumper/liner to crib rails. 7.7.2.4 Test each placement marked in 7.7 by lowering the firmness test fixture with the bottom disk horizontal until the fixture is supported by the crib bumper/liner. Gently adjust the orientation of the base manually if needed until it is horizontal while resting. Record any contact with the feeler gauge at each placement as a failure of the firmness requirement. Repeat steps 7.7.2.2 and 7.7.2.3 if any placement is within 457 mm (18 in.) of a prior placement, or if 5 minutes have elapsed since completing 7.7.2.2. 7.7.2.5 Repeat firmness testing 7.7.2.1 to 7.7.2.4 until all remaining located placements have been tested or a failure has been recorded. 7.7.2.6 Repeat firmness testing on the other side of the bumper/liner. Testing the other side is not required for crib bumpers/liners that cannot be reasonably installed on the other side.	Continuation of Crib Bumper/Liner Firmness test methods section.

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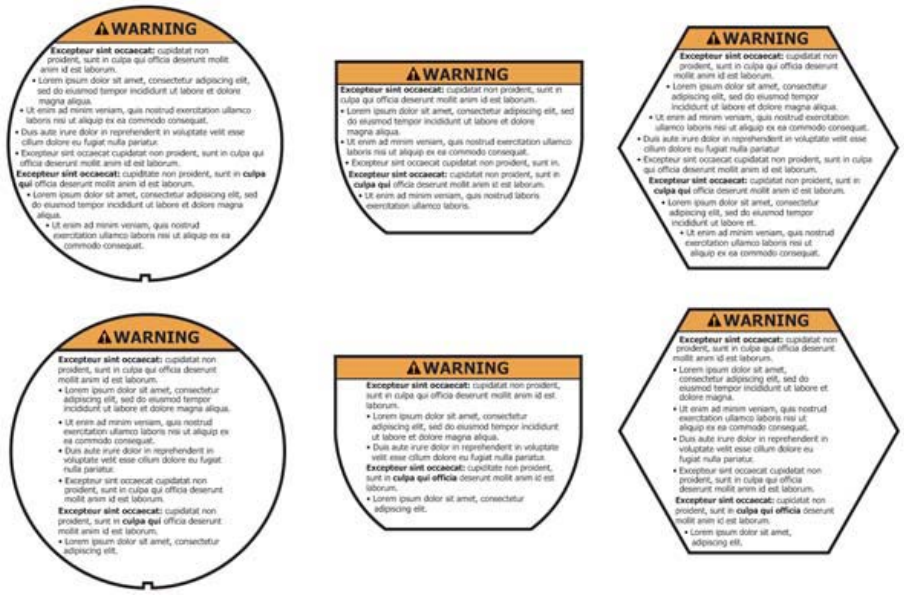
(No requirement)	7.8 *Crib Bumper/Liner Entrapment in Openings Test*—Choose a location most likely to admit the head probe, including between the top and bottom edges of the crib bumper/liner and the test platforms or mattress. Create an accessible opening by exerting a force on the bumper/liner using an appropriate clamping device, equal to 3-lbf (13 N) and directed horizontally away from, and perpendicular to, the test platform. The force is be applied gradually over a 5 s period and maintained throughout the head probe test. Insert the head test probe, tapered end first, into any opening created between the crib bumper/liner and the test platform or mattress, and rotate the small head test probe to the orientation most likely to fail. Apply a force of 10 lbf (45 N) at the base of the small head test probe in a direction that is perpendicular to the plane of the opening. The force is be applied gradually over a 5 s period and maintained throughout the head probe test. Repeat this test at any other locations on the crib bumper/liner most likely to fail. 7.8.1 *Test Equipment* 7.8.1.1 Head Probe—The head probe specified in ASTM F963 (see Fig. 3) shall be used for entrapment tests. 7.8.1.2 Test Platforms—Testing shall be conducted on all test platforms in this section. All test platforms shall have four vertical sides, be rectangular in plan, and have an internal length of 52-3/8 +/- 5/8 in and internal width of 28 +/- 5/8 in. Test platforms shall have a rectangular mattress support that supports a standard 5-in full-size crib mattress. Spacing between components, including between slats, shall be 2-3/8 +0/-1/32 in. Each of the long and short panels shall be rectangular in form with a top, bottom, left, and right side rails. Top rail shall be 26 in above a horizontal mattress support. All spindles shall have ends secured into top and bottom rails. Left and right side rails shall end into top and bottom rails. All rails shall be 1.0 in thick. The top and bottom rail shall have 1.5 in depth. Each long and short panel shall form a vertical corner between the left or right sides when assembled. Round spindles shall be 5/8 in diameter. Flat spindles shall be 1-1/8 in wide by 3/8 in thick with 1/16 in radius edges. Crib bumpers/liners intended for circular cribs shall be tested on a commercially available circular crib. Test Platform A—This test platform is composed of two long panels with 16 round spindles each and two short panels with eight round spindles each. Test Platform B—This test platform is composed of one long panel with 16 round spindles, one solid long panel, and two short panels with eight round spindles each. Test Platform C—This test platform is composed of two long panels with 16 round spindles each and two solid short panels. Test Platform D—This test platform is composed of two long panels with 14 rectangular spindles each and two short panels with seven rectangular spindles each. Test Platform E—This test platform is composed of one long panel with 14 rectangular spindles, one solid long panel, and two short panels with seven rectangular spindles each. Test Platform F—This test platform is composed of two long panels with 14 rectangular spindles each and two solid short panels.	Added attachment test methods for staff's new entrapment requirement for crib bumpers. These test methods are based on the Attachment task group recommendations, but with test platforms specified to improve consistency of testing among test labs. The platforms represent typically available crib configurations with varying features such as solid panels and different slat/splindle shapes.

ASTM F1917 – 12, Section 8. Product/Package Marking Requirements

ASTM F1917 – 12	Staff's Recommended Revisions	Rationale Summary
8. Product/Package Marking 8.1 Each product shall have a permanent conspicuous label that identifies the name and address (city, state, and zip code) of the manufacturer, distributor, or seller, or a label that identifies the Registered Identification Number (RN) or Wool Products Labeling Act Number (WPL).[1]	**8. ~~Product/Package~~ Marking and Labeling** ~~8.1 Each product shall have a permanent conspicuous label that identifies the name and address (city, state, and zip code) of the manufacturer, distributor, or seller, or a label that identifies the Registered Identification Number (RN) or Wool Products Labeling Act Number (WPL).[1]~~ 8.1 Each product and its retail package shall be marked or labeled clearly and legibly to indicate the following: 8.1.1 The name, place of business (city, state, and mailing address, including zip code), and telephone number of the manufacturer, distributor, or seller. 8.1.2 A code mark or other means that identifies the date (month and year as a minimum) of manufacture. 8.2 The marking and labeling on the product shall be permanent. 8.3 Any upholstery labeling required by law shall not be used to meet the requirements of this section. 8.4 Crib bumpers/liners shall be marked or labeled clearly and legibly, in the English language at a minimum, to identify which segments of the bumper/liner are intended for the short and long sides of the crib, unless the bumper/liner is intended for a circular crib or is less than 28 inches in length, not including attachment means.	Revised to be consistent with the approved language of the Ad Hoc Language Task Group, as of May 28, 2019 (Revision E). Also, added a requirement for crib bumpers to be marked to indicate which portions are intended for the short and long sides of a crib, to avoid confusion about how to install the bumper.

8.2 *Product Warning Labels*—A permanent conspicuous label(s) shall be on each infant bedding and related accessory as specified in this section. The label(s) shall be in the ANSI format, which would include a delineated signal word panel containing the safety alert symbol before the signal word and a contrasting background. The label(s) shall begin with the word "WARNING," the letters of which shall not be less than 0.2 in. (5 mm) high. The remaining text shall be in letters whose upper case shall be not less than 0.1 in. (2.5 mm) high.	~~8.2 *Product Warning Labels*—A permanent conspicuous label(s) shall be on each infant bedding and related accessory as specified in this section. The label(s) shall be in the ANSI format, which would include a delineated signal word panel containing the safety alert symbol before the signal word and a contrasting background. The label(s) shall begin with the word "WARNING," the letters of which shall not be less than 0.2 in. (5 mm) high. The remaining text shall be in letters whose upper case shall be not less than 0.1 in. (2.5 mm) high.~~ 8.5 *Warning Design for Product:* 8.5.1 The warnings shall be easy to read and understand and be in the English language at a minimum. 8.5.2 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. 8.5.3 The warning statements shall be conspicuous and permanent. 8.5.4 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. 8.5.4.1 In sections 6.2.2, 7.3, 7.5, and 8.1.2, replace "should" with "shall." 8.5.4.2 In section 7.6.3, replace "should (when feasible)" with "shall." 8.5.4.3 Strike the word "safety" when used immediately before a color (for example, replace "safety white" with "white"). NOTE—For reference, ANSI Z535.1 provides a system for specifying safety colors. 8.5.5 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 uppercase shall be at least 0.1 in. (2.5 mm) high. 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. 8.5.6 *Message Panel Text Layout*: 8.5.6.1 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. Please see Fig. 6 for examples of left aligned text. 8.5.6.2 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. 8.5.7 An example in the format described in this section is shown in Fig. 7.	Revised to be consistent with the approved language of the Ad Hoc Language Task Group, as of May 28, 2019 (Revision E).

ASTM F1917 – 12	Staff's Recommended Revisions	Rationale Summary
8.2.1 *Crib Headboard/Bumper Set or Bumper*—For all headboard/bumper sets or bumpers sold as multiple panels and that can be used separately, all separate panels shall contain the warning label in this section. The warning label(s) for a headboard/bumper set or bumper shall read as follows: **⚠ WARNING** To reduce the risk of suffocation, keep top of bumper up and in position. DO NOT allow bumper to sag down or in toward the sleeping surface. DO NOT use bumper if sagging cannot be corrected. To prevent entanglement or strangulation, position ties to outside of crib and be sure they are secure. Remove bumper when child can sit up unaided or can pull to a standing position.	~~8.2.1 *Crib Headboard/Bumper Set or Bumper*—For all headboard/bumper sets or bumpers sold as multiple panels and that can be used separately, all separate panels shall contain the warning label in this section. The warning label(s) for a headboard/bumper set or bumper shall read as follows:~~ ~~**⚠ WARNING**~~ ~~To reduce the risk of suffocation, keep top of bumper up and in position. DO NOT allow bumper to sag down or in toward the sleeping surface. DO NOT use bumper if sagging cannot be corrected.~~ ~~To prevent entanglement or strangulation, position ties to outside of crib and be sure they are secure.~~ ~~Remove bumper when child can sit up unaided or can pull to a standing position.~~ 8.6 *Warning Statements for Crib Bumpers/Liners*—Each crib bumper/liner, or each crib bumper/liner panel if the bumper/liner is sold as multiple panels that can be used separately, shall have warning statements to address the following, at a minimum: "To reduce the risk of **SUFFOCATION**: • **Keep tight against side of crib.** Do not use if product is loose or sags down toward sleeping surface. • **Never put pillows or anything else in crib** that could trap baby against this product. • **Only use in a crib without broken parts or missing slats.** This product will not fix a broken crib or prevent baby from falling out. **Never use in a toddler bed or bassinet**. To help prevent **ENTANGLEMENT** or **STRANGULATION**, position ties to outside of crib and secure tightly. [Exception: If product does not include an attachment means greater than 7 inches in length, this statement may be omitted.] Remove this product when baby can pull to a stand using crib side (starting about 6 months). Older babies can use product to climb out of crib." 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.	Revised to be consistent with the approved language of the Ad Hoc Language Task Group, as of May 28, 2019 (Revision E). Revisions and additions to the required warnings are based on known hazard patterns and incidents, and include: • a clearer description of how the bumper should look when properly installed, and more concise language about when consumers should not use bumpers, based on their appearance; • language that warns against placing pillows or other products into a crib that could trap an infant against the bumper; • language that warns against using the product in a broken crib; • language that directs consumers to use the product only in a crib; and • language that identifies the approximate age at which bumpers should be removed, and why removing the bumper is necessary at this age or developmental stage. Also, revised warning requirement so entanglement/strangulation statement is only included on products that use ties or similar attachment means.

ASTM F1917 – 12	Staff's Recommended Revisions	Rationale Summary
(No requirement)	 **FIG. 6 Examples of Left Aligned Text**	Added to be consistent with the approved language of the Ad Hoc Language Task Group, as of May 28, 2019 (Revision E). This figure is not shown in actual size.
(No requirement)	**⚠WARNING** To reduce the risk of **SUFFOCATION**: • **Keep tight against side of crib.** Do not use if product is loose or sags down toward sleeping surface. • **Never put pillows or anything else in crib** that could trap baby against this product. • **Only use in a crib without broken parts or missing slats.** This product will not fix a broken crib or prevent baby from falling out. **Never use in a toddler bed or bassinet.** To help prevent **ENTANGLEMENT** or **STRANGULATION**, position ties to outside of crib and secure tightly. Remove this product when baby can pull to a stand using crib side (starting about 6 months). Older babies can use product to climb out of crib. **FIG. 7 Example – Warning Statement Text Layout**	Added an example warning, consistent with the approved language of the Ad Hoc Language Task Group, as of May 28, 2019 (Revision E).

ASTM F1917 – 12, Section 9. Instructional Literature Requirements

ASTM F1917 – 12	Staff's Recommended Revisions	Rationale Summary
(No requirement)	**9. Instructional Literature** 9.1 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, installation, maintenance, cleaning, and use, where applicable. 9.2 The instructions shall include all warnings specified in 8.6, where applicable. 9.3 The warnings in the instructions shall meet the requirements specified in 8.5.4, 8.5.5 and 8.5.6, except that sections 6.4 and 7.2–7.6.3 of ANSI Z535.4 need not be applied. However, the signal word and safety alert symbol shall contrast with the background of the signal word panel, and the warnings shall contrast with the background of the instructional literature. NOTE—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. 9.4 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. NOTE—For additional guidance on the design of warnings for instructional literature, please refer to ANSI Z535.6, American National Standard: Product Safety Information in Product Manuals, Instructions, and Other Collateral Materials.	Added a new Instructional Literature section, which is included in most ASTM juvenile products standards, and is consistent with the approved language of the Ad Hoc Language Task Group, as of May 28, 2019 (Revision E). F1917 – 12 section 9, *Keywords*, would be renumbered as section 10.

TAB G: ESMC Staff Memorandum, "Testing Methods to Measure Airflow through Crib Bumpers and Other Types of Infant Bedding"

TAB G

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
ROCKVILLE, MD 20850

MEMORANDUM

Date: August 14, 2019

To: Timothy P. Smith, Project Manager
Crib Bumper Rulemaking,
Division of Human Factors, Directorate for Engineering Sciences

Through: Joel R. Recht, Ph.D., Associate Executive Director
Directorate for Engineering Sciences

Mark Kumagai, P.E., Director,
Division of Mechanical and Combustion Engineering

From: Hope E J. Nesteruk, Children's Program Manager, and
Brynn Adams, Student Intern,
Division of Mechanical and Combustion Engineering, Directorate for Engineering Sciences

Subject: Testing Methods to Measure Airflow through Crib Bumpers and Other Types of Infant Bedding

I. INTRODUCTION

In the fiscal year 2017 (FY17) Operating Plan of the U.S. Consumer Product Safety Commission (CPSC),[125] the Commission directed CPSC staff to develop a proposed a mandatory consumer product safety standard for crib bumpers under section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA). The Commission stated that this standard must be more stringent than the current ASTM International (ASTM) voluntary standard and must further reduce the risk of injury associated with these products. The Commission also identified three tasks for the staff in developing the standard. One task was to "develop a performance requirement and test method based on known infant inhalation and exhalation requirements and anthropometric parameters to demonstrate that a crib bumper matches or exceeds the airflow characteristics of mesh or mesh-like materials, taking into account the safety of infants with compromised breathing." This memorandum provides a summary of the research and testing undertaken by Engineering Science's Division of Mechanical and Combustion Engineering (ESMC) to assess and develop an airflow test method.

In the late 1960s and early 1970s, The Bedding Industry Standards Committee for Nursery Bedding in Britain was concerned with occasional reports of accidental suffocations of young children in bed, and worked to develop a "safe pillow for infants" through development of a standard for airflow (BSI, 1970, p. ii). The Committee developed a testing method for pillows, published in BS 4578:1970, *Specification for Methods of test for hardness of, and for air flow through, infants' pillows*, that measures the pressure change needed to maintain a constant airflow rate of 200 milliliters/second through a 36 mm diameter tube when obstructed by the pillow. This test method is used in conjunction with the performance requirements in BS 1877-8:1974, *Specification for Domestic bedding — Part 8: Pillows and bolsters for*

[125] The final, approved FY17 Operating Plan can be found here: https://www.cpsc.gov/s3fs-public/CPSCFY2017OpPlan.pdf. The Commission reaffirmed this decision in the FY18 Operating Plan, which can be found here: https://www.cpsc.gov/s3fs-public/FY_2018_Operating_Plan_August302017.pdf.

domestic use (excluding cellular rubber pillows and bolsters), which states "the pressure differential, when measured in accordance with the test set out in BS 4578:1970, shall not exceed 20 mm H_2O" [126] (0.79 inch).

ESMC staff is not aware of any other standard, nationally or internationally, that is specifically intended to measure airflow through pillows or other bedding materials with a focus on potential infant suffocation. However, the test method is over 40 years old, and staff is not aware of widespread use in the United States. Therefore, ESMC staff undertook a two-phase study to verify the utility of the test method and to investigate whether it may be appropriate for testing airflow through crib bumpers. In phase 1, ESMC staff varied several aspects of the test method to explore potential modifications to the test that might make the test more applicable to bumpers and identify the factors that should be considered when developing an airflow test method. Specifically, ESMC staff varied the airflow rate and probe shape to explore variables more directly based on infant breathing and anthropometry. The phase 2 study focused on quantifying the air flow characteristics of mesh using the existing BS 4578:1970 test method and comparing them to the airflow characteristics of bumpers.

II. PHASE I

A. Methods

i. Factor summary

The experimental design described below accounts for:

- Two airflows (high/adult and low/infant),
- Two[127] probes/thrust combinations (BS 4578-1970 probe at 2.5 lb and anthropometry-based probe at 4 lb),
- Two test locations (on-slat and between-slat), and
- Four product types (blankets, pillows, mattresses, and bumpers),

ii. Airflow

BS 4578:1970 specifies an airflow rate of 200 ml/sec (12 L/min), a rate that Health Sciences generally accepts as an infant engaged in moderate activity or an adult engaged in "light activity" (see Tab D). Health Science considers 12 L/min to be "too high to be representative of any infant, child, or adult while sleeping." (Tab D, p. 47). Because the Commission direction for the crib bumpers rulemaking included direction for an airflow test "based on known infant inhalation and exhalation requirements" that "[takes] into account the safety of infants with compromised breathing," ESMC staff researched infant tidal volume and selected a second flow rate intended to mimic the flow rate of air through an infant's lungs (0.6 L/min). This was calculated by finding the tidal volume, or average flow rate of air through an infant's lungs (240-360 mL/kg/min) (Null & Suresh, 2017). Null & Suresh (2017) also reported that the average baby weighs 2.5-4.5kg, and staff took the lower number (2.5 kg) and multiplied by the lower flow rate (240 mL) to estimate a very low flow rate for infants of 0.6 L/min.

[126] The standard did not provide a rationale for 20 mm H_2O.
[127] A total of four probes were tested; however, two are not described in this memorandum due to their similarity to BS 4578-1970 in both design and results.

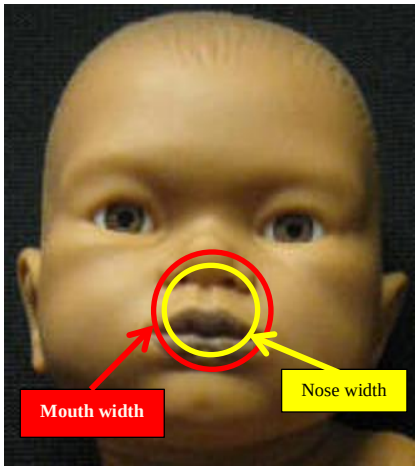
iii. Probe shape

Section 4.1 of BS 4578:1970 specifies that the testing apparatus is "a metal tube 150 mm in length, with an internal diameter of 36 mm. On the bottom of the tube is a metal flange with an outside diameter of 100mm" (BSI, 1970). The tester places the tube, or probe, on a pillow, applies 10 N (2.2 lb or 1.0 kg) of thrust to the pillow, and then measures any change in air pressure through the tube.

In order to address the Commission direction "based on known . . . anthropometric parameters," staff modified the British probe to develop a new probe that includes a third dimension to represent the three-dimensional shape of an infant's face. Using the same basic size and shape as the British probe, the inner diameter was modified to more accurately represent the known mouth width of infants. In addition, a cone-shaped extension with perforations was added to simulate an infant's nose. Staff hypothesized that when the cone-shaped bottom is pressed into the bedding until the bottom disk is flush, this would simulate a full submersion of a child's nose and mouth into the crib bedding. Because this probe was based on infant anthropometry, it could, potentially, also inform development of a firmness test, provided appropriate pass/fail criteria are established, such as complete contact around the probe.

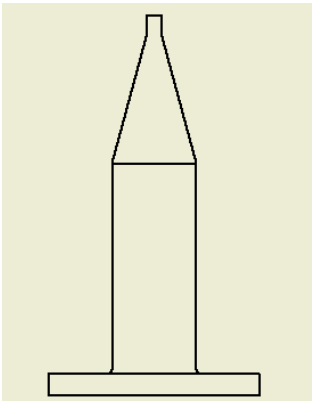
The following anthropometric dimensions were used to develop the cone probe shape:

- A internal tube diameter of 30.6 mm (C), based on the smallest mouth width reported for infants 0-5 months (Farkas, 1994, table A-V-2)
- A second diameter of 24.5 mm (D), based on the smallest nose width reported for infants 0-5 months (Farkas, 1994, table A-IV-2)
- A height of 8.4 mm (C to D), measuring the smallest nasal tip protrusion reported for infants 0-5 months (Farkas, 1994, table A-IV-8)



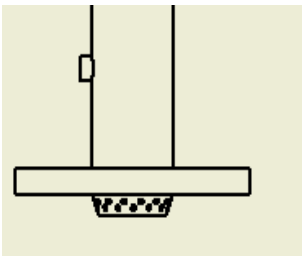
A truncated cone with perforated sides of the dimensions above was created and attached to a probe similar in shape to the BS 4578-1970 probe to create an anthropometry-based probe. In addition, the force applied to the anthropometry-based probe during airflow testing was based on the average head mass for 6-month-old infants, 1.8 kilograms (4 lb), suggested by the regression equation for average infant head mass developed by Sun and Jensen (1994).

BS 4578-1970 Probe
(the "standard" tube/probe)



Internal tube diameter: 36 mm
Base diameter: 100mm
Length (before taper): 150mm

Staff Modification



Perforated cone shape on bottom based on known anthropometric parameters:
Internal tube diameter of 30.6 mm (1)
Upper diameter of 24.5 mm (2)
Height of 8.4 mm (3)

Figure 1. Probes used in testing

iv. Crib Slats

The British standard places the pillow to be measured on an unperforated (solid), flat surface. Because crib bumpers are typically applied to crib sides, staff tested all samples on a crib side,[128] held horizontally, and tested separately on a slat and between slats.

v. Samples

A convenience sample of products was selected for this study from samples on hand, including: 17 samples of bumpers purchased for the infant bumper project, four types of blankets (muslin, fleece, quilt, and crochet), four types of pillows and cushions (a banned infant pillow, toddler pillow, throw pillow, and chair cushion), and four types of mattresses (2 crib mattresses and 2 play yard pads). Characteristics of the samples, including thickness, filling, and exterior fabric material, are described in Table 1.

[128] A crib was selected from sample cribs available at the National Product Test and Evaluation Center. Staff selected the crib because it had wide, flat slats in order to test potential effects of a solid surface underneath the product.

Table 1. Description of Samples

		Thickness[129] (inches)	Material	Filling
Bumpers	1	0.44	Cotton	Polyester
	2	0.32	Cotton	Polyester
	3	1.1	Cotton	Polyester
	4	0.54	Poly-Cotton Blend	Polyester
	5	0.22	Cotton	Polyester
	6	0.60	Polyester	Polyester
	7	4.7	Polyester	Poly-Fiber
	8	0.25	Polyester	Polyester
	9	2.0	Polyester Fiber	Polyester Fiber
	10	1.9	Cotton	Foam
	11	0.36	Cotton	Poly-Foam
	12	0.84	Cotton	Plastic Insert
	13	0.02	Polyester	None
	14	0.02	Poly-Cotton Blend	None
	15	0.28	Poly-Cotton Blend	Polyester
	16	0.38	Cotton	Polyester
	17	0.73	Poly-Fiber	Polyester
Blankets	Flannel blanket	0.02	Muslin	None
	handmade baby quilt	0.12	Cotton Weave	Cotton Batting
	Fuzzy/Soft blanket	0.14	Fleece	None
	Crochet blanket	0.17	Yarn	None
Pillows	Toddler pillow	2.6	Cotton	Fiber Fill
	Chair cushion	2.5	Cotton	Fiber Foam
	Throw pillow	5.0	Polyester	Fiber Fill
	Banned infant pillow	3.0	Poly-Cotton Blend	Polystyrene Pellets
Mattresses	Play yard pad 1	0.59	Poly-Fiber	Poly-Foam
	Play yard pad 2	0.83	Poly-Fiber	Poly-Foam
	Crib mattress 1	2.7	Vinyl	Foam
	Crib mattress 2	4.0	Vinyl	Foam

vi. Design of Experiment

Staff of CPSC's Directorate for Epidemiology, Division of Hazard Analysis (EPHA), designed a split-plot factorial experimental design,[130] with groups of four to six samples per experiment. After EPHA staff produced each experimental block, mechanical engineering staff conducted the testing. The dependent

[129] Products less that one inch were measured with calipers to two significant digits.
[130] A full factorial experimental design for four levels of probe (see footnote 127), two levels of flow rate, 2 levels of support structure (between or on slats), and four types of products would yield and unwieldy experiment requiring several million individual tests. Split-plot factorial was used in order to product a robust experimental design, while limiting the number of tests.

variable was the pressure change, measured in inches of water. Each sample was measured on a crib slat and between crib slats in three areas (left, middle, and right). Figure 2 illustrates the test apparatus schematic as shown in BS 4578:1970 and CPSC staff's test setup.

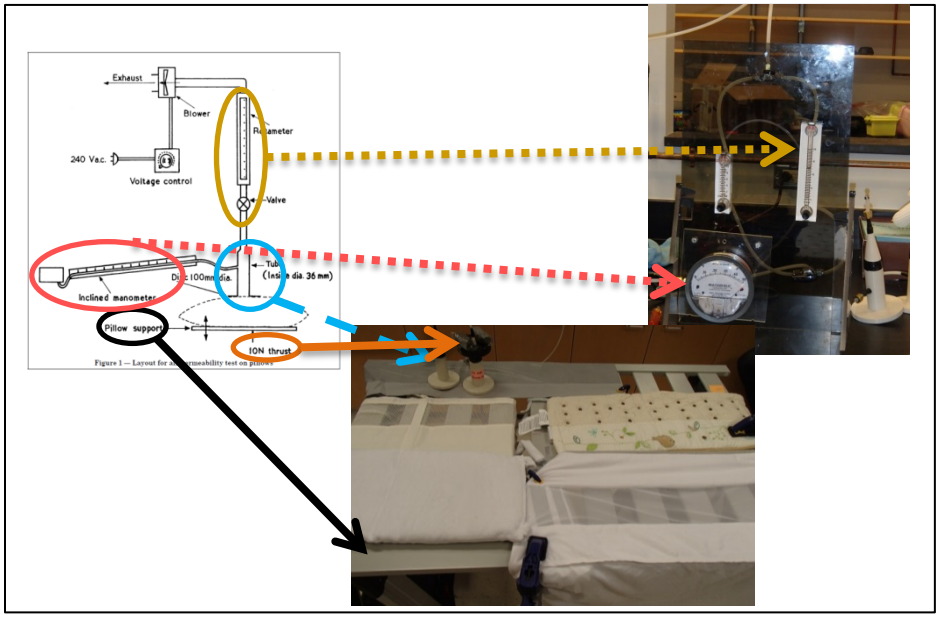


Figure 2. Testing setup

B. Results

i. *Flow rate*

The low flow rate (0.6 l/min) proved ineffective for distinguishing among product types, samples, or probes. Over 70 percent of trials with the low flow rates showed no observable pressure change. Because the statistical model for the experimental design was based on the assumption of measuring real differences in materials, the high number of zero-readings resulted in the model being unable to detect any variance. For purposes of further statistical analysis, the data for low flow rate were removed from the data set and flow rate as a factor was removed from the model.

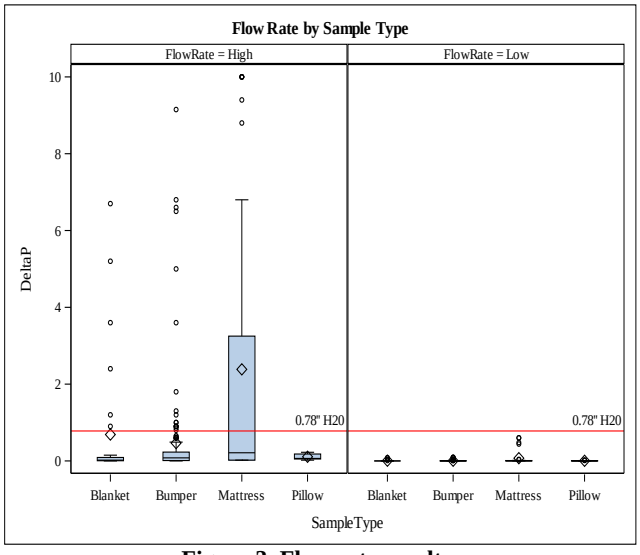


Figure 3. Flow rate results

Although the low flow rate may be seen as more representative of "known infant inhalation and exhalation requirements," these data suggest that the low flow rate is too low to detect measureable differences in materials. This indicates that it will be difficult to develop a test requirement using such a low flow rate because it appears unlikely to produce measurable differences between materials.

The high flow rate, on the other hand, did produce measurable differences between samples. However, this flow rate more accurately represents an infant engaged in moderate activity or older toddlers and adults engaged in light activity doing light activity, which is not relevant to infant sleep (Tab D, Table 3). Figure 3 shows box plots of the pressure changes observed at each flow rate. The red line represents the 20 mm H_20 performance criteria in BS 4578:1970.

ii. Test location (on slat/between slat)

The test location was a significant factor for blankets and bumpers ($p < 0.05$), but it was not significant for mattresses and pillows. Staff hypothesizes that for some products the solid supports (*i.e.*, "on slat" test location) blocked airflow for the probe based on the BS 4578:1970 standard on the thinner products. In addition, interaction effects of test location and probe type were observed within some, but not all, experimental blocks. Overall, the highest pressure readings (> 5″ H20) were all in the on-slat test condition, and included a variety of products including a mattress, a flannel blanket, a mesh crib liner. Therefore, the support structure should be considered and controlled in any future tests.

iii. Probe

BS 4578:1970

Pressure reading results varied greatly when using the probe specified in the BS 4578:1970 standard at the higher airflow rates. All pillows, including a 1990 sample of an infant pillow that is subject to the infant pillow ban, passed the 20 mm H_20 performance criteria in BS 4578:1970. However, all mattress samples "failed" the same performance criteria. Several of the mattress samples tested included waterproof covers, which staff hypothesizes contributed to the probe opening "sealing" and reducing airflow. For the blankets that were tested, more than half of the readings were below 20 mm H_20; however, a number of readings were much higher. Staff hypothesized that the slat was blocking the airflow in those tests with very high results. Bumpers, in general, passed the 20 mm H_20 criteria; however, the test was not able to differentiate bumpers by filling or covering material ($p > 0.11$).

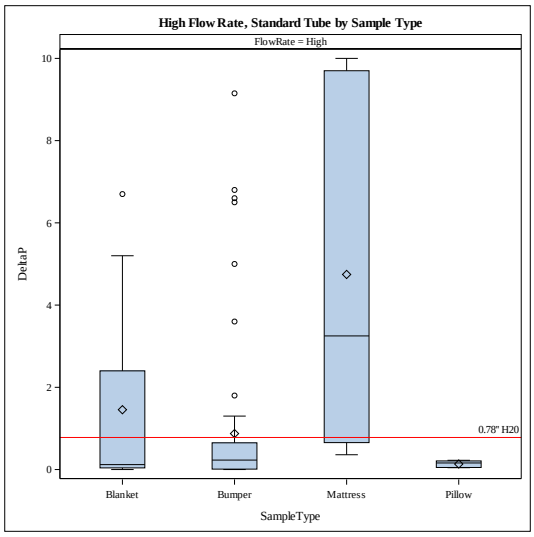


Figure 4. BS 4578:1970 probe results

Anthropometry-based Probe

All results for all products and test conditions were below 0.6 inches H_20; therefore, all products "passed" the 20 mm H_20 criteria in BS 4578:1970. Mattress readings were consistently low, suggesting that the anthropometric probe did not depress into the mattress enough to block airflow. The anthropometric probe was able to identify significant differences among *some* bumper fillings and material types ($p < 0.002$ for some t-tests).

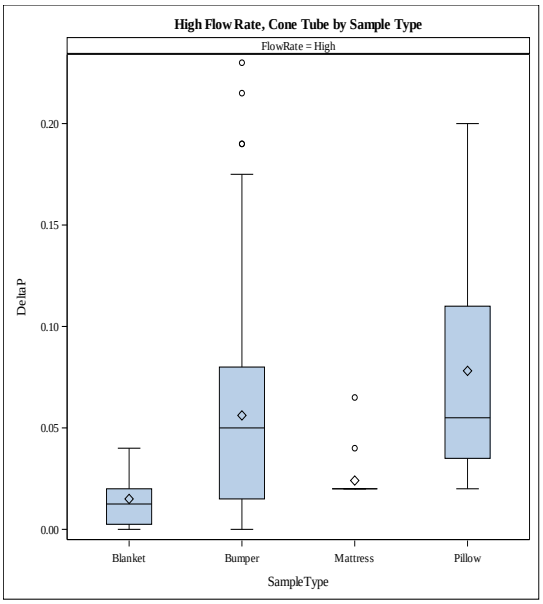


Figure 5. Anthropometry-based probe results

C. Discussion

The test method in BS 4578:1970 is designed to measure airflow through pillows; however, staff has concerns that it may not be appropriate for testing of flat products specifically based on the results when testing crib and play yard mattresses. In addition, the test appeared to "pass" an infant pillow that has been identified by the Commission as a banned hazardous product, suggesting the airflow through a flat opening in a tube may not account for all factors of potential suffocation hazards, especially given the effect on the support structure on airflow. Although this test method is the only known method for airflow specifically aimed at infant products, staff has identified several concerns with using it to differentiate among bumpers.

Staff concludes that the anthropometric-based probe, with the third dimension and appropriate head weight, may show some potential for airflow testing. However, the results of this study indicate that further work would be necessary to develop a test. Specifically, staff has concerns about flow rate selection, anthropometric shape of probe, and performance criteria.

Table 2. T-test p values for bumpers only
Significant ($p<0.05$) values are highlighted in yellow, $p< 0.0001$ are highlighted in red

Filling					
		Poly-Fiber	Perforated Plastic	Foam	None
Standard	Poly-Fiber	NA	0.90	0.19	0.12
	Perforated Plastic	0.90	NA	0.22	0.12
	Foam	0.19	0.22	NA	0.18
	None	0.12	0.12	0.18	NA
Cone	Poly-Fiber	NA	0.0000000000012	0.30	0.000000000026
	Perforated Plastic	0.0000000000012	NA	0.0080	0.07
	Foam	0.30	0.0080	NA	0.011
	None	0.000000000026	0.07	0.011	NA

Material					
		Cotton	Poly-Cotton Blend	Polyester	Polyester Mesh
Standard	Cotton	NA	0.49	0.14	0.15
	Poly-Cotton Blend	0.49	NA	0.19	0.13
	Polyester	0.14	0.19	NA	0.11
	Polyester Mesh	0.15	0.13	0.11	NA
Cone	Cotton	NA	0.28	0.39	0.000010
	Poly-Cotton Blend	0.28	NA	0.89	0.003
	Polyester	0.39	0.89	NA	0.000017
	Polyester Mesh	0.000010	0.003	0.000017	NA

- **Flow rate:** The low flow rate, based on a low infant tidal volume, was too low to produce meaningful results; however, the high flow rate, which allowed some differentiation among products, is more appropriate to infants engaged in moderate activity or toddlers and adults

engaged in light activity and not to sleeping infants. At the time these phase 1 studies were conducted, Health Sciences staff had not identified what flow rate would be appropriate to represent "known infant inhalation and exhalation requirements . . . [taking] into account the safety of infants with compromised breathing." Optimizing these two factors will be difficult, as it may be difficult to detect differences with lower flow rate; however, higher rates may not be appropriate to represent "known infant inhalation and exhalation requirements.

- **Anthropometric dimension:** Although the probe was developed with known facial anthropometric parameters, staff believes that it may be worth considering other factors. This probe was only 8.4 mm deep, based on infant nasal protrusion. However, the AS/NZS 8811.1 mattress firmness standard allows for a depression of up to 15 mm, and it is not clear how that would affect results. In addition, Figure 6 shows several other potential sizes for a probe. The red circle represents the mouth width used in the current study. Staff believes menton-sellion height (yellow circle) and forehead width (white circle) are also dimensions that could play a role in mechanical blockage of breathing.

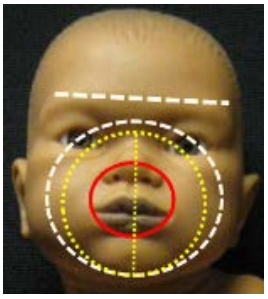


Figure 6. Anthropometric factors

- **Performance criteria:** Only two bumper samples tested were mesh, which is not enough of a sample to determine performance criteria that "matches or exceeds the airflow characteristics of mesh or mesh-like materials." As detailed in Tab D, there is no consensus as to what performance criteria is appropriate to evaluate "breathability."

Based on the testing in phase I, recommendations for phase II testing were:

(1) the anthropometric tube needs further work to refine its size and shape before moving into the phase II study. In addition, the anthropometric tube involved a firmness component and firmness is being addressed with the firmness test; therefore, further testing using BS 4578:1970 is appropriate;
(2) neither flow rate tested is appropriate for the stated goals, and further research is needed to determine an appropriate flow rate that both characterizes infant breathing, yet produces useable data; and
(3) phase II testing should use a consistent support surface for all testing, to avoid the interaction observed in testing between and on a slat.

III. PHASE II

A. Samples

i. Mesh Liners

In order to characterize the airflow of all mesh products, staff needed to obtain multiple samples from multiple manufacturers. Reviewing products available in local stores, all products staff found available were from the same company. Therefore, staff turned to an online source. Staff identified 10 different mesh liner products available on the website of a major online retailer; however, only eight products were

available to ship from a location within the United States so they could be received within a reasonable amount of time (*e.g.*, less than one month[131]). Staff selected all eight remaining products for the study.

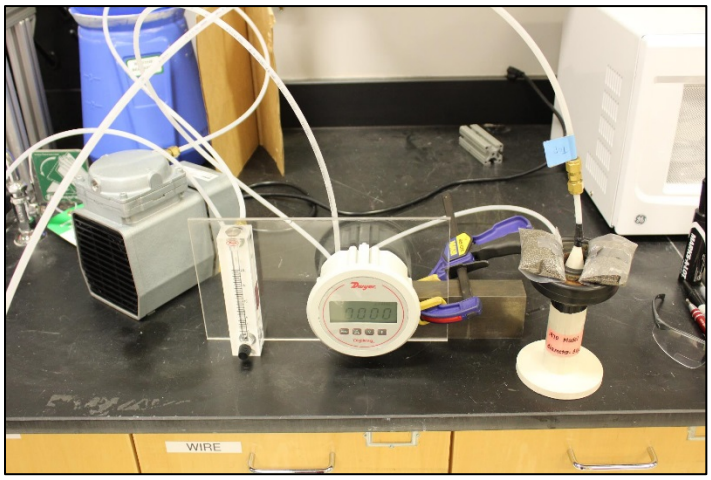
ii. Bumpers (fabric covering an inner material)

The previous study used 16 bumper samples. Staff randomly selected eight of these samples for the current study. The eight samples ranged from 0.25 inches (0.65 cm) to 0.73 inches (1.8 cm) thick. Six samples were stuffed with a polyester fiber, one had a closed-cell foam filling, and one contained perforated plastic half tubes. Four samples had a cotton fabric exterior surface, while four had polyester or a cotton-poly blend fabric.

B. Methods

Equipment set up for this study was essentially the same as the previous study. Modifications include:

- Replacing the analog magnahelic pressure gauges with digital pressure gauges. Specifically, staff used two Dwyer DigiMag Series DM-1000 Differential Digital Pressure Gauges, one with range 0-0.25 inches of water column (″ WC, ±2%), the second with range 0-5″ WC (±1%). This change was made to obtain higher accuracy instead of reading from an analog gauge.



Measurement equipment

Test example

Figure 7. Test Setup

Staff used a wire metal shelving system, shown in Figure 7, as the supporting structure to minimize airflow restrictions due to the supporting structure. In the first study, staff observed an effect from testing on versus between the slats; therefore, staff endeavored to find a supportive structure that was very porous, to minimize any potential effects, and therefore, characterize the airflow properties of the product itself.

- Because the primary goal of this study was to quantify the airflow characteristics of bumpers and mesh liners, only the probe and weights based on the British Standard BS-4578:1970 were used.

[131] Longer ship times were typically associated with products shipped directly from overseas. While these products can be shipped to the US, and therefore are products that could be in U.S. consumer homes, the shipping delays would have delayed the study by 1-2 months.

- Two airflow rates were again compared. One rate, 12 L/min, is the rate specified in BS-4578:1970. The second infant representative rate selected was 2 L/min, based on research from CPSC's directorate for Health Sciences, which suggest that the average tidal volume for 3 month olds is about 2 L/min (Tab D).

Samples were grouped together by type and randomized within flow rate, producing four unique measurement sequences. Three measurements (right, middle, and left; randomized) were obtained from each sample, resulting in a total of 24 measurements per block of bumper or liner samples. Pressure change values were noted from the 0-5″ WC gauge, and the study was repeated with the 0-0.25″ WC gauge. Because the two measurement gauges introduce different potential sources of measurement uncertainty (*e.g.*, censoring[132]), the data was first analyzed to identify any inadvertent effects from measurement gauge. No effect was found ($p = 0.6$). Seeing no effect from measurement gauge, staff used the data set that provided the most robust data for the condition. That is, because the 0-0.25″ WC gauge truncated any readings above 0.25, blocks that contained truncated data were removed from analysis and the values from the 0-5″ WC gauge were used for analysis. Similarly, the 0-5″ WC gauge censored values below 0.005, due to the inherent precision of the gauge, and blocks that produced very low values were analyzed with the data from the 0-0.25″ WC dataset. The highlighted cells represent the datasets used in analysis. Data was analyzed using t-tests and ANOVA in R Studio.

	0-5″ WC Gauge		**0-0.25″ WC Gauge**	
	2 L/min	**12 L/min**	**2 L/min**	**12 L/min**
Mesh liners	8 samples	8 samples	8 samples	8 samples
Bumpers	8 samples	8 samples	8 samples	8 samples

C. Result

Overall, staff noted effects for airflow (2 L/min vs 12 L/min, $p < 0.005$) and Sample Type (mesh vs traditional bumpers, $p < 0.005$). Test location (right, middle, left) was not a significant predictor in the ANOVA model ($p = 0.97$).

```
                Df Sum Sq Mean Sq F value   Pr(>F)
Airflow          1 0.2249 0.22494   21.21 1.35e-05 ***
Sample Type      1 0.2855 0.28547   26.92 1.30e-06 ***
Location         3 0.0029 0.00096    0.09    0.965
Residuals       90 0.9543 0.01060
```

[132] Because the range of the meter was 0-0.25″ WC, any product with a higher pressure change than 0.25″ WC would have been "censored" at 0.25″ WC, rendering any statistical analysis extremely difficult.

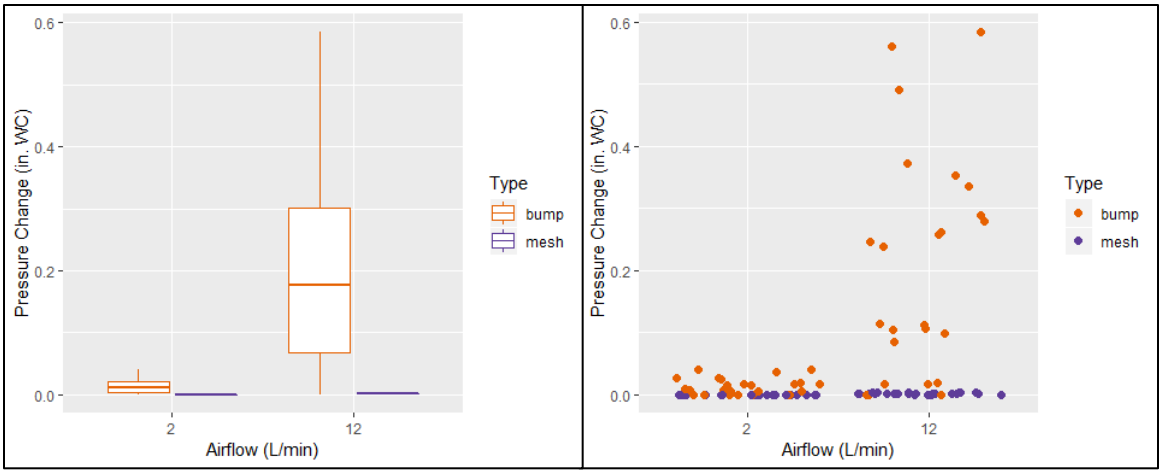


Figure 8. Pressure readings (result) by airflow and sample type

i. 2 L/min

At 2 L/min, no mesh liners registered a detectible pressure change (*i.e.*, the reading was 0.000″ WC) for any trial. However, pressure changes were detected ($\mu = 0.0139$; sd = 0.0131; $\neq 0$, $p < 0.005$; 95% c.i: (0.008, 0.019)) for the bumper samples. The highest pressure change reading observed was 0.041″ WC. Two bumper samples, the thinnest product (0.254 in) and the one with perforated plastic half-tubes, registered no discernable pressure change (0.000″ WC).

ii. 12 L/min

At an airflow of 12 L/min, both mesh and traditional bumpers showed measurable pressure changes.

- For mesh liners, pressure changes ranged from undetectable (0.000″ WC) to 0.003″ WC ($\mu = 0.002$, sd = 0.001; $\neq 0$, $p < 0.005$; 95% c.i: (0.001, 0.002)).
- For traditional bumpers, pressure changes ranged from undetectable to 0.585″ WC ($\mu = 0.11$, sd = 0.15; $\neq 0$, $p < 0.005$; 95% c.i: (0.130, 0.281)). One sample, with perforated plastic half-tubes as filling, registered no discernable pressure change (0.000″ WC).

D. Discussion

The primary goal of this second phase was to use the established test method in BS 4578:1970 to quantify the airflow characteristics of mesh and compare to an airflow rate that represents the tidal volume of infants. A secondary goal was to compare the airflow of mesh liners to traditional bumpers, hypothesizing that it is possible to establish an airflow value that would distinguish between product types. This secondary goal is important, due to the difficulty determining a pressure differential that would be "safe" for young, sleeping infants at greatest risk of death in sleep settings (for more information, see Tab D, from the Directorate of Health Science). For example, if both mesh liners and bumpers performed the same on a proposed test, there may be questions as to whether such a proposed test was meeting the Commission's stated goal: "develop performance requirements and test methods that identify which types of crib bumpers have characteristics that present safety hazards" after Petition CP 12-2, which requested a standard to differentiate between "distinguish and regulate 'hazardous pillow-like' crib bumpers from 'non-hazardous traditional' crib bumpers." Because these statements imply that there exists a difference

between two types of product, any proposed test should identify differences, which staff's test did, albeit at very low levels.

Although several of the samples in the "traditional bumper" group produced very low (<0.001″ WC) pressure changes, those that produced the lowest values were not filled with the same padding that one would typically associate with "padded bumpers" or could not be considered "pillow-like." In addition, these data suggest that it is possible to make a non-mesh bumper with similar airflow properties as mesh bumpers, which might be considered "mesh-like". Figure 3 visually demonstrates the spread of the pressure readings and the two airflows. From these data, staff concludes that, at a 2 L/min airflow, a pressure change detected above 0.003″ (0.076 mm) WC would separate mesh liners from padded crib bumpers. Although, at this airflow rate, all mesh liners failed to register a detectable pressure change, 0.003″ (0.076 mm) WC is equal to the highest pressure change observed for mesh across both flow rates and allows a tolerance to account for the precision and accuracy of measuring devices. Similarly, at the higher flow rate, staff suggests 0.005″ (0.13 mm) WC as the cut off, which allows a 15 percent tolerance above the highest pressure observed for mesh, yet still separated mesh liners from most bumpers (except as noted above).

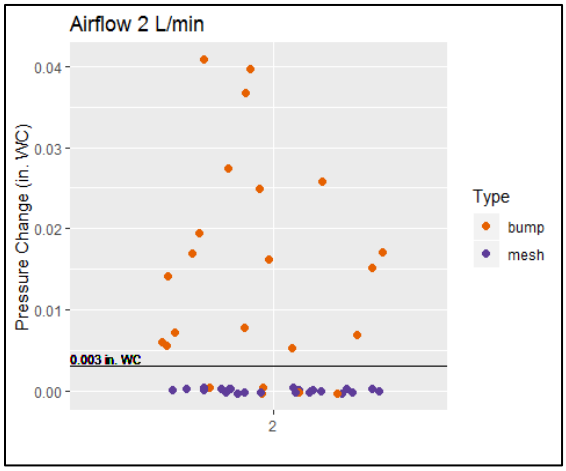


Figure 9. Pressure changes observed at 2 L/min. Divided at 0.003 in. WC

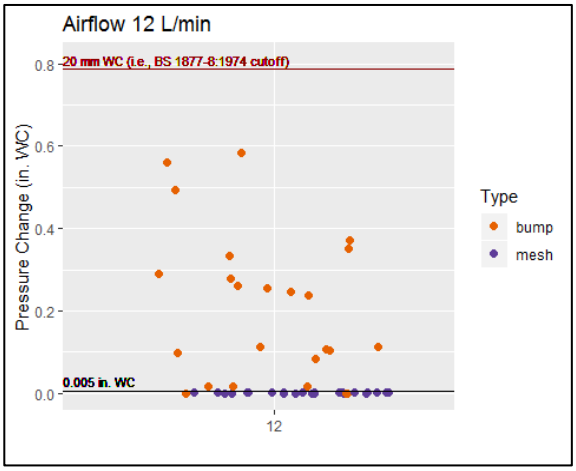


Figure 10. Pressure changes observed at 2 L/min. Divided at 0.005 in. WC. BS 1877-8:1974 limit

IV. CONCLUSION

Taken as a whole, this two-phase study suggests that it is possible to develop an airflow test that differentiates between mesh and non-mesh bumpers, but that the available airflow standard is not appropriate in this context. Particularly, the airflow rates and the interaction of the test tube with a solid, flat surface, or other surface that can allow the tube to compress the product to be tested and "seal" along the edges to a non-permeable surface, suggesting that the BS 4578:1970 is not appropriate for testing bumpers as written. The modifications staff made during the phase II testing appear to alleviate the solid-surface interaction effect noted for the bumpers and mesh liner products tested. In addition, the 2 L/min flow rate appeared to produce measurable pressure changes in traditional bumpers, allowing for a potential differential line to be established. However, it is unclear what, if any, effect the extremely small pressure changes (< half a millimeter) observed at this low flow rate have on infant breathing abilities. BS 1877-8:1974 sets the cutoff at 20 mm WC, which is almost 1800 percent higher than the suggested cutoffs, and, as shown (see Figures 3 and 10) by both phases at higher airflows, would "pass" most bumpers tested; therefore, not contributing to differentiating between the products. It remains unclear if 20 mm WC is an appropriate pressure change for infant breathing abilities.

V. REFERENCES

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TAB H: EC Staff Memorandum, "Small Business Impacts of Including an Air Flow Requirement in the Crib Bumper Standard"

TAB H

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

MEMORANDUM

Date: August 22, 2019

TO**:** Timothy P. Smith
Project Manager, Crib Bumper Project
Directorate for Engineering Sciences

THROUGH**:** Gregory B. Rodgers
Associate Executive Director
Directorate for Economic Analysis

Robert Franklin
Senior Staff Coordinator
Directorate for Economic Analysis

FROM**:** Mark Bailey
Directorate for Economic Analysis

SUBJECT**:** Small Business Impacts of Including an Air Flow Requirement in the Crib Bumper Standard

Background

The Commission voted to consider crib bumpers to be durable infant products and directed the staff to develop a notice of proposed regulation for crib bumpers under section 104 of the Consumer Product Safety Improvement Act. Additionally, the Commission directed staff to "develop a performance requirement and test method based on known infant inhalation and exhalation requirements and anthropometric parameters to demonstrate that a crib bumper matches or exceeds the airflow characteristics of mesh or mesh-like materials, taking into account the safety of infants with compromised breathing;" for possible inclusion in a crib bumper standard. CPSC staff has carefully researched potential air flow standards, but has not been able to show that crib bumpers that met an air flow standard that match or exceeds the air flow characteristics of mesh or mesh-like materials would reduce deaths or injuries associated with crib bumpers and, therefore, staff has not included an air flow requirement in the standard it is recommending to the Commission.[133,134]

[133] Inkster, Sandra E. CPSC Memorandum to Timothy Smith, "Crib bumper firmness and airflow, considering infant vulnerability to respiratory compromise," U.S. Consumer Product Safety Commission, Rockville, Maryland (August 22, 2019).
[134] Nesteruk, Hope, Adams, Brynn. CPSC Memorandum to Timothy Smith, "Testing Methods to Measure Airflow through Crib Bumpers and Other Types of Infant Bedding," U.S. Consumer Product Safety Commission, Rockville, Maryland (August 14, 2019).

Staff prepared an initial regulatory flexibility analysis (IRFA) of the draft proposed rule for crib bumpers, and because staff did not recommend an air flow requirement, and such a requirement would not reduce burden on small businesses, an analysis of the impact is not provided in the IRFA. The purpose of this memorandum is to discuss the impact on small businesses if the Commission voted to include an air flow requirement that distinguished between crib bumpers made from mesh or mesh-like and other traditional or padded crib bumpers.

Impact on Small Businesses

As discussed in the memorandum "Testing Methods to Measure Airflow through Crib Bumpers and Other Types of Infant Bedding," CPSC staff has conducted testing on crib bumpers using standards similar to the ones in BS 4578:1970 *Specification for Methods of test for hardness of, and for air flow through, infants' pillows,* ASTM D737 – 18 *Standard Test Method for Air Permeability of Textile Fabrics,* and performance requirements outlined in BS 1877-8:1974 *Specification for Domestic Bedding*.[135] Depending upon the test specification, the testing could distinguish mesh liners from padded crib bumpers, although some non-mesh bumper designs exhibited similar results to mesh liners.[136] If the Commission adopted an air flow requirement that differentiated mesh liners from padded crib bumpers, that action could effectively result in removing most padded crib bumpers from the market. Some manufacturers of padded crib bumpers may be able to remove the padding or change the design of their products to meet the requirement.

Testing completed by staff of the Directorate for Engineering Sciences, Division of Mechanical and Combustion Engineering (ESMC), and of the Directorate for Laboratory Sciences, Division of Mechanical Engineering (LSM), shows that some non-mesh bumper designs exhibited similar results to mesh liners. Because a majority of crib bumper firms supply padded crib bumpers, this requirement could have an impact on a substantial number of small firms if they are unable to modify their products.[137] Staff identified a total of 207 small manufacturers and importers that an air flow requirement could impact. The size of the impact would depend upon factors such as the cost to modify the products, the importance of padded crib bumpers to the firm in terms of revenue or consumer preference for a padded crib bumper over a thin mesh liner. Nearly all firms supplying the U.S. market with crib bumpers also supply other infant products including, but not limited to crib mattresses, crib sheets, and blankets.[138]

In addition to effectively removing padded crib bumpers from the market an increase in third party testing costs is expected from an air flow requirement. Staff estimates the testing costs associated with testing to an air flow requirement to be between $150 and $350 per sample

[135] Nesteruk, Hope, Adams, Brynn. CPSC Memorandum to Timothy Smith, "Testing Methods to Measure Airflow through Crib Bumpers and Other Types of Infant Bedding," U.S. Consumer Product Safety Commission, Rockville, Maryland (August 14, 2019).
[136] Staff note that if the performance requirement outlined in BS 1877-8:1974 of a maximum pressure differential equal to 20 mm H_2O is selected nearly all currently available crib bumper products will pass the requirement.
[137] Approximately 90 percent of small handcrafter firms provide traditional padded crib bumpers.
[138] Staff identified one firm that only produces crib bumper products.

tested.[139] Because the average number of crib bumper models per firm is two, this equates to an expected annual cost between $300 and $700 to test and certify both models. Generally, we consider impacts that exceed one percent of revenue to be potentially significant.[140] This cost could be considered a significant impact on the very small firms identified in the IRFA, some of which have annual revenues of less than $25,000.[141]

[139] Based on quotes from testing laboratories that currently test children's products to ASTM standards.
[140] Small Business Administration. (2017). *A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act*. Washington, DC. SBA
[141] Bailey, Mark. CPSC Memorandum to Timothy Smith, "Initial Regulatory Flexibility Analysis for Crib Bumper NPR," U.S. Consumer Product Safety Commission, Bethesda, Maryland (August 22, 2019).

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Nesteruk, Hope, Adams, Brynn. CPSC Memorandum to Timothy P. Smith, "Testing Methods to Measure Airflow through Crib Bumpers and Other Types of Infant Bedding," U.S. Consumer Product Safety Commission, Rockville, Maryland (August 14, 2019).

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TAB I: EXC Staff Memorandum, "Crib Bumpers: Summary of Recalls – July 1990 through April 2019"

TAB I

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

MEMORANDUM

Date: August 28, 2019

TO : Timothy Smith, Crib Bumper Project Manager,
Directorate for Engineering Sciences, Division of Human Factors

THROUGH : Robert Kaye, Assistant Executive Director, EXC
Jennifer Timian, Director, Division of Regulatory Enforcement
Carolyn Manley, Supervisory Compliance Officer, Division of Regulatory Enforcement

FROM : Justin Jirgl, Compliance Officer, Division of Regulatory Enforcement

SUBJECT : Crib Bumpers: Summary of recalls – July 1990 through April 2019

Staff is proposing changes to the infant bedding standard, ASTM F1917 – 12, *Standard Consumer Safety Performance Specification for Infant Bedding and Related Accessories*, to define crib bumpers and include specific labeling and performance requirements. This memorandum presents a summary of information related to crib bumper recalls.

COMPLIANCE ACTIVITIES

Compliance staff reviewed recalls of crib bumpers which occurred from July 9, 1990, to April 17, 2019. During that time period, there were five consumer-level recalls involving crib bumpers negotiated by the Defect Investigations Division in Compliance. The recalls were conducted to mitigate against risks of entanglement, entrapment, suffocation and choking from loose threads and bumper ties which either detached from the product or were too long. One recall involved a choking hazard affecting approximately 43,000 units of crib bumpers as a result of tearing/separating of bumper pad ties. There was one recall for strangulation and/or suffocation hazards affecting 1,372 units of crib bumpers, where the crib bumper ties unraveled. Two additional recalls were the result of entanglement/entrapment hazards affecting approximately 43,000 crib bumper units as a result of breaking threads and seams. Finally, there was a recent recall of approximately 200 crib bumpers due to a strangulation hazard presented by crib bumper ties which were too long.

The following table presents information on the five recalls conducted between July 9, 1990, and April 17, 2019, including: the firm involved, the hazard presented, and the number of units affected.

Table
Crib Bumper Recalls
January 1, 1990, to April 17, 2019

Date	Firm	Hazard	# Recalled
07/09/1990	Kolcraft Enterprises, Inc.	Choking	Approximately 43,000
03/21/2000	The Company Store	Strangulation/Suffocation	1,372
07/24/2007	Pottery Barn Kids	Entanglement	Approximately 31,000
05/29/2013	Pottery Barn Kids	Entanglement/Entrapment	Approximately 12,000
05/10/2018	Tobi USA LLC	Strangulation	Approximately 200