

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

DATE: September 30, 2020

## **BALLOT VOTE SHEET**

TO:	The Commission Alberta E. Mills, Secretary
THROUGH:	John G. Mullan, General Counsel Mary T. Boyle, Executive Director
FROM:	Mary A. House, Acting Assistant General Counsel Regulatory Affairs
SUBJECT:	Notice of Proposed Rulemaking: Safety Standard for Crib Mattresses

BALLOT VOTE DUE <u>Tuesday</u>, October 6, 2020

Staff is forwarding a briefing package to the Commission, recommending that the Commission publish in the *Federal Register* the attached draft notice of proposed rulemaking (NPR) to establish a consumer product safety standard for crib mattresses. Pursuant to section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), the draft NPR would incorporate by reference the most recent voluntary standard, ASTM F2933-19, *Standard Consumer Safety Specification for Crib Mattresses*, as the mandatory federal safety standard for crib mattresses that fall within the scope of ASTM F2933-19, including full-size crib mattresses, non-full-size crib mattresses, and after-market mattresses for play yards and non-full-size cribs, with modifications to make the standard more stringent, to further reduce the risk of injury associated with crib mattresses.

The draft NPR also proposes to amend the consumer registration rule, 16 CFR part 1130, to identify "crib mattresses" as a category of "durable infant or toddler products" subject to part 1130. Finally, the draft NPR proposes to amend the Commission's regulation at 16 CFR part 1112 to add "crib mattresses" to the list of products that require third party testing. The Office of the General Counsel is providing the attached draft NPR for the Commission's consideration.

Please indicate your vote on the following options:

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

(Signature)

(Date)

Consumer Hotline and General Information: 1-800-638-2772 \* CPSC's Web Site: http://www.cpsc.gov

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

(Signature)

(Date)

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

(Signature)

(Date)

IV. Take other action specified below:

(Signature)

(Date)

Attachment: Draft *Federal Register* Notice: Notice of Proposed Rulemaking to Establish a Safety Standard for Crib Mattresses

Billing Code 6355-01-P

**CONSUMER PRODUCT SAFETY COMMISSION** 

16 CFR Parts 1112, 1130, and 1241<sup>1</sup>

[CPSC Docket No. 2020-XXXX]

Safety Standard for Crib Mattresses

AGENCY: Consumer Product Safety Commission.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Danny Keysar Child Product Safety Notification Act, section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), requires the 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" the applicable voluntary standard, or more stringent than the voluntary standard, if the Commission determines that more stringent requirements would further reduce the risk of injury associated with the product. The Commission is proposing a safety standard for crib mattresses. The scope of the proposed rule includes full-size and non-full-size crib mattresses, as well as after-market mattresses for play yards and non-full-size cribs. The Commission is also proposing to amend CPSC's consumer registration requirements to identify crib mattresses within the scope of the proposed rule as durable infant or toddler products, and proposing to amend CPSC's list of notice of requirements (NORs) to include such crib mattresses.

**DATES:** Submit comments by [INSERT DATE 75 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

<sup>&</sup>lt;sup>1</sup> Previously, on November 21, 2016, the Commission issued a notice of proposed rulemaking for a Safety Standard for Portable Generators, proposing to codify the standard at 16 CFR part 1241. 81 FR 83556. The Commission is reusing part 1241 for this proposed rule for a Safety Standard for Crib Mattresses, to keep all regulations for durable infant or toddler products in one section of the Code of Federal Regulations (CFR). The Commission intends to renumber the CFR citation for portable generators when that rulemaking is finalized.

**ADDRESSES:** Comments related to the Paperwork Reduction Act aspects of the marking, labeling, and instructional literature requirements of the proposed mandatory standard for crib mattresses 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-2020-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. CPSC does not accept comments submitted by electronic mail (e-mail), except through www.regulations.gov. CPSC encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

*Mail/hand delivery/courier Written Submissions*: Submit comments by mail/hand delivery/courier to: Division of the Secretariat, Consumer Product Safety Commission, Room 820, 4330 East-West Highway, Bethesda, MD 20814; telephone: (301) 504-7479; email: cpsc-os@cpsc.gov.

*Instructions:* All submissions must include the agency name and docket number for this notification. CPSC may post all comments received without change, including any personal identifiers, contact information, or other personal information provided, to: https://www.regulations.gov. Do not submit electronically: Confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If you wish to submit such information, please submit it according to the instructions for mail/hand delivery/courier submissions.

*Docket:* For access to the docket to read background documents or comments received, go to: <u>http://www.regulations.gov</u>, and insert the docket number, CPSC-2020-XXXX, into the "Search" box, and follow the prompts.

### FOR FURTHER INFORMATION CONTACT: Hope E J. Nesteruk, Project Manager,

Directorate for Engineering, U.S. Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone: (301) 987-2547; email: <u>HNesteruk@cpsc.gov</u>.

## **SUPPLEMENTARY INFORMATION:**

### I. Background and Statutory Authority

#### A. Background

On June 16, 2015, the president of Keeping Babies Safe (KBS) and the mother of a child who died in an incident involving an after-market play yard mattress, petitioned the CPSC, requesting a ban on supplemental mattresses for play yards with non-rigid sides (petition CP 15-2: Petition Requesting Rulemaking on Supplemental Mattresses for Play Yards with Non-Rigid Sides). The petitioner alleged that "thicker mattresses create a suffocation hazard because they create a gap between the mattress pad sides and the side of the portable crib where a baby can suffocate when the baby's head falls in such gap while lying in the prone position." Petitioner asserted that "no feasible consumer product safety standard would adequately protect babies from the unreasonable risk of injury and death associated with the product."

CPSC staff prepared a briefing package for the petition, recommending that the Commission defer action on the petition, so that staff could work on voluntary standards for crib mattresses and play yards to address the hazards identified in the petition. Staff noted that any work on the play yard voluntary standard could become a mandatory standard through the P.L. 112-28 update process, because the Commission has an existing mandatory standard for play yards (16 CFR part

1221); however, any changes to the crib mattress voluntary standard would remain a voluntary standard, because the Commission does not have a mandatory rule for crib mattresses.

On May 25, 2017, in response to the petition request and staff's recommendation to defer the petition, the Commission voted<sup>2</sup> (3-2) to "take other action" and granted the petition, directing staff to: (1) initiate a rulemaking under section 104 of the CPSIA for a mandatory consumer product safety standard that will address the risk of injury associated with the use of crib mattresses, (2) include "supplemental and aftermarket mattresses used in play yards and portable cribs" <sup>3</sup> within the scope of the crib mattress rulemaking, and (3) update the product registration card rule (16 CFR part 1130) to include "crib mattresses" in the list of durable infant or toddler products subject to the rule.

The Commission issues this notice of proposed rulemaking (NPR) under section 104 of the CPSIA to propose a mandatory consumer product safety standard for crib mattresses. Unless otherwise stated, the term "crib mattresses" in this NPR includes products within the scope of the voluntary standard for crib mattresses, ASTM F2933-19, *Standard Consumer Safety Specification for Crib Mattresses* (ASTM F2933-19): full-size crib mattresses, non-full-size mattresses, and aftermarket mattresses for play yards and non-full-size crib mattresses.

#### B. Statutory Authority

Section 104(b) of the CPSIA requires the Commission to: (1) examine and assess the effectiveness of voluntary consumer product safety standards for durable infant or toddler products, in consultation with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts; and (2) promulgate consumer product safety

<sup>&</sup>lt;sup>2</sup> <u>https://www.cpsc.gov/s3fs-public/RCA-Petition\_CP\_15-2\_Requesting\_Ban\_on\_Supplemental\_Mattresses\_for\_Play\_Yards\_with\_Non-Rigid\_Sides\_052517.pdf</u>

<sup>&</sup>lt;sup>3</sup> Although the petitioner used the term "supplemental mattress," ASTM F2933-19 uses and defines the term "aftermarket" mattress. Both terms refer to a mattress that is bought separately from a play yard or non-full-size crib. This NPR will use the defined term "after-market" mattress. Section 3.1.1 of ASTM F2933-19 defines an "after-market mattress for a play yard or non-full-size crib" as "a mattress sold or distributed for a play yard or non-full-sized crib." Section 3.1.1.1 of ASTM F2933-19 states that it does not include a replacement mattress sold by an original equipment manufacturer as a replacement, if it is equivalent to the mattress originally provided with the product.

standards for durable infant or toddler products. 15 U.S.C. 2056a(b). 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 determines that more stringent requirements would further reduce the risk of injury associated with the product. *Id.* at 2056a(b)(1)(B).

Regarding the consultation requirement in section 104(b)(1) of the CPSIA, CPSC staff regularly participates in the juvenile products subcommittee meetings of ASTM International (ASTM). ASTM subcommittees consist of members who represent producers, users, consumers, government, and academia.<sup>4</sup> The consultation process for the crib mattresses rulemaking commenced during the ASTM subcommittee meeting in May 2018, when CPSC staff presented initial recommendations for updating the crib mattress voluntary standard to address the incident data. Since then, staff has actively participated with the ASTM F15.66 subcommittee for Crib Mattresses in revising ASTM F2933, *Standard Consumer Safety Specification for Crib Mattresses*, to address the associated hazards.

Section 104(d) of the CPSIA requires manufacturers of durable infant or toddler products to establish a product registration program and comply with CPSC's implementing rule, 16 CFR part 1130. Any product defined as a "durable infant or toddler product" in part 1130 must comply with the product registration requirements, as well as testing and certification requirements for children's products, as codified in 16 CFR parts 1107 and 1109. Section 104(f)(1) of the CPSIA defines a "durable infant or toddler product" as a "durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years." 15 U.S.C. 2056a(f)(1). Section 104(f)(2) of the CPSIA includes a list of categories of products that are durable infant or

<sup>&</sup>lt;sup>4</sup> ASTM International website: <u>www.astm.org</u>, About ASTM International.

toddler products, including infant sleep products, such as cribs (full-size and non-full-size), toddler beds, bassinets and cradles, and play yards. *Id*. 2056a(f)(2).

Although crib mattresses are used with infant sleep products, crib mattresses are not included in the statutory list of durable infant or toddler products. The Commission proposes to amend part 1130 to include "crib mattresses" within the scope of ASTM F2933, as durable infant or toddler products. As set forth in section IX of this preamble, the Commission previously explained that the statutory product list is not exhaustive, and the Commission has added products to the list of durable infant or toddler products. The Commission proposes to include "crib mattresses" as a "durable infant or toddler product" because: (1) they are intended for use, and may be reasonably expected to be used, by children under the age of 5 years; (2) they are products similar to the products listed in section 104(f)(2) of the CPSIA; (3) they are used in conjunction with other durable infant or toddler products used for unattended infant sleep, such as cribs, bassinets, and play yards; and (4) CPSC cannot fully address the risk of injury associated with such infant sleep products without addressing the hazards associated with the use of crib mattresses in these infant sleep products.

## C. NPR Overview

Pursuant to section 104 of the CPSIA, the Commission proposes to issue a mandatory standard for crib mattresses, incorporating by reference ASTM F2933-19, with modifications to make the standard more stringent, to further reduce the risk of injury associated with the use of crib mattresses. Proposed modifications in this NPR address: (1) suffocation hazards associated with crib mattresses, due to overly soft mattresses, by adding a test for mattress firmness based on sections 6 and 8 of AS/NZS 8811.1:2013 – Methods of testing infant products – Method 1: Sleep Surfaces – Test (AS/NZS 8811.1); (2) entrapment hazards associated with full-size crib mattresses, due to poor mattress fit from compression by sheets, by repeating the dimensional conformity test

and measuring for corner gaps, after installing a shrunken (by washing twice) cotton sheet; (3) entrapment hazards associated with after-market, non-full-size crib mattresses, due to lack of dimensional requirements for rectangular-shaped products, by extending the dimensional requirements in ASTM F2933-19 section 5.7.2 to all non-full-size crib mattresses, regardless of mattress shape, and regardless of whether the mattress is sold with a non-full-size crib or as an after-market mattress; (4) laceration hazards associated with coils and springs breaking and poking through mattresses, by adding a cyclic impact test for mattresses that use coils and springs; and (5) the risks of SIDS and suffocation related to infant positioning, soft bedding, and gap entrapment, by improving the labeling and instructional literature requirements to communicate risks better to consumers, and to clarify requirements for manufacturers and test labs.

The Commission also proposes to amend the consumer registration rule, part 1130, to identify "crib mattresses" as a category of "durable infant or toddler products" subject to the rule. Finally, the Commission proposes to amend its regulation at 16 CFR part 1112 to add "crib mattresses" to the list of products that require third-party testing as a basis for certification.

This NPR is based on information provided in the September 30, 2020, Staff Briefing Package: Draft Notice of Proposed Rulemaking for Crib Mattresses<sup>5</sup> Under the Danny Keysar Child Product Safety Notification Act (Staff's NPR Briefing Package), available at: [Insert link].

### **II. Product Description**

#### *A. Scope of Products Within the NPR*<sup>6</sup>

The scope of the NPR includes all crib mattresses<sup>7</sup> within the scope of ASTM F2933-19, which addresses three types of crib mattresses:

<sup>&</sup>lt;sup>5</sup> As well as supplemental and after-market mattresses used in play yards and portable cribs.

<sup>&</sup>lt;sup>6</sup> See Staff's NPR Briefing Package at Tab B for additional information on the scope of ASTM F2933-19.

<sup>&</sup>lt;sup>7</sup> Section 3.1.4 of ASTM F2933-19 defines a "crib" as a "bed that is designed to provide sleeping accommodations for an infant which have specific interior dimensions as determined by it being either a full size or non-full size crib." Section 3.1.5 of ASTM F2933-19 defines a "mattress" as "ticking filled with a resilient material used alone or in combination with other products intended or promoted for sleeping on it."

*I. Full-size crib mattresses* – Full-size crib mattresses within the scope the proposed rule are typically sold separately from the crib in which they are intended to be used. Industry refers to full-size crib mattresses as a "standard" crib mattress. Full-size crib mattresses are also used for toddler beds, meaning that one full-size crib mattress may be used from birth through the toddler years. The fit of a crib mattress inside of a crib is key to preventing infants from becoming trapped between the side of the crib and the mattress, and suffocating. Accordingly, section 5.7 of ASTM F2933-19 requires that the dimensions of a full-size crib mattress shall measure at least 27 <sup>1</sup>/<sub>4</sub> in. wide and 51 5/8 in. long. The interior dimensions of full-size cribs are  $28 \pm 5/8$  in. (710  $\pm$  16 mm) wide and 52  $3/8 \pm 5/8$  in. (1330  $\pm$  16 mm) long. Full-size crib mattresses come in a variety of designs and are made of a broad array of materials. Full-size crib mattresses typically have a fabric or vinyl ticking, which covers inner-spring coils or foam. Inner-spring mattresses often have a layer of foam or batting between the springs and the ticking.

2. *Non-full-size crib mattresses* – Non-full-size cribs are cribs that differ in dimension or shape from "standard" full-size cribs. The NPR addresses all non-full-size crib mattresses, regardless of whether they are sold separately (after-market), or are sold with a non-full-size crib (referred to as original equipment manufactured mattresses or OEM mattresses), and regardless of whether they are rectangular or non-rectangular in shape.<sup>8</sup> Because non-full-size cribs do not come in a standard size, non-full-size crib mattresses do not have defined dimensions. Rather, ASTM F2933-19 sets a minimum effective crib-side height for non-full-size cribs and a maximum gap between the mattress edge and the crib side.<sup>9</sup> Section 5.7.2.1 of ASTM F2933-19 requires that the

<sup>&</sup>lt;sup>8</sup> We note that OEM non-full-size crib mattresses are also addressed in the Commission's mandatory rule for non-fullsize cribs, 16 CFR part 1220, which incorporates by reference ASTM F406. The requirements in F406 for OEM nonfull-size crib mattresses are the same requirements that appear in ASTM F2933 section 5.7.

<sup>&</sup>lt;sup>9</sup> The most common rectangular, non-full-size crib mattress available for sale in the U.S. crib mattress market is the "mini" crib mattress. The mini crib mattress is smaller than the so-called "standard" or full-size crib mattress. The typical size of a "mini" crib mattress is 24" wide and 38" long. The depth of a "mini" crib mattress varies, but typically ranges from 1" to 6."

dimensions of a mattress supplied with a non-full-size baby crib shall be such that the mattress, when inserted in the center of the crib, in a non-compressed state, shall not leave a gap of more than  $\frac{1}{2}$  in. at any point between the perimeter of the mattress and the perimeter of the crib. Currently, section 5.9 of ASTM F2933-19 requires that after-market, non-rectangular, non-full-size crib mattresses be identical to the OEM non-full-size crib mattresses they are intended to replace, but only requires warning labels regarding dimensions on after-market, rectangular-shaped, non-full-size crib mattresses. The Commission proposes in the NPR to extend this dimensional requirement to all after-market, non-full-size cribs, including non-rectangular and rectangular, non-full-size mattresses.

3. After-market mattresses for play yards – After-market mattresses are products sold separately from a play yard,<sup>3</sup> and that are not sold by the OEM as a replacement mattress for their product. Pursuant to CPSC's mandatory rule for play yards, part 1221, which incorporates by reference ASTM F406 – 19, *Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards* (ASTM F406), all play yards must be sold with a mattress that is specifically designed to fit that product. Part 1221 regulates OEM play yard mattresses, but does not address after-market play yard mattresses. This Commission proposes in the NPR to address after-market mattresses for play yards, as set forth in ASTM F2933-19 section 5.9, by requiring that they meet the same specifications and performance requirements for OEM play yard mattresses. Additionally, the NPR would require that after-market mattresses intended for use in the bassinet of a play yard with a bassinet attachment must also meet the specifications in ASTM F2194, *Consumer Safety Specifications for Bassinets and Cradles*.

## B. Market Description<sup>10</sup>

Crib mattresses are designed to be used with infant sleep products, such as full-size cribs, non-full-size cribs, bassinets and cradles, and play yards, to provide sleeping accommodations for an infant. According to estimates published by Statista-Grand View Research, the size of the U.S. market for standard and portable cribs was \$86.8 million in 2018.<sup>11</sup> According to data collected by staff, approximately 75 percent of crib mattresses available for sale in the United States are standard (full-size) crib mattresses, and 7 percent are mini crib mattresses.

Crib mattresses range in price from \$20 to \$500, with the more expensive crib mattresses typically being full-size crib mattresses with a firm coil or high-end foam core. Crib mattresses are sometimes also sold with waterproof covers and fitted sheets, specifically designed to be used with the mattress. While some manufacturers produce a large variety of crib mattress models, others produce only a small selection. Many crib mattresses are GreenGuard Certified, which is a UL-sponsored standard intended to reduce the emissions of volatile organic compounds from products.<sup>12</sup> Additionally, many full-size crib mattresses are advertised online as meeting the CPSC mattress and mattress pad flammability requirements.<sup>13</sup>

If finalized, a mandatory rule for crib mattresses will require third party testing for conformance to the new crib mattress rule, 16 CFR part 1241, and a certificate of compliance. Crib mattresses already require third party testing and certification, because crib mattresses are already defined as "children's products," and are currently subject to various other federal safety rules, such as mattress flammability, lead, and phthalate testing. Accordingly, a final rule for crib mattresses

<sup>&</sup>lt;sup>10</sup> See Staff's NPR Briefing Package at Tab F for additional information on the marketing and use of crib mattresses.

<sup>&</sup>lt;sup>11</sup> November 2019 Statista estimates, Grand View Research.

<sup>&</sup>lt;sup>12</sup> <u>https://www.ul.com/resources/ul-greenguard-certification-program.</u>

<sup>&</sup>lt;sup>13</sup> Review of manufacturers' websites, product labels, and materials.

will incrementally increase the amount of crib mattress testing and certification requirements already in place.

## C. Crib Mattress Use<sup>11</sup>

Based on information from the 2013 CPSC Durable Nursery Products Exposure Survey (DNPES) 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.<sup>14</sup> 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). Cribs, for the purposes of the DNPES, included both full-size and non-full-size cribs, which are designed to be used with a crib mattress; therefore, staff estimates at least 9.2 million (full-size and non-full-size) crib mattresses were in use in 2013.<sup>15</sup> According to DNPES results, 84 percent of respondents indicated they used a fitted sheet on the crib mattresses, and 50 percent indicated they used a mattress pad. Six percent of respondents indicated that nothing was placed under the child in the crib, other than the intended mattress, indicating that the crib mattress was used bare.

According to the same survey, an estimated 5.8 million play yards were in use in households with young children. This represented about 54 percent of the estimated 10.9 million total play yards owned by households (*i.e.*, about 5.1 million play yards were owned, but not in use). Most play yards are designed to be used with a play yard mattress; therefore, staff estimates at least 5.8 million play yard mattresses were in use in 2013. Twenty-five percent of respondents indicated that

<sup>&</sup>lt;sup>14</sup> Respondents were asked to include in their count of cribs owned, cribs that had been converted into toddler beds; but they were instructed to include only the time used in the product *as a crib,* in response to use questions.

<sup>&</sup>lt;sup>15</sup> In addition to the products in use in households with young children, as estimated from the survey, cribs and crib mattresses are probably in use in some households without young children (*e.g.*, unsurveyed homes of older adults providing care for grandchildren).

nothing was placed under the child in the play yard, other than the intended mattress; 12 percent indicated they used a mattress pad, but no respondents indicated that they used a fitted sheet.

The DNPES did not cover child care facilities. One childcare industry group's 2018 directory<sup>16</sup> lists more than 115,000 licensed childcare centers and more than 137,000 home daycare providers, some of which may use crib or play yard mattresses. 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.<sup>17</sup> Based on the Commission's contacts with childcare and lodging facilities, crib, play yard, and crib mattresses are commonly used in such establishments.<sup>18</sup>

## III. Incident Data and Hazard Patterns<sup>19</sup>

Staff of CPSC's Directorate for Epidemiology, Division of Hazard Analysis (EPHA),

searched the Consumer Product Safety Risk Management System<sup>20</sup> (CPSRMS) and the National Electronic Injury Surveillance System (NEISS) for fatalities, incidents, and concerns associated

with crib mattresses, reported to have occurred between January 1, 2010 and March 31, 2020.<sup>21</sup>

Staff identified 21 NEISS cases associated with a crib mattress. Because the data did not meet the

<sup>&</sup>lt;sup>16</sup> Child Care Centers estimate entire U.S. (2018, April 27). http://childcarecener.us/.

<sup>&</sup>lt;sup>17</sup> U.S. Bureau of Labor Statistics, "Quarterly Census of Employment and Wages," April 2018. http://www.bls.gov/iag/tgs/iag721.htm.

<sup>&</sup>lt;sup>18</sup> Staff contacts included phone inquiries with daycare and hotel establishments.

<sup>&</sup>lt;sup>19</sup> See Staff's NPR Briefing Package at Tab A, for additional information on staff's review of crib mattress incidents.
<sup>20</sup> CPSRMS is the epidemiological database that houses all anecdotal reports of incidents received by CPSC, "external cause"-based death certificates purchased by CPSC, all in-depth investigations of these anecdotal reports, as well as investigations of select NEISS injuries. Examples of documents in CPSRMS are: hotline reports, Internet reports, news reports, medical examiner's reports, death certificates, retailer/manufacturer reports, and documents sent by state/local authorities, among others.

<sup>&</sup>lt;sup>21</sup> Some of the nonfatal reports described concerns about potential hazards associated with a crib mattress, without an actual incident occurring. Staff initially extracted incident reports and NEISS injury cases using nine product codes, with no other restrictions on the extraction criteria. Staff then reviewed each record to determine whether a report was associated with a crib mattress. Staff searched the following product codes: *playpens and play yards* (1513), *portable cribs* (1529), *bassinets or cradles* (1537), *baby mattresses or pads* (1542), *cribs, nonportable* (1543), *cribs, not specified* (1545), *mattresses, not specified* (4010), *toddler beds* (4082), and a catch-all product code 9101.

minimum criteria for reporting an estimate,<sup>22</sup> staff included the 19 NEISS injuries and two NEISS fatalities with the other reported incident data for crib mattresses.

## A. Incident Severity

The Commission is aware of 439 reports associated with a crib mattress. Table 1 presents the severity of the reported cases, in order of severity. Of the 439 reports, 116 reports (26 percent) involved a fatality; 15 reports (3 percent) required an infant to receive treatment in an emergency room; and 4 reports (1 percent) required hospital admission. Reports for 199 incidents (45 percent) describe incidents that resulted in no injuries; and 16 reports (4 percent) describe no actual incidents or injuries. In the 199 incident reports with no injuries reported, staff observed that, generally, caregivers intervened once they identified a problem with the crib mattress, and the mattress was no longer used after the caregiver identified the hazard.

Sandary 1, 2010 March 31, 2020				
Severity	Number of Reports	%		
Fatalities	116	26%		
Emergency Department Treatment Received	15	3%		
Hospital Admission	4	1%		
Seen by Medical Professional	1	<1%		
First Aid Received by Non-Medical Professional	1	<1%		
Level of care not known	66	15%		
Incident, No Injury	199	45%		
No First Aid or Medical Attention Received	8	2%		
No Incident, No Injury	16	4%		
Unspecified	13	3%		
Total	439	100%		

 Table 1: Reports Associated with Crib Mattresses by Severity

 January 1, 2010–March 31, 2020

*Source:* CPSRMS and NEISS databases Reporting is ongoing; 2018–2020 are considered incomplete.

 $<sup>^{22}</sup>$  NEISS estimates are reportable, provided the sample count is greater than 20, the national estimate is 1,200 or greater, and the coefficient of variation (CV) is less than 0.33.

## B. Hazard Categories for Fatal and Nonfatal Reports

The Commission is aware of 116 reported deaths and 323 nonfatal incidents and concerns associated with crib mattresses that were reported to have occurred between January 1, 2010 and March 31, 2020. Table 2 presents hazard categories, which are further defined in the *Fatal Reports* and *Reported Nonfatal Incidents and Concerns* sections below.

January 1, 2010–March 31, 2020					
Hazard Category	Fatal Reports	Nonfatal Reports	Total Reports		
Chemical/Flammability	0	23	23		
Coil or Spring	0	124	124		
Crib Mattress Used in a Play Yard	2	1	3		
Expand or Inflate	0	6	6		
Face in Mattress	13	1	14		
Fit Issues	20	88	108		
Found Prone	66	3	69		
Mattress Falls Apart	0	18	18		
Softness	0	36	36		
Multiple Contributing Factors (MCF)	15	17	32		
Other	0	6	6		
Total	116	323	439		

 Table 2: Fatal and Nonfatal Reports Associated with Crib Mattresses by Hazard Category

 January 1, 2010–March 31, 2020

*Source:* CPSRMS and NEISS databases Reporting is ongoing; 2018–2020 are considered incomplete.

## C. Fatal Reports

The Commission is aware of 116 reported deaths associated with crib mattresses that were

reported to have occurred between January 1, 2010 and March 31, 2020. Table 3 presents hazard

categories associated with fatalities.

Table 3: Reported Fatalities Associated with Crib Mattresses by Hazard Category
January 1, 2010–March 31, 2020

Hazard Category	Reported Deaths	%
Crib Mattress Used in a Play Yard	2	2%
Face in Mattress	13	11%
Fit Issues	20	17%
Found Prone	66	57%
Multiple Contributing Factors (MCF)	15	13%
Total	116	100%

*Source:* CPSRMS and NEISS databases Reporting is ongoing; 2018–2020 are considered incomplete.

1. *Crib Mattress Used in a Play Yard*: Two percent of the fatalities involved use of a crib mattress in a play yard (2 out of 116). Reports state that infants were found wedged between the crib mattress and the mesh of the play yard, due to the crib mattress not fitting snugly in the play yard.

2. *Face in Mattress*: Eleven percent (13 out of 116) of fatalities were associated with the face of an infant, when found, reportedly in contact with a crib mattress or crib sheet covering the crib mattress. Based on the available information about each fatality, bedding, other than a sheet, was present in the sleeping environment in some of these reports, but the bedding was not touching the infant, nor did staff determine that the bedding was a contributing factor in the death.

3. *Fit Issues*: Seventeen percent (20 out of 116) of fatalities involved issues with the fit of a crib mattress in the sleeping environment. In all of these fatalities, the infants became wedged in gaps between at least one of the sides of a crib mattress and the crib rails or play yard mesh.

4. *Found Prone*: Fifty-seven percent (66 out of 116) of fatalities involved an infant found in a prone position with no mention of whether the face of the child was in contact with the crib mattress or crib sheet, and no mention of the face being obstructed by other crib bedding, or other items in the sleep environment. Given the available information about each fatality, bedding was present in the sleeping environment in some of these reports, but staff did not determine that bedding was a contributing factor in the deaths.

5. *Multiple Contributing Factors (MCF)*: Thirteen percent (15 out of 116) of fatalities involved multiple factors that potentially played a role in the fatality, and the crib mattress was likely one of the contributing factors. Examples of other contributing factors are entrapment between the mattress and bumper pads, entrapment between the mattress and a crib rail with limb entrapment, usage of a swaddle, sharing of the sleep environment with another infant, and congenital or recent health conditions.

CPSC staff identified the age and gender of the infant in every reported fatality. The oldestaged children associated with crib mattress fatalities were: one 3-year-old, and two 2-year-old children. Staff observed considerably more reported prone fatalities between the ages of 1 month and 5 months, and most of the deaths in the fit, face in mattress, and MCF hazard categories involved infants between the ages of 1 month and 8 months, compared to other ages. Of the 116 reported fatalities associated with crib mattresses, 74 deaths (64 percent) were male and 42 deaths (36 percent) were female.

## D. Nonfatal Reports and Concerns

The Commission is aware of 323 reported nonfatal incidents and concerns associated with crib mattresses that were reported to have occurred between January 1, 2010 and March 31, 2020. Table 4 presents the hazard categories associated with nonfatal crib mattress reports.

January 1, 2010 – March 51, 2020				
Hazard Category	Nonfatal Reports	%		
Chemical/Flammability	23	7%		
Coil or Spring	124	38%		
Crib Mattress Used in a Play Yard	1	<1%		
Expand or Inflate	6	2%		
Face in Mattress	1	<1%		
Fit Issues	88	27%		
Found Prone	3	1%		
Mattress Falls Apart	18	6%		
Softness	36	11%		
Multiple Contributing Factors (MCF)	17	5%		
Other	6	2%		
Total	323	100%		

 Table 4: Nonfatal Reports Associated with Crib Mattresses by Hazard Category

 January 1, 2010 – March 31, 2020

Source: CPSRMS and NEISS databases

Reporting is ongoing; 2018–2020 are considered incomplete.

As shown in Table 4, the hazard categories with the most reported nonfatal incidents

associated with crib mattresses are issues with coils or springs, and crib mattresses that do not fit

properly in the sleep environment.<sup>23</sup> We describe the non-fatal incidents associated with each identified hazard category as follows:

1. *Chemical/Flammability*: Seven percent (23 out of 323) of the nonfatal incidents reported a crib mattress having a chemical odor (5), causing rashes (7), or not meeting mandatory federal flammability standards (11). Infants were reported to have suffered from rashes and upper respiratory issues.

2. *Coil or Spring*: Thirty-eight percent (124 out of 323) of nonfatal incidents involved a coil or spring found protruding through the crib mattress. A 2-year-old received two stitches in the hospital emergency department for a laceration injury. Another 2-year-old with a toe laceration was treated and released from the hospital emergency department.

3. *Crib Mattress Used in a Play Yard*: Less than 1 percent (1 out of 323) of nonfatal incidents involved an infant's back being scratched by protruding coils or springs of a crib mattress being used in a play yard.

4. *Expand or Inflate*: Two percent (6 out of 323) of nonfatal incidents involved a crib mattress that failed to expand or inflate properly. Staff identified related hazards, including fit issues with gaps appearing around the crib mattress causing entrapment or wedging, and an uneven crib mattress that may cause an infant to roll over.

5. *Face in Mattress*: Less than 1 percent (1 out of 323) of nonfatal incidents involved an infant found limp, pale, and with blue around the lips while face down in contact with a crib mattress. Staff found no other details about the sleep environment in this incident. The 1-month-old infant was admitted to the hospital.

<sup>&</sup>lt;sup>23</sup> In the most recent 2 years, from January 2018 to March 2020, CPSC observed fewer nonfatal reports of coil or spring issues associated with crib mattresses, compared to years 2014 through 2017. Eighty-nine percent (78 out of 88 nonfatal reports) of nonfatal reports involving fit issues occurred between 2010 and 2015.

6. *Fit Issue*: Twenty-seven percent (88 out of 323) of nonfatal incidents involved issues with the fit of a crib mattress in the sleeping environment. In all of these reports, staff determined that gaps were present on one or more sides around the perimeter of a crib mattress, creating wedging or entrapment hazard between the crib mattress and the crib rails or play yard mesh. A 3-month-old went into cardiac arrest and was admitted to the hospital after being found between a crib mattress and a crib frame. Six children between the ages of 6 months old and 2 years old, and a 10-year-old with Rett syndrome,<sup>24</sup> were treated and released from the hospital emergency department due to entrapment between a crib mattress and crib rails, and sustaining injuries, such as an arm or leg fracture, a mid-back injury, a foot injury, lip hematoma, and a nursemaid's elbow.

7. *Found Prone*: One percent (3 out of 323) of nonfatal incidents involved an infant found in a prone position without any mention of the face being in contact with the mattress or crib sheet, and no mention of the face being obstructed by other crib bedding or other items in the sleep environment. Staff found no other details about the sleep environment in any of these three reported incidents. Among these three infants, an 8-month-old was admitted to the hospital after being found breathing poorly; and two infants received treatment in the emergency department: a 4-month-old was found breathing poorly, and a 1-month-old was found not breathing, while vomiting and choking.

8. *Mattress Falls Apart*: Six percent (18 out of 323) of nonfatal incidents involved part of a crib mattress coming apart. In most of these reports, the seams of the mattress unraveled, creating: a strangulation hazard due to the stitching of the mattress being exposed; and a choking or ingestion hazard due to the inner filling coming out of the mattress in small pieces and into the sleep

<sup>&</sup>lt;sup>24</sup> According to https://www.rettsyndrome.org, "Rett syndrome is a rare genetic neurological disorder that occurs almost exclusively in girls and leads to severe impairments, affecting nearly every aspect of the child's life: their ability to speak, walk, eat, and even breathe easily. The hallmark of Rett syndrome is near-constant repetitive hand movements. Rett syndrome is usually recognized in children between 6 to 18 months as they begin to miss developmental milestones or lose abilities they had gained."

environment. Examples of reported small pieces of a crib mattress filling that came apart are fibers, string, or wool. Staff found that in six incidents, string from crib mattress seams or piping was found wrapped around the neck of the infant, which could have led to a serious outcome if the child was not found in time. One incident involved an infant choking on a plastic piece of 'shredded' crib mattress, and 1 incident involved a 2-year-old who was treated and released from the hospital emergency department due to ingesting plastic pieces of a crib mattress.

9. Softness: Eleven percent (36 out of 323) of nonfatal incidents involved a crib mattress inner cushioning that was reportedly too soft. Staff found 17 reports of depressions or indentations in the crib mattress, accompanied by the following descriptions: "bunches up/squishy," "depression/dips/indentation/sinks in/sunken," and "deflates/like an air mattress not fully inflated." Twelve reports describe a crib sheet being placed on a crib mattress and causing the mattress to bend or bow, resulting in a gap or fit issue between the mattress and crib rails, creating an entrapment hazard. Four reports claim that a crib mattress is not breathable. Three reports allege that a crib mattress is too thin and that the inner cushioning is too soft.

10. *Multiple Contributing Factors (MCF)*: Five percent (17 out of 323) of nonfatal incidents involved multiple factors that played a role, of which the crib mattress was likely one factor. Staff found that in 10 reports, an infant was found wedged between a crib mattress and the crib rail, while an arm, leg, or foot was caught in between the slats of the crib. Additionally, one infant in a sleep sack was found face down while reportedly attempting to turn over, and another child was found face down in a crib while having a seizure. Among the most serious injuries reported were two children who were treated and released from the hospital emergency department: a 5-month-old received a leg fracture after becoming entrapped under a crib mattress while also having an arm caught between the slats of the crib, and an 18-month-old was found face down on a crib mattress while having a seizure.

11. *Other*: Two percent (6 out of 323) of nonfatal incidents involved miscellaneous other issues associated with a crib mattress. Reports in this category include: a blade found in a crib mattress; an infant's arm was "tangled in a crib mattress"; an infant "slipped on a crib mattress," causing a slat entrapment; an infant's arm became "stuck on a crib mattress"; a crib mattress had a loose plastic bag for a cover; and a concern about crib mattresses not having proper warning labels to direct caregivers to place infants on their backs when putting them down in a crib. The 7-monthold infant who was "tangled in a crib mattress" was admitted to the hospital due to a leg fracture. The 9-monthold who was "stuck on a crib mattress" was treated and released from the hospital emergency department due to a nursemaid's elbow.

## *E. Explanation of Hazards Associated With Crib Mattress Use*<sup>25</sup>

After reviewing the incident data, CPSC staff identified various mattress-use factors associated with deaths and serious injuries related to sudden and unexpected infant death (SUID), including, but not limited to, prone positioning of sleeping infants, soft bedding added to sleep areas, and gaps/pockets between mattresses and infant product sides.<sup>26,27,28</sup> Physiologically, infants experiencing a compromised airflow are likely to undergo a cycle of decreased heart and respiration rate, resulting eventually in fatal cessation of breathing. Numerous public awareness campaigns have aimed to educate caregivers regarding the identified hazards; these campaigns include: "Back

<sup>26</sup> The Centers for Disease Control and Prevention (CDC) defines "SUID" as the sudden and unexpected death of a baby less than 1-year-old, in which the cause was not obvious before investigation. See <a href="https://www.cdc.gov/sids/about/index.htm?CDC\_AA\_refVal=https%3A%2F%2Fwww.cdc.gov%2Fsids%2FAboutSUI">https://www.cdc.gov%2Fsids%2FAboutSUI</a> <a href="https://www.cdc.gov%2Fsids%2FAboutSUI">DandSIDS.htm</a>; accessed July 20, 2020.

<sup>27</sup> The American Academy of Pediatrics (AAP, 2016) explains that SUID, also known as "sudden unexpected death in infancy" (SUDI), includes explained and unexplained deaths, and it can be attributed to suffocation, asphyxia, entrapment, infection, ingestions, metabolic diseases, arrhythmia-associated cardiac channelopathies, and trauma. See <a href="https://pediatrics.aappublications.org/content/pediatrics/138/5/e20162938.full.pdf">https://pediatrics.aappublications.org/content/pediatrics/138/5/e20162938.full.pdf</a>; accessed May 5, 2020.

<sup>&</sup>lt;sup>25</sup> Staff's NPR Briefing Package at Tabs C and E contain more detailed analysis of incidents and hazards associated with crib mattress use.

<sup>&</sup>lt;sup>28</sup> Sudden infant death syndrome (SIDS) is a subcategory of SUID that refers to infant deaths that cannot be explained after a thorough case investigation. The terms SUID and SIDS are used interchangeably, as SIDS commonly is used to refer to SUID in warning labels and articles and given that consumers are more familiar with the term SIDS as opposed to SUID.

to Sleep" (Moon *et al.*, 2016, as cited in Fors Marsh Group, 2019), the "ABC's of safe sleep" (alone (no bed sharing), back-sleeping, and crib uncluttered),<sup>29</sup> and "Safe Sleep/Bare is Best."<sup>30,31</sup> Health and safety advocates, including the AAP, CDC,<sup>32</sup> CPSC, and Kids in Danger (KID)<sup>33</sup> support these efforts.

To make infant sleep environments more comfortable, caregivers commonly use soft bedding and after-market mattresses, instead of, or in addition to, an OEM mattress. Infants can maneuver themselves into vulnerable positions in a sleep environment, from which they cannot free themselves:

Infants in the age range associated with fatal incidents, i.e., between 2 and 6 months, develop new skills, such as rolling over and crawling, in stages. According to Bayley (1969), several developmental milestones occur within the first 6 months of life; some notable motor skills typically achieved are turning from side to back (average age: 1.8 months old), turning from back to side (average age: 4.4 months old), and turning from back to stomach (average age: 6.4 months old). Children as young as 8 to 12 weeks are likely to move around a play yard, including moving to the edge and possibly moving into vulnerable situations. However, children may not be able to remove themselves by reversing their actions because they may not have developed the skill.<sup>34</sup>

Infants can become trapped in a gap between a crib mattress and the side wall(s) of their

sleep environment, with their nose and mouth pressed against the mattress or side wall,

experiencing compromised airflow. Gap entrapment is a hazard associated with ill-fitting

mattresses in full-size cribs, play yards, and non-full-size cribs. To minimize the risk for

<sup>&</sup>lt;sup>29</sup> See <u>https://www.aappublications.org/news/2016/10/24/SIDS102416</u>; accessed May 7, 2020.

<sup>&</sup>lt;sup>30</sup> See <u>https://www.cpsc.gov/Safety-Education/Neighborhood-Safety-Network/Posters/Safe-Sleep-for-Babies;</u> accessed May 6, 2020.

<sup>&</sup>lt;sup>31</sup> See <u>https://www.cpsc.gov/safety-education/safety-guides/kids-and-babies-cribs/safe-sleepbare-best</u> and <u>https://www.nationwidechildrens.org/family-resources-education/health-wellness-and-safety-resources/helping-hands/safe-sleep-practices-for-babies;</u> accessed May 11, 2020.

<sup>&</sup>lt;sup>32</sup> See <u>https://www.cdc.gov/vitalsigns/safesleep/index.html;</u> accessed May 2, 2020.

<sup>&</sup>lt;sup>33</sup> See <u>https://kidsindanger.org/protect-your-child/sleep/;</u> accessed May 6, 2020.

<sup>&</sup>lt;sup>34</sup> See page 5, <u>https://www.cpsc.gov/s3fs-public/Petition%20CP%2015-2%20-</u>

<sup>%20</sup>Petition%20Requesting%20Ban%20on%20Supplemental%20Mattress%20for%20Play%20Yards%20with%20Non -Rigid%20Sides%20-%20May%2010%202017\_3.pdf; accessed September 14, 2020.

entrapment in a gap, a full-size crib and full-size crib mattress that meet the applicable standards would allow a maximum side gap of 1<sup>3</sup>/<sub>8</sub> inches.<sup>35</sup> Given non-flexible sides and infant head dimensions,<sup>36</sup> requirements in these standards work in tandem to help prevent head entrapment and suffocation between the mattress and crib sides, even though a full-size crib manufacturer is not required to provide the mattress.<sup>37</sup> Still, incidents of gap entrapment involving these products continue to occur, including when the full-size crib and *non-compressed* full-size crib mattress measure the appropriate dimensions. For example, gaps involving full-size crib mattress can develop if the mattresses are too soft, such as when the mattress is compressed by mattress sheets.

Gaps between the infant's mattress and sleep product sides are especially hazardous when after-market mattresses with thicker depth dimensions than the OEM mattress are used in products with flexible (*e.g.*, mesh or fabric) sides, such as play yards and non-rigid-sided portable cribs. The side walls of these products typically expand more towards the center of the side wall, and, consequently, as the thickness of mattresses used in these products increases, the risk of gap entrapment often increases as well.

### *F. Product Recalls*<sup>38</sup>

From June 1, 2010 to June 1, 2020, CPSC negotiated five consumer-level recalls involving crib mattresses to mitigate against risks of flammability and suffocation. Four recalls involved non-compliance with mandatory federal flammability requirements. These four recalls included

<sup>&</sup>lt;sup>35</sup> Per 16 CFR part 1219, and by reference ASTM F1169 – 19, a full-size crib must have interior dimensions of  $28 \pm \frac{5}{8}$  inches wide by  $52^{3}/_{8} \pm \frac{5}{8}$  inches long. Per the existing voluntary standard for crib mattresses, ASTM F2933-19, a full-size crib mattress shall measure at least  $27^{1}/_{4}$  inches wide by  $51^{5}/_{8}$  inches long by 6 inches thick.

<sup>&</sup>lt;sup>36</sup> According to Snyder (1975), the 5<sup>th</sup> percentile head breadth, *i.e.*, the maximum breadth of the head above and behind the ears, of children 0 to 3 months old is approximately  $3^{3}/_{10}$  inches, which is more than twice as wide as the maximum allowable side gap between full-size cribs and full-size crib mattresses. ESHF staff selected head "breadth," as opposed to length or height, to err on the side of caution, as head breadth is the smallest of these three head dimensions that could cause a fatal entrapment. Similarly, staff selected the 5<sup>th</sup> percentile measurement for 0-to-3-month-old infants to reduce the likelihood of death or serious injury to those most vulnerable to the identified hazards.

<sup>&</sup>lt;sup>37</sup> See <u>https://www.cpsc.gov/Business--Manufacturing/Business-Education/Business-Guidance/Full-Size-Baby-Cribs/</u>, accessed May 1, 2020.

<sup>&</sup>lt;sup>38</sup> See Staff's NPR Briefing Package at Tab D.

approximately 80,000 units in total. The Commission cannot provide an exact number of units because of a lack of differentiation between crib and adult mattress populations in recalls that included both. The fifth recall of crib mattresses involved a dimensional issue, where the crib mattress models were ill-fitting, presenting an entrapment hazard. This recall included approximately 300,000 units.

## IV. International Standards for Crib Mattresses<sup>39</sup>

The Commission is aware of two international voluntary standards pertaining to crib mattresses:<sup>40</sup>

- BS EN 16890:2017 Children's Furniture Mattresses for cots and cribs Safety requirements and test methods (BS EN 16890); and
- Australian/New Zealand Standard 8811.1:2013 Methods of testing infant products (AS/NZS 8811.1).

Table 5 compares each of these international standards to ASTM F2933-19 to assess how each standard addresses the identified hazard patterns and other common hazards. Tab B of Staff's NPR Briefing Package contains a more detailed analysis of the comparison, and how each standard addresses the hazard patterns described in Table 5.

#### Table 5. Comparison of Crib Mattress Voluntary Standards by Hazard Pattern

Hazard Pattern	ASTM F2933	AS/NZS 8811.1	EN 16890	Comments
Chemical Hazards	16 CFR part 1303 Ban of Lead- Containing Paint, 16 CFR part 1500 Hazardous Substances Act Regulations	Not addressed	Provision for specific controlled toxic substances	ASTM is adequate to address US incident data

<sup>&</sup>lt;sup>39</sup> See Staff's NPR Briefing Package at Tab B.

<sup>&</sup>lt;sup>40</sup> The Commission is also aware of a draft, unpublished, standard, ISO 23767 *Children's furniture – Mattresses for cots and cribs – Safety requirements and test methods*. Although this draft ISO standard is not yet an official standard, CPSC staff reviewed it for relevancy and found that it is nearly identical to BS EN 16890.

Hazard Pattern	ASTM F2933	AS/NZS 8811.1	EN 16890	Comments	
Coil or Spring	Prohibition of sharp points	Not addressed	Prohibition of sharp points	NPR proposes addition of cyclic testing	
Crib Mattress Used in a Play Yard	Labeling requirements, requirements for after-market mattresses and required testing to ASTM F406 mattress requirements	Not addressed	Labeling requirements	ASTM more stringent	
Expand or Inflate	Dimensional conformity, mattress thickness, and labeling requirements	Not addressed	Dimensional conformity, labeling requirements	ASTM more stringent	
Face in Mattress	Labeling requirements	Firmness test	Firmness test	NPR proposes mattress firmness test based on sections 6 and 8 of AS/NZS 8811.1 firmness test, in addition to label requirements in ASTM F2933-19	
Fit Issues	Dimensional conformity and after-market mattress requirements	Not addressed	Dimensional conformity, conical probe test, cyclic test	NPR proposes fitted sheet compression test	
Found Prone	Labeling requirements	Firmness test	Firmness test	NPR proposes mattress firmness test based on sections 6 and 8 of AS/NZS 8811.1 firmness test, in addition to label requirements in ASTM F2933-19	
Mattress Falls Apart	Mattress seam stitching requirement and small parts prohibition	Not addressed	Mattress seam stitching requirement and small parts prohibition	ASTM more stringent	

Hazard Pattern	ASTM F2933	AS/NZS 8811.1	EN 16890	Comments
Softness	Not addressed	Firmness test	Firmness test	NPR proposes mattress firmness test based on sections 6 and 8 of AS/NZS 8811.1 firmness test
Multiple Contributing Factors (MCF)	General requirements and instructional literature	Not addressed	General requirements and instructional literature	ASTM General Requirements are adequate but safety info is inadequate
Small Parts	Prohibited per 16 CFR part 1501	Not addressed	Same as ASTM	ASTM is adequate to address U.S. incident data
Sharp Points/Edges	Prohibited per 16 CFR 1500	Not addressed	Prohibited but no performance requirements	ASTM is more stringent
Flammability	Prohibited per 16 CFR 1632 and 1633	Not addressed	Must comply with EN 71- 2:2011 and EN 597-1	ASTM is adequate to address U.S. incident data
Small Openings	Openings between 0.210" and 0.375" prohibited	Not addressed	Not addressed	ASTM is adequate and more stringent
Label Permanency	Must not detach with < 15-lb. pull force	Not addressed	Must not detach after 30 attempts to remove with feeler gauge	ASTM is adequate and more stringent
Dimensional Conformity	Must be at least 27.25" x 51.625" during application of forces	Not addressed	Must be within 10 mm of nominal dimensions	ASTM is adequate and more stringent
Entanglement	All accessible stitching must be lock stitching	Not addressed	Maximum free length of 220 mm	ASTM is adequate to address U.S. incident data
Seam Stitching	All accessible stitching must be lock stitching	Not addressed	Seams must not be penetrated > 6 mm with 12 mm diameter probe	ASTM is adequate and more stringent
After-Market Mattresses	Mattresses shall have same thickness, floor support structure and attachment method as the mattress it is intended to replace	Not addressed	Not addressed	ASTM is more stringent; NPR proposes to extend dimension requirements in 5.7.2 to all after- market non-full- size crib mattresses

Hazard Pattern	ASTM F2933	AS/NZS 8811.1	EN 16890	Comments
Warning Labels/Instructions	Warning labels required, instructions not required	Not addressed	Instructions required/warning labels do not address as many hazards	ASTM is inadequate. See human factors assessment in Tab C of Staff's NPR Briefing Package.

With the exception of mattress firmness, the Commission concludes that ASTM F2933-19 is equivalent to, or more stringent than, AS/NZS 8811.1 or EN 16890 because it more fully addresses the hazard patterns identified by CPSC staff in the reported incident data. Compared to these international standards, ASTM F2933-19 is more comprehensive because it also addresses non-fullsize crib mattresses and after-market mattresses for play yards and non-full-size cribs. Furthermore, the Commission notes that ASTM F2933-19 was developed through collaboration between CPSC staff and stakeholders, and has been revised three times in the attempt to address incident data provided by CPSC staff. Therefore, the Commission concludes that ASTM F2933-19, when modified to include a test for mattress firmness based on sections 6 and 8 of AS/NZS 8811.1:2013, is more appropriate than AS/NZS 8811.1:2013 or EN 16890 to address hazard patterns associated with crib mattresses.

### V. Voluntary Standard–ASTM F2933<sup>41</sup>

### A. History of ASTM F2933

The ASTM Committee F15 on Consumer Products first published the voluntary standard for crib mattresses in 2013, as ASTM F2933-13, *Standard Consumer Safety Specification for Crib* 

<sup>&</sup>lt;sup>41</sup> See Staff's NPR Briefing Package at Tab B for additional information about the history and performance requirements in ASTM F2933-19.

*Mattresses*. The first publication established requirements for the standard and addressed the following issues:

- Sharp points and sharp edges,<sup>42</sup>
- Small parts,
- Lead and other toxic substances in paints,
- Finger entrapment,
- Mattress dimension conformity,
- Mattress thickness, and
- Marking and labeling.

Since 2013, ASTM has revised and updated the voluntary standard three times to address safety issues, as outlined below:

## ASTM F2933-16 (approved 12/1/2016):

• Revised warning label permanency requirements in 5.6.1, to include requirement that

"[n]on-coated paper warning label shall not be applied on either side of sleeping surface." Added a note under this section, stating that non-coated paper label may absorb water and can deteriorate.

## ASTM F2933-18 (approved 8/15/2018):

• Revised scope to include a new section 1.5, stating the standard was developed in

accordance with internationally recognized principles on standardization.

- Added definition of "after-market mattress for play yard or non-full-size crib," to section 3, Terminology.
  - Added a new requirement for after-market mattresses for play yards and non-full-size crib

mattresses in section 5, General Requirements, stating that after-market mattresses for soft-sided

<sup>&</sup>lt;sup>42</sup> Tapered ends that do not meet the requirements of 16 CFR § 1500.48 and metal or glass tapered surfaces that do not meet the requirements of 16 CFR § 1500.49.

and non-rectangular, rigid-sided products shall have the same thickness, floor support structure, and attachment method as the mattress it is intended to replace and shall meet the specifications of Mattress Vertical Displacement test from ASTM F406-19, *Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards*.

• Added additional marking and labeling requirements for after-market mattresses in sections 7.5 through 7.7. To comply with these sections, after-market mattresses and their retail packaging shall include specified suffocation warning language related to hazardous gaps and stacked mattresses. Sections 7.5 and 7.6 have additional requirements that distinguish between types of products. Section 7.5 has requirements specific to mesh/fabric-sided and rigid-sided, non-rectangular products, including as follows: after-market mattresses shall have all the warnings that the original manufacturer had and provide instructions that are on the original mattress, and both the after-market mattress and the retail packaging shall identify the brand and model numbers of products in which it is intended to be used. Section 7.6 contains requirements specific to rigid sided rectangular products including as follows: after-market mattresses and their retail packaging shall have a specified statement regarding mattress dimensions and fit.

### ASTM F2933-19 (approved 6/15/2019):

• Added a new requirement for mattress seam stitching in section 5, General Requirements, requiring that all seam stitching that is accessible to the occupant be lock stitching.

#### B. Description of Performance Requirements in ASTM F2933-19

In addition to the general requirements typically found in other ASTM juvenile product standards, such as requirements for openings, label permanency, and the prohibition of sharp points/edges, small parts, and lead in paints, section 5 of ASTM F2933-19 contains the following four additional requirements that apply specifically to mattresses for cribs, non-full-size-cribs, and to after-market mattresses for non-full-size cribs and play yards:

• *§ 5.7 Mattress Dimensions*: Describes the dimensional requirements for full-size mattresses and OEM non-full-size crib mattresses, to prevent an infant from becoming wedged in a gap caused by a too small crib mattress. To ensure the crib mattress dimensions are within the allowable range, the test requires a mattress to be placed in a test box and pushed against the side of the box with a force prescribed in the test method.

• § 5.7.2.2 Mattress Thickness: Applies to OEM non-full-size crib mattresses, to prevent occupants from falling out of the product. The requirement states that a mattress supplied with a non-full-size crib shall have a thickness that will provide a minimum effective crib-side height dimension of at least 20 inches when the crib side is in its highest adjustable position and the mattress support is in its lowest adjustable position. Additionally, the mattress shall have a thickness that will provide a minimum effective crib-side height dimension of at least 3 inches when the crib side is in its lowest adjustable position, and the mattress support is in its lowest adjustable position, and the mattress support is in its highest adjustable position.

• § 5.8 *Mattress Seam Stitching*: Applies to all crib mattresses within the scope of the standard, and requires that all seam stitching that is accessible to the occupant be lock stitching to prevent accessible stitching from becoming loose and creating a small part or strangulation hazard.

• § 5.9 After-Market Mattress for Play Yards and Non-Full-Size Cribs: Applies to aftermarket mattresses for play yards and non-full-size cribs, and requires that mesh/fabric sided products, and rigid sided non-rectangular products, must have the same thickness, floor support structure, and attachment method as the mattress it is intended to replace. Accordingly, aftermarket mattresses for play yards and non-rectangular rigid sided products must be identical to the

OEM mattress.<sup>43</sup> After-market mattresses must also meet the Mattress Vertical Displacement test in ASTM F406.<sup>44</sup> Finally, section 5.9.1.3 requires "replacement" mattresses intended to be used in the bassinet of a play yard with a bassinet attachment to meet the requirements of ASTM F2194, when tested with each brand and model the mattress is intended to replace.

### VI. Assessment of the Voluntary Standard ASTM F2933-19

### A. Adequacy of Performance Requirements<sup>45</sup>

ASTM developed ASTM F2933 to mitigate the risk of injury associated with the use of crib mattresses. Hazard mitigation strategies include performance requirements and instructions and onproduct warnings to help inform caretakers of the primary hazards during use of the product. Based on CPSC staff's Engineering, Human Factors, and Health Sciences assessments, Tabs B, C, and E of Staff's NPR Briefing Package, respectively, the requirements in the current voluntary standard, ASTM F2933-19, adequately address the hazard patterns related to expanding or inflating crib mattresses, mattresses falling apart, and most hazards associated with multiple contributing factors, or other hazards. However, ASTM F2933-19 does not adequately address the most prevalent or severe identified hazards associated with the use of crib mattresses, such as coil spring issues, face in mattress, fit issues, found prone, and softness. The warning labeling for factors within multiple contributing factors (such as, face in mattress, found prone, and softness) are also inadequate. Accordingly, the Commission proposes additional requirements in the NPR to make the standard more stringent, to further reduce the risks of death and injury from these hazard patterns. Table 6

<sup>&</sup>lt;sup>43</sup> Requirements for OEM mattresses sold with play yards and non-full-size cribs are codified at 16 CFR parts 1220 (non-full-size cribs) and 1221 (play yards), which incorporate by reference ASTM F406, *Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards* (ASTM F406).

<sup>&</sup>lt;sup>44</sup> The purpose of requiring after-market mattresses to be identical to OEM mattresses is to reduce the risk of infant entrapment and suffocation associated with after-market mattresses that are too thick, or that do not fit correctly or attach to a play yard or non-full-size crib. ASTM developed this requirement in collaboration with CPSC staff and the ASTM Play Yard Vertical Displacement Task Group and the Play Yard Mattress Fit and Thickness Task Group.
<sup>45</sup> Staff's NPR Briefing Package at Tab B contains additional details on the CPSC staff's analysis of ASTM F2933-19 and its ability to address identified hazards.

summarizes CPSC's assessment of the adequacy of ASTM F2933-19 to address the identified

hazard patterns.

Identified Hazard	Applicable	How addressed in ASTM	Adequacv	Comments
Pattern	Mattresses	F2933–19	1	
(potential injury)				
Chemical/ Flammability Hazards (odors, rash)	All	<ul> <li>16 CFR part 1303</li> <li>Lead-Containing Paint</li> <li>16 CFR part 1500 Hazardous</li> <li>Substances Act Regulations</li> <li>(Sections 5.1 and 5.4)</li> <li>16 CFR part 1632 Flammability of</li> <li>Mattresses and Mattress Pads</li> <li>16 CFR part 1633 Flammability</li> <li>(Open Flame) of Mattress Sets</li> </ul>	Adequate	Staff's NPR Briefing Package (SBP) Tab B
Coil or Spring (laceration)	Coil or spring mattresses (primarily full-size)	Prohibition of sharp points (Section 5.2)	Inadequate	Propose additional cyclic testing to identify potential for springs to break through surface during foreseeable use and misuse. SBP Tab B.
Crib Mattress Used in a Play Yard (suffocation due to ill- fitting mattress)	Aftermarket play yard mattresses	Labeling requirements, requirements for after-market mattresses. Testing requirements harmonized with ASTM F406. (Section 7.5)	Adequate	SBP Tabs B & C.
Expand or Inflate (suffocation due to ill- fitting mattress that does not expand or inflate properly)	Foam products, typically full-size and shipped as "bed in a box"	Dimensional conformity, mattress thickness, and labeling requirements (Section 5.7)	Adequate	SBP Tab B.
Face in Mattress (suffocation)	All	Labeling requirements (Section 7.3)	Inadequate	NPR proposes a test based on sections 6 and 8 of AS/NZS 8811.1 firmness test. SBP Tabs B & C.
Fit Issues (suffocation due to ill- fitting mattress)	All	Dimensional conformity and after- market mattress requirements (Sections 5.7 and 5.9)	Inadequate	NPR proposes additional fitted sheet compression test for full-size crib mattresses and extending dimensional requirements in section 5.7 to all after- market, non-full-size crib mattresses. SBP Tab B.

Identified Hazard Pattern	Applicable Mattresses	How addressed in ASTM F2933–19	Adequacy	Comments
(potential injury)				
Found Prone (suffocation due to prone position)	All	Labeling requirements (Section 7.3)	Inadequate	Propose additional mattress firmness test based on sections 6 and 8 of AS/NZS 8811.1 and strengthening warning label requirements. SBP Tabs B & C
Mattress Falls Apart (choking/ingestion)	All	Mattress seam stitching requirement and small parts prohibition (Sections 5.3 and 5.8)	Adequate	SBP Tab B.
Softness (suffocation due to soft surface)	All	Not addressed	Inadequate	Propose additional mattress firmness test based on sections 6 and 8 of AS/NZS 8811.1 firmness test. SBP Tab B.
Multiple Contributing Factors (MCFs, <i>e.g.</i> , entrapment in bumper pads, limb entrapment, crib sharing with another infant, existing health condition)	All	General requirements and warning labels (Sections 5.7 and 7.3)	Inadequate	Some MCFs addressed by proposed additional requirements, while others are related to another product use or other factor out of the scope of the crib mattresses standard.

### 1. Coil or Spring Lacerations

Laceration hazards due to an exposed coil or spring accounted for 124 of the 440 incident reports (38% of nonfatal incidents). Currently, ASTM F2933-19 does not address this hazard. A cyclic test could address this hazard, by loading and unloading any mattress that contains coils or springs for a set number of cycles, to exercise metal coil springs and identify springs that cannot withstand normal use without breaking, or that may otherwise break the surface of the mattress.

In July 2018, the ASTM Crib Mattress Cyclic Testing task group discussed a cyclic impact test based on the Mattress Support Vertical Impact Test from section 7.4 of ASTM F1169 – 19 (the standard for full-size cribs). At the F15.66 Crib Mattress subcommittee meeting held in October 2018, the subcommittee discussed both the Mattress Support Vertical Impact Test and the Mattress Durability Roller Testing for spring/coil mattresses, based on ASTM F1566, *Standard Test Methods* 

*for Evaluation of Innersprings, Boxsprings, Mattresses or Mattress Sets,* section 7, as possible cycle loading tests. In the following months, CPSC staff and other members of the Crib Mattress Cyclic Testing task group performed variations of the Mattress Support Vertical Impact Test to determine a test that would be most applicable to crib mattresses with coil springs.

On April 29, 2019, CPSC staff sent a letter to the subcommittee chair in response to ballot F15 (19-04), stating staff's initial test results. In the task group meeting in July 2019, staff and one manufacturer discussed the results of their continued testing and refined the requirements. The task group focused testing on the Mattress Support Vertical Impact Test because this test uses the same equipment employed in full-size crib testing. After replicating the full-size crib impact test (45 pounds dropped 750 times), staff assessed that the test was too onerous. During task group discussions, consensus was to lower the weight to 30 pounds and increase the number of cycles to 1,000.

ASTM has not held additional task group meetings or issued ballots on this issue since the July 2019 task group meeting. The Commission's proposed requirement in the NPR to address coils and springs is based on the last work of the task group, and the test requires a 30-pound impactor drop, similar to the full-size crib standard, on a mattress in four specified locations for a total of 1000 impacts. Tab B of Staff's NPR Briefing Package provides additional details of staff's work to address coil and spring lacerations and the proposed cyclic test.

2. Fit Issues

Fit issues are associated with 108 of 439 incidents; 20 were fatal, and 88 were nonfatal. In these reports, gaps between the crib mattress and the crib rail or play yard mesh, on one or more areas around the perimeter of a crib mattress, created a wedging or entrapment hazard. Reports of mattresses that fail to expand, compress, or buckle, indicate the potential to form hazardous gaps between the corner of a crib and the corner of the mattress. This hazard can arise when a fitted

sheet is placed on the mattress, creating large corner gaps that could lead to entrapment. Fit issues can also occur when a mattress is not dimensionally appropriate for use with a specific crib.

## a. Mattress Compression with Fitted Sheet

ASTM F2933-19 contains a mattress dimensional conformity test intended to address hazardous gaps between the edge of a crib and the mattress. However, staff testing found that tight-fitting sheets over crib mattresses can create gaps between the corners of the mattress and the interior corner of the crib, creating an entrapment hazard. ASTM F2933-19 does not adequately addresses this mattress compression issue that creates an entrapment hazard between a full-size crib mattress and the side or corner of a full-size crib.

For further examination, staff obtained 11 full-size crib mattresses and eight 100 percent cotton full-size crib mattress sheets to investigate this reported hazard pattern. Staff washed four sets of sheets twice in hot water then dried them at the highest temperature setting; staff did not wash the remaining four sheet sets. Staff measured the length and width of two corner seams of the eight mattress sheets with the corner seams straightened. Staff measured length and width by holding the innermost ends of two adjacent corner seams, separating them until a straight edge was formed, and measuring the straight edge.

Staff set aside for mattress testing the smallest sheet of each group, as determined by the smallest length and width dimensions. The sheets were then fitted on the mattresses to determine the change in dimensions and whether any potentially hazardous gaps were created. Staff shared the test results, detailed in Tab B of Staff's NPR Briefing Package, with the subcommittee chair on March 20, 2020, but no ASTM subcommittee or task group meetings for crib mattresses have occurred since then, due to the COVID-19 pandemic. To strengthen the standard, the Commission proposes in the NPR to add a test for full-size mattresses to assess compression and fit issues caused
by a tight-fitting sheet. This additional test may also help with complaints around mattresses inflating or expanding, because the proposed test would repeat the dimensional conformity test.

#### b. Dimension Requirements for After-Market Non-Full-Size Crib Mattresses

ASTM F2933-19 addresses dimensional requirements for non-full-size crib mattresses in two places: section 5.7, which addresses mattresses "supplied with" a non-full-size crib (OEM mattresses), and section 5.9, which addresses after-market mattresses for non-full-size cribs (mattresses purchased separately from a crib, which are not intended by the OEM as a replacement mattress). Dimensional requirements for non-full-size crib mattresses are a key requirement in ASTM F2933-19, because size requirements prevent hazardous gaps from forming between the edge of a mattress and the side of the crib, where infants can become entrapped and suffocate. Table 7 presents the types of crib mattresses covered by ASTM F2933 and the current dimensional requirements for each mattress type.

		ASTM	16 CFR 1221	16 CFR 1220	ASTM	ASTM
		F2933-19	ASTM F406	ASTM F406	F2933-19	F2933-19
		Crib		Non-Full-Size	Crib	Crib
		Mattresses	Play Yards	Cribs	Mattresses	Mattresses
		5.7.1.1	5.16.2	5.17	5.7.2	5.9.1
Full-Size	All	Х				
Dlay Varda	Original*		Х			
Flay Falus	After-market					X**
Rectangular	Original*			Х	Х	
NFS	After-market					
Non-	Original*			Х	Х	
Rectangular NFS	After-market					Х

**Table 7: Current Performance Requirements for Crib Mattress Dimensions** 

\*Includes "replacement mattresses," which are assumed to be sold by an original equipment manufacturer (OEM) and equivalent in dimension and specification to the original mattress (*see* ASTM F2933-19 section 3.1.1.1).

\*\* After-market play yard mattresses that are also used in a bassinet attachment to that play yard must also meet ASTM F2194, for bassinets.

Table 7 demonstrates a gap in the dimensional requirements for after-market, rectangular-

shaped, non-full-size crib mattresses in section 5.9 ASTM F2933-19 (shaded), which does not

appear to have a performance requirement for mattress dimension. The Commission proposes in

the NPR to address this gap by expanding the non-full-size crib mattress requirements in 5.7.2, which currently only apply to OEM mattresses, to apply to all non-full-size crib mattresses.

Although the after-market requirements in section 5.9 are purportedly intended to apply to "After-market mattress for play yard and non-full size crib," the requirements in section 5.9.1 are limited to "mesh/fabric sided products" (meaning play yards) and "rigid sided non-rectangular products" (meaning non-rectangular non-full-size cribs). Because section 5.7 of ASTM F2933-19 only applies to OEM mattresses, no performance requirements in the standard apply to after-market, rectangular-shaped, non-full-size crib mattresses. CPSC staff reviewed the rationales for changes to the after-market requirements for crib mattresses in the ASTM standards, and notes that the ASTM intentionally limited performance requirements in section 5.9.1 by omitting rectangular mattresses for rigid-sided products (*i.e.*, rectangular non-full-size cribs). Staff reviewed ASTM minutes and ballot F15 (17-02), which implemented this requirement in F2933; however, staff could not determine the rationale for limiting the requirements to only *non-rectangular* products.

Although ASTM F2933-19 contains no dimension requirements for after-market, rectangular-shaped, non-full-size crib mattresses, the standard does contain warning requirements pertaining to the size of after-market mattresses for rectangular non-full-size cribs. Staff's NPR Briefing Package details these warnings requirements in section 7 of ASTM F2933-19. Generally, solely relying on a warning label puts the onus on the consumer to read, understand, and follow the direction to only use an OEM mattress. CPSC staff concluded that warnings alone are insufficient to address the hazards associated with ill-fitting, after-market, non-full-size crib mattresses.

# 3. Found Prone, Face into Mattress, and Softness

CPSC staff separated the hazard patterns for found prone, face into mattress, and softness in the incident review, as reflected in Table 6. However, due to available details in each incident, CPSC staff considers these hazard patterns to be related. Accordingly, the Commission's proposed

modifications in the NPR related to each of these hazard patterns may address incidents associated with all three hazard patterns.

Staff found that in 57 percent (66 out of 116) of the reported fatalities and three reported nonfatal incidents (1%), the infant was found in a prone position (face down) with no mention of whether the face of the child was in contact with the crib mattress or crib sheet, and no mention of whether the face was obstructed by other crib bedding or other items in the sleep environment. However, in 11 percent (13 out of 116) of fatalities, when discovered, the child was found prone and the report specifically indicated the face of the child was in contact with a crib mattress or crib sheet covering the crib mattress. Based on the available information about each fatality, staff found that some reports indicate that bedding was present in the sleeping environment, but bedding was not touching the infant or did not appear to be a contributing factor in the death. Additionally, staff found that in 11 percent (36 out of 323) of the nonfatal incidents, the report stated that a crib mattress inner cushioning was too soft. Although these incidents did not involve a fatality, soft bedding, such as pillows and comforters, is associated with infant fatalities, and staff deduces that an excessively soft mattress (*i.e.*, one that may mold around or otherwise occlude an infant's airway), such as mattresses made of memory foam,<sup>46</sup> could present the same hazard.

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. A crib mattress must be sufficiently firm to prevent a child's nose and mouth from being obstructed by a mattress that is too soft and pillow-like. Prone positioning is a known risk factor for SUID, and may be related to limited physical and developmental capabilities of infants, who may not arouse themselves in a low-oxygen situation. Suffocation-type asphyxial deaths (*e.g.*, smothering) involve occlusion of airways and can occur

<sup>&</sup>lt;sup>46</sup> Memory foam is a viscoelastic-foam product that is sensitive to pressure and temperature and intended to conform to the body.

when an infant is placed to sleep or rolls into a prone position on a surface capable of conforming to the body or face of an infant, such that the mouth and nose are physically blocked, preventing air passage. Moreover, published guidance from the American Academy of Pediatrics (AAP) states: "A soft sleeping surface (*e.g.*, memory foam) can increase the risk of rebreathing or suffocation"<sup>47</sup>; and "Soft mattresses, including those made from memory foam, could create a pocket (or indentation) and increase the chance of rebreathing or suffocation if the infant is placed in or rolls over to the prone position."<sup>48</sup> Tab E of Staff's NPR Briefing Package contains additional information about the suffocation hazard.

Other than through warnings, ASTM F2933-19 does not address mattress firmness or softness hazards potentially related to prone and face into mattress incidents. ASTM F2933-19 contains warning requirements regarding prone positioning; however, based on CPSC staff's analysis, warnings alone are inadequate to address the suffocation hazard. The Commission proposes in the NPR a performance requirement to measure mattress firmness, to address some prone-positioning deaths<sup>49</sup>—in which it was not clear that that face was *in* the mattress. In a letter to the ASTM subcommittee chair for crib mattresses, dated December 11, 2019, staff recommended that the subcommittee continue their previous work on mattress firmness. The firmness task group met on January 8, 2020, to discuss this recommendation. In a task group meeting held on February 13, 2020, staff verbally shared the results of staff's testing to AS/NZS 8811.1:2013 and a draft test method in ISO/CD 23767, although most members had yet to perform any testing. Staff also shared testing results in a letter to the subcommittee and task group chair on March 20, 2020. The task group planned to discuss CPSC testing results at the April subcommittee meeting, which was

<sup>&</sup>lt;sup>47</sup> <u>https://www.aafp.org/afp/2017/0615/p806.html.</u>

<sup>&</sup>lt;sup>48</sup> https://pediatrics.aappublications.org/content/138/5/e20162938#ref-19.

<sup>&</sup>lt;sup>49</sup> Many factors contribute to prone positioning deaths, and suffocation face down in a soft mattress is just one possible factor. Staff could not definitively associate soft mattresses with specific incidents. However, staff did not associate incidents with firm mattresses, and staff is aware of deaths associated with other products with conforming surfaces (*e.g.*, pillows, blankets).

canceled due to the COVID-19 pandemic. CPSC staff's testing, detailed in Tab B of Staff's NPR Briefing Package, found few failures with either test method, based on 11 sample mattresses available from big box retail stores.

After evaluating the hazards associated with soft surfaces, the Commission proposes in the NPR additional performance requirements to make the standard more stringent, to further reduce the risk of death and injury associated with mattresses that are too soft and have the ability to conform to an infant's face. Although the warning label change and the firmness test will not make prone sleeping safe, they may help to reduce the instances in which an infant maneuvers into a prone position with its face *in* the mattress that could have been mitigated with a firmer surface. CPSC staff determined that the AS/NZS 8811.1:2103 is more repeatable and more stringent than the draft test in ISO/CD 23767. Accordingly, the Commission proposes a mattress firmness test in the NPR for all crib mattresses within the scope of the standard that is based on sections 6 and 8 of AS/NZS 8811.1:2013.<sup>50</sup> Tab B of Staff's NPR Briefing Package contains additional details regarding staff's testing of mattress firmness and the rationale for recommending the addition of the performance test based on AS/NZS 8811.1:2013.

### B. Adequacy of Marking, Labeling, and Instructions<sup>51</sup>

Universally, labeling experts view warning about a hazard as less effective at addressing hazards than either designing the hazard out of a product, or guarding the consumer from the hazard. The use of warnings is lower in the hazard-control hierarchy than design-based approaches because the effectiveness depends on persuading consumers to alter their behavior in some way to

<sup>&</sup>lt;sup>50</sup> Staff also used a test based on AS/NZS 8811.1:2013 to address a smothering-type suffocation hazard presented by crib bumpers separating from the crib or otherwise protruding into the sleep area and getting underneath an infant. In these situations, the crib bumper behaves like a quilt or soft bedding that is able to conform to, and occlude, airway openings. Extending the requirement to the mattress will similarly reduce the risk of suffocation posed by soft depressions or indentations in crib mattresses.

<sup>&</sup>lt;sup>51</sup> Staff's NPR Briefing Package at Tab F contains additional details on the basis for the Commission's proposed modifications to the marking, labeling, and instructional literature requirements for crib mattresses.

avoid hazards, rather than eliminating hazards or inhibiting exposure to hazards. Therefore, when a standard relies on warnings to address a hazard, warning statements must be as strong as possible; *i.e.*, the warnings must be noticeable, understandable, and motivating. 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*, recommends that on-product warnings include content that addresses the following three elements:<sup>52</sup>

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

Section 7 of ASTM F2933-19 specifies requirements for marking and labeling for full-size crib mattresses, non-full-size crib mattresses, and after-market mattresses for play yards and non-full-size cribs. Based on CPSC staff's examination of literature, incident data, and consumer feedback, the crib mattress warnings specified in ASTM F2933-19 do not adequately address these warning elements regarding the identified hazards. While there are warnings pertaining to infant positioning, soft bedding, and gap entrapment, the wording and formatting of the warning message needs to be improved to communicate the hazards effectively. Below we summarize the relevant warnings in ASTM F2933-19 and the Commission's concerns with the warnings.

1. Warnings Regarding Infant Positioning

Regarding positioning babies on their backs to sleep, ASTM F2933-19 requires the

following warning:

Failure to follow these warnings could result in serious injury or death. To prevent deaths, the U.S. Consumer Product Safety Commission (CPSC), the American Academy of Pediatrics (AAP), and the National Institute of Child Health and Human Development (NICHD) recommend the following:

<sup>&</sup>lt;sup>52</sup> All three elements may not be necessary in some cases, such as if certain information is open and obvious or can be readily inferred by consumers. However, people often overestimate the obviousness of such information to consumers.

To reduce the risk of Sudden Infant Death Syndrome (SIDS) and suffocation, pediatricians recommend healthy infants be placed on their backs to sleep, unless otherwise advised by your physician.

The warning to place babies on their backs to sleep includes, and is presented after, a significant amount of unnecessary text. Given that at least 102 of the 116 deaths involved prone positioning, many of which indicated no other known contributing factors, it is imperative that this warning be as clear and direct as possible. As discussed in Tab C of Staff's NPR Briefing Package, and the Appendix to Tab C, the Commission proposes in the NPR to modify this warning statement and its position on the warning label to increase the likelihood of consumers reading and understanding the hazard of prone sleeping.

# 2. Warnings Regarding Soft Bedding

Regarding soft bedding, ASTM F2933-19 includes the following warnings:

- Infants can suffocate on soft bedding. Never place a pillow or comforter under sleeping infant for additional padding or as a mattress substitute.
- Do not cover the heads of babies with a blanket or over bundle them in clothing and blankets. Overheating can lead to SIDS.
- [For full-size crib mattresses] Only use sheets and mattress pads designed specifically for crib mattresses.
- [For non-full-size crib mattresses] Only use sheets and mattress pads designed specifically for this mattress size.

Staff's review indicates that unnecessary wording is included in the warnings pertaining to soft bedding, and that the warnings are not clearly organized. Reports for at least 49 incidents indicate that caregivers added soft bedding to the sleep area, and survey<sup>53</sup> and focus group<sup>54</sup> feedback demonstrates that consumers commonly use soft bedding in infant sleep areas. As advocated in numerous public awareness campaigns by health and safety professionals, warnings regarding soft

<sup>&</sup>lt;sup>53</sup> See section II.C of this preamble for information about the DNPES.

<sup>&</sup>lt;sup>54</sup> The 2019 "Consumer Product Safety Commission (CPSC): Caregiver Perceptions and Reactions to Safety Messaging Final Report," by Fors Marsh Group, includes a discussion of feedback from parents and grandparents who participated in focus groups pertaining to safe sleep practices. *See* Staff's NPR Briefing Package at Tab C for more information.

bedding must be communicated effectively. The Commission proposes to modify the warning

content and formatting to increase the readability and directness of the warnings.

3. Warnings Regarding Gaps

Regarding gaps, in addition to specifying consumers use only sheets and mattress pads

designed for the crib mattress, ASTM F2933-19 includes the following warnings:

- [For full-size crib mattresses] Do not use this mattress in a crib having interior dimensions that exceed 28<sup>5</sup>/<sub>8</sub> by 53 in. (73 by 135 cm) as measured from the innermost surfaces of the crib.
- [For non-full-size rigid sided rectangular products] Check for proper fit of the mattress. This mattress measures \_\_\_\_\_ long, \_\_\_\_ wide, and \_\_\_\_\_ thick when measured from seam to seam. (The blank is to be filled in.)
- [For play yards and non-full-size cribs] **Suffocation hazard: Babies have suffocated:** 
  - In gaps between wrong-size mattress and side walls of product.
  - Between the side walls and extra padding, such as stacked mattresses.

**ALWAYS** check mattress fit by pushing mattress tight to one corner. Look for any gaps between the mattress and the side walls. If this gap is larger than 1 in., the mattress does not fit and should **NOT** be used.

NEVER stack with another mattress. Use only ONE mattress.

For full-size crib mattresses, staff's review shows that these warnings do not provide consumers with enough information about the gap entrapment hazard. Reports for at least 14 of the cases resulting in death describe gaps involving a full-size crib mattress (at least 119 incident reports including complaints with and without injuries). Regarding this hazard, the warnings in ASTM F2933-19 inform consumers that only the full-size crib mattress is to be used in a crib with the specified dimensions (full-size crib dimensions in compliance with 16 CFR part 1219), and that consumers are to use only sheets and mattress pads designed specifically for crib mattresses. A single statement about specified dimensions is not sufficient, given the prevalence of this hazard and that factors such as rounded edges and compression can increase the size of side wall or corner gaps. The Commission proposes to modify these warnings to present more clearly and accurately the hazard information, including the hazard information for full-size crib mattresses.

# 4. Additional Concerns Regarding the Warnings

The Commission has additional concerns with the safety information requirements in ASTM

F2933-19, which undercut the effectiveness of the communication of the identified hazards. These

concerns include, but are not limited to, the following:

- the definition of "conspicuous" in section 3 is ambiguous;
- the warning labels do not have a clear and comprehensive hazard identifier;
- the packaging requirements for marking and labeling are limited and exclude full-size crib mattresses;
- there are no requirements for warnings in instructional literature;
- the warning message includes a significant amount of superfluous text, resulting consequently in warning labels that are more difficult to understand and less likely to be read in their entirety; and
- the requirements in section 7 are worded and organized poorly, which may lead to confusion among manufacturers, test labs, and others viewing the standard.

The Commission proposes in the NPR to improve the requirements for safety information in

ASTM F2933-19 to address the above concerns and further reduce the risk of injury and death from

the identified hazards. In a side-by-side redline of the current and proposed labeling provisions in

the Appendix to Tab C of Staff's NPR Briefing Package, staff identifies the specific weaknesses of

ASTM F2933-19 for addressing the hazards, and provides explanations for the proposed

modifications.

# 5. Basis for NPR Proposed Modifications to Safety Information

The Commission proposes in the NPR substantial modifications to the requirements for

marking and labeling specified in ASTM F2933-19, including a new section on instructional

literature. Figure 1 shows a comparison of full-size crib mattress warning labels compliant with

ASTM F2933-19 current requirements versus the NPR's proposed labeling requirements.

Current warning in ASTM F2955-19	Proposed NPR warning					
Failure to follow these warnings could result in serious injury or death. To prevent deaths, the U.S. Consumer Product Safety Commission (CPSC), the American Academy of Pediatrics (AAP), and the National Institute of Child Health and Human Development (NICHD) recommend the following: To reduce the risk of Sudden Infant Death Syndrome (SIDS) and suffocation, pediatricians recommend healthy infants be placed on their backs to sleep, unless otherwise advised by your physician. • Infants can suffocate on soft bedding. Never place a pillow or comforter under sleeping infant for additional padding or as a mattress substitute.	<b>ALWARNING</b> SIDS AND SUFFOCATION HAZARDS         ALWAYS place baby on back to sleep to reduce the risks of SIDS and suffocation.         Babies have suffocated:         • on pillows, comforters, and extra padding         • in gaps between a wrong-size mattress, or extra padding, and side walls of product.         NEVER add soft bedding, padding, or an extra mattress.         USE ONLY one mattress at a time.         DO NOT cover the faces or heads of babies with a blanket or over-bundle them. Overheating can increase the risk of					
<ul> <li>Do not cover the heads of babies with a blanket or over bundle them in clothing and blankets. Overheating can lead to SIDS.</li> <li>Do not use this mattress in a crib having interior dimensions that exceed 285/8 by 53 in. (73 by 135 cm) as measured from the innermost surfaces of the crib.</li> <li>Only use sheets and mattress pads designed specifically for crib mattresses. DO NOT remove these important safety instructions.</li> </ul>	<ul> <li>SIDS.</li> <li>ALWAYS check mattress fit every time you change the sheets, by pushing mattress tight to one corner. Look for any gaps between the mattress and the side walls. If a gap is larger than 1<sup>3</sup>/<sub>8</sub> in. (3.5 cm), the mattress does not fit – do not use it.</li> <li>DO NOT use this mattress in a crib having interior dimensions that exceed 28<sup>5</sup>/<sub>8</sub> by 53 in. (73 by 135 cm) as measured from the innermost surfaces of the crib.</li> <li>USE ONLY sheets and mattress pads designed specifically for crib mattresses.</li> <li>DO NOT remove these important safety warnings.</li> </ul>					
Figure 1, Current (left) and proposed (right) example warning labels for full-size crib mattresses.						

Figure 1. Current (left) and proposed (right) example warning labels for full-size crib mattresser. These labels are not shown in actual size.

Proposed modifications to safety information in the NPR consider improvements to the

safety information from ASTM F15.66 and additional members of the ASTM F15 committee on

consumer products.<sup>55</sup> Recently, ASTM F15 balloted changes to ASTM F2933-19, which were

developed by ASTM F15.66.<sup>56</sup> The recommendations by ASTM F15.66, as well as those provided

in comments by ASTM F15 members on the ballot, include improvements to the warning content

<sup>&</sup>lt;sup>55</sup> Since May 2018, staff has been participating in ASTM F15.66 to address the identified hazards. Subcommittee members include manufacturers, safety and health advocacy groups, and other interested parties.

<sup>&</sup>lt;sup>56</sup> ASTM F15 balloted revisions to ASTM F2933-19, particularly section 7, on April 6, 2020, resulting in 97 affirmatives, 7 negatives, and 293 abstentions (ASTM ballot F15 (20-02), item #15, *Proposed Changes to ASTM F2933-19 Standard Consumer Safety Specification for Crib Mattresses (WK 72077)*). Currently, ASTM F15.66 has not resolved the negative comments, so ESHF staff has considered the negative comments in developing staff's recommended changes to the safety information in ASTM F2933-19.

and format, and clarifications for manufacturers, regulators, and test labs regarding the requirements of the standard. Many of the changes incorporate efforts to align with recommendations from the Ad Hoc Language task group.<sup>57</sup>

In 2016, ASTM juvenile products standards began adopting "Ad Hoc" labeling recommendations, 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. The warning format recommendations from Ad Hoc are based primarily on the requirements of ANSI Z535.4, while also accounting for the wide range and unique nature of durable nursery products, the concerns raised by industry representatives, and CPSC staff's recommendations associated with durable nursery product rulemaking projects over the past several years. These recommendations include requirements for the following:

- 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:
  - 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 recommendations also include text for general labeling issues, such as labeling

permanency, and content related to manufacturer contact information and date of manufacture. The

majority of the Commission's proposed modifications incorporate recommendations from

stakeholders participating in ASTM F15, but several proposed modifications in the NPR deviate

<sup>&</sup>lt;sup>57</sup> The "Recommended Language Approved by Ad Hoc Task Group Revision E," dated May 28, 2019, documents recommendations from the ASTM Ad Hoc Language task group for ASTM juvenile products standards.

from what has been balloted and recommended by ASTM F15. These modifications in the NPR are based on staff's further consideration of the available data, and have not yet been reviewed by ASTM.

# VII. Proposed Standard for Crib Mattresses

The Commission proposes in the NPR a mandatory standard for crib mattresses that incorporates by reference ASTM F2933-19 with modifications to make the standard more stringent, to further reduce the risk of injury associated with crib mattresses. Below we summarize the proposed modifications in the NPR.

### A. Cyclic Test for Coil or Spring Lacerations

To further reduce the risk of infant lacerations from exposed coils and springs, the Commission proposes in the NPR to require a cyclic loading test for all crib mattresses that use coils and springs, as follows:

1. Mattress shall be tested in an enclosed frame measuring 29 inches x 53 inches (737 mm by 1346 mm) for the purpose of restricting mattress movement. A crib meeting the requirements of ASTM F1169-19 would suffice.

2. The mattress can be placed on top of a  $\frac{3}{4}$ " piece of plywood or OSB, which is rigidly supported along the perimeter.

3. An impactor with the dimensions of the vertical impactor of ASTM F1169-19 weighing 30 lbs. shall be dropped from a height of 6 inches from the top of the mattress surface to the bottom of the impactor, 250 times in four locations (specified in Figure 1), for a total of 1,000 cycles. Cyclic loading rate shall be one drop every  $4 \pm 1$  seconds.

4. At the conclusion of the cyclic loading test, the mattress shall be removed from the test enclosure and visually inspected for exposed wires or coil springs.





Figure 1. Impact test locations.

# B. Test for Mattress Compression from Fitted Sheets

To further reduce the risk of injury associated with corner gap entrapment from compression by fitted sheets, the Commission proposes in the NPR the following new test for full-size crib mattresses:

1. To condition the sheet for compression testing, a store-bought fitted mattress sheet intended for the tested mattress size, consisting of 100 percent cotton, shall be washed in hot water (50° C [122° F] or higher) and dried a minimum of two times on the highest setting, using household textile laundering units.

2. The shrunken fitted sheet shall be placed fully on the mattress, such that each sheet edge is wrapped fully around and under the mattress.

3. The mattress, with the shrunken sheet, shall meet the *Mattress Dimension* requirements in ASTM F2933-19.

3.1. A full-size crib mattress shall be measured according to section 6.2 of the standard.

3.1.1. After dimensional measurements are taken, while no force is being applied, measure the corner gap between the adjoining Walls C and D and the crib mattress. See Figure 1 for illustration. The gap shall not exceed 1.75 in.

3.1.1.1.Corner gap measurements shall be repeated after rotating the mattress 180° and repositioning it in the corner following sections 6.2.2.1 and 6.2.2.2 of ASTM F2933-19.

The Commission is not aware of incidents related to non-full-size crib mattresses compressing when sheets are installed. Therefore, at this time, the Commission is not proposing a similar sheet compression test for non-full-size crib mattresses. However, the Commission seeks more information on whether to require the sheet compression test for non-full-size crib mattresses, and whether such a test would help reduce corner gap entrapments in non-full-size cribs. Accordingly, the Commission invites comments regarding the applicability of the sheet compression test for non-full-size crib mattresses and the use of sheets with non-full-size mattresses.

# C. Dimension Requirements for After-Market Non-Full-Size Crib Mattresses

To further reduce the risk of injury associated with after-market non-full-size crib mattresses, the Commission proposes in the NPR to require a dimensional performance requirement for all non-full-size crib mattresses. The Commission proposes that the current performance requirements for OEM non-full-size crib mattresses in section 5.7.2 of ASTM F2933-19 be modified to apply to all non-full-size crib mattresses, regardless of whether the mattress is sold with a crib, and regardless of the shape of the mattress. The size and thickness requirements for OEM non-full-size crib mattresses. The size and thickness requirements for OEM non-full-size crib mattresses in section 5.7.2 of ASTM F2933-19 be modified to apply to all non-full-size crib mattresses. The size and thickness requirements for OEM non-full-size crib mattresses in section 5.7.2 of ASTM F2933-19 repeat the requirements for OEM non-full-size crib mattresses in section 5.7.2 of ASTM F2933-19 repeat the requirements for non-full-size crib mattresses in section 5.7.2 of ASTM F2933-19 repeat the requirements for non-full-size crib mattresses in section 5.7.2 of ASTM F2933-19 repeat the requirements for non-full-size crib mattresses in section 5.17 of ASTM F406. To preclude the size requirements in each

standard from unintentionally diverging in the future, the Commission proposes in the NPR to revise section 5.7.2 to refer to the requirements for non-full-size crib mattresses in F406, rather than repeating the same requirements in F2933.

# D. Corrections to Section 5.9 of ASTM F2933-19

To accommodate the modification for non-full-size cribs in section 5.7, the Commission proposes in the NPR to remove references to after-market non-full-size crib mattresses from section 5.9 of ASTM F2933-19, such that section 5.9 focuses solely upon performance requirements for after-market play yard mattresses.

The Commission also notes an inconsistency in the language of ASTM F2933-19 section 5.9.1.3, which requires that a "replacement mattress" for a play yard bassinet with a bassinet attachment meet certain specifications in ASTM F2194, when tested with each brand and model it is intended to replace. This requirement for bassinet mattresses appears in the section for "after-market" mattresses. Section 3.1.1 of ASTM F2933-19 specifically exempts "replacement" mattresses from the term "after-market," because "replacement" mattresses are supplied by an OEM and are equivalent to the original mattress. The Commission proposes in the NPR to clarify that the requirements in section 5.9.1.3 apply to after-market mattresses, by replacing the term "replacement," with the word "after-market."

Appendix B to Tab B of Staff's NPR Briefing Package contains a redline of the proposed changes to sections 5.7.2 and 5.9 of ASTM F2933-19. The Commission invites comments on this proposal. Staff intends to continue to work with ASTM to address concerns with exempting aftermarket, rectangular-shaped, non-full-size crib mattresses from performance requirements.

### E. Mattress Firmness Test

To further reduce the risk of infant suffocation associated with surface softness in crib mattresses, the Commission proposes the following mattress firmness test for all crib mattresses

within the scope of the standard, based on a test for mattress firmness in section 8 of AS/NZS 8811.1:2013:

1. Mark three equidistant points along the longitudinal center line, with one at the center and the other two equidistantly between the center and the edge of the mattress. Choose one more "worst-case" scenario test location(s) where an infant's head might lie in a particularly soft spot, or an infant's nose or mouth might contact a protrusion above the sleep surface.

2. Hold the test fixture with its base horizontally, and rotate it so the feeler arm is aligned with the center line of the sleep surface, and pointing in the same direction for each test; then gently set down the fixture on one of the test locations, ensuring that the edge of the bottom disk does not extend beyond the edge of the sleep surface.

3. If the level indicates that the feeler arm is approximately level when the fixture is resting on the sleep surface, observe whether the feeler arm makes any contact with the top of the sleep surface or cover. If the feeler arm is not level, decompress the mattress, allow it to settle, and start again. If the feeler arm contacts the sleep surface even when the test fixture is tilted back so as to raise the feeler arm, assume that such contact would occur had the fixture come to rest horizontally.

4. Repeat steps at remaining locations.

## F. Proposed Modifications to Safety Information

As detailed in Tab C of Staff's NPR Briefing Package, and the Appendix to Tab C, the Commission proposes in the NPR to include a significant number of modifications to the requirements for the safety information that accompanies crib mattresses, including warning labels, packaging, and instructions. Labeling modifications include the following:

- Improved definition of "conspicuous" to clarify that the warning label's placement must make it visible to someone who positions the mattress for use;
- Updated the general marking and labeling requirements;

- Improved warning labels and examples;
- Re-organized and clarified the marking and labeling requirements for manufacturers, test labs, and other viewers of the standard;
- Added warning requirements for full-size crib mattress packaging and improved the warning requirements for packaging of after-market mattresses for play yards and non-full-size cribs; and
- Added a new section on instructional literature, which provides an additional medium by which to communicate safe-use information.

These modifications are intended to further reduce the risk of death and serious injury associated with crib mattresses, such as SUID related to prone positioning of infants, soft bedding in sleep areas, and hazardous gaps between crib mattresses and product sides. The majority of the modifications incorporate recommendations from stakeholders participating in ASTM F15, with several deviations based on CPSC staff's further consideration of the available data, which have not yet been reviewed by ASTM. While safety information is unlikely to effectively address the identified hazards, these modifications are likely to support the effectiveness of the proposed performance requirements, increase the likelihood of consumers understanding the hazards, and clarify the requirements for manufacturers, test labs, and other viewers of the standard.

# VIII. Proposed Amendment to 16 CFR Part 1112 to Include NOR for Crib Mattresses

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 1241, *Standard Consumer Safety Specification for Crib Mattresses*, 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 issued previously by the Commission.

All new NORs for new children's product safety rules, such as the crib mattress standard, require an amendment to part 1112. To meet the requirement that the Commission issue an NOR for the crib mattress 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 mattresses 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 mattresses 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 1241, *Standard Consumer Safety Specification for Crib Mattresses*, 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.

# IX. 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 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. Pub. L. 110-314, section 104(d).

Section 104(f) of the CPSIA defines the term "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 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.

Pub. L. 110-314, section 104(f).

The product categories listed in section 104(f)(2) of the CPSIA represent a non-exhaustive list of durable infant or toddler product categories, including infant sleep products such as cribs

(full-size and non-full-size), toddler beds, bassinets and cradles, and play yards. *Id*. 2056a(f)(2). Although crib mattresses are used with infant sleep products, crib mattresses are not included in the statutory list of durable infant or toddler products.

In 2009, the Commission issued a rule implementing the consumer registration requirement. 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).

This Commission proposes in the NPR to amend part 1130 to include "crib mattresses," as defined in ASTM F2933, including full-size crib mattresses, non-full-size crib mattresses, and after-

market mattresses for play yards and non-full-size cribs, as durable infant or toddler products. The Commission proposes to include "crib mattresses" as a "durable infant or toddler product" because: (1) they are intended for use, and may be reasonably expected to be used, by children under the age of 5 years; (2) they are products similar to the products listed in section 104(f)(2) of the CPSIA; (3) they are used in conjunction with other durable infant or toddler products used for unattended infant sleep, such as cribs, bassinets, and play yards; and (4) CPSC cannot fully address the risk of injury associated with such infant sleep products without addressing the hazards associated with the use of crib mattresses in these infant sleep products.

# X. Incorporation by Reference

The Commission proposes to incorporate by reference ASTM F2933-19, with modifications to further reduce the risk of injury associated with crib mattresses. 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 V of this preamble summarizes the provisions of ASTM F2933-19 that the Commission proposes to incorporate by reference. ASTM F2933-19 is copyrighted. By permission of ASTM, the standard can be viewed as a read-only document during the comment period on this NPR, at: <u>http://www.astm.org/cpsc.htm</u>. To download or print the standard, interested persons may purchase a copy of ASTM F2933-19 from ASTM, through its website (<u>http://www.astm.org</u>), or by mail from ASTM International, 100 Bar Harbor Drive, P.O. Box 0700, West Conshohocken, PA 19428. Alternatively, interested parties may inspect a copy of the standard at CPSC's Division of the Secretariat by contacting Alberta E. Mills,

Division of the Secretariat, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone: 301-504-7479; e-mail: <u>cpsc-os@cpsc.gov.</u>

#### **XI.** Effective Date

The Administrative Procedure Act (APA) generally requires that the effective date of a rule be at least 30 days after publication of the final rule. 5 U.S.C. 553(d). The Commission proposes a 6-month effective date for a final rule on crib mattresses. Barring evidence to the contrary, 6 months is typically 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 the Juvenile Products Manufacturers Association 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. The Commission notes that this NPR for crib mattresses contains additional testing requirements and labeling changes, and that the current global COVID-19 pandemic has affected supply chains. The Commission invites comments, particularly from small businesses, regarding the amount of time they will need to come into compliance with a final rule.

# XII. Regulatory Flexibility Act<sup>58</sup>

### A. Introduction

The Regulatory Flexibility Act (RFA) requires that agencies review a proposed rule for the rule's potential economic impact on small entities, including small businesses. Section 603 of the RFA generally requires that agencies prepare an initial regulatory flexibility analysis (IRFA) and make the analysis available to the public for comment when the agency publishes an NPR. 5 U.S.C. 603. Section 605 of the RFA provides that an IRFA is not required if the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small

<sup>&</sup>lt;sup>58</sup> See Tab F of Staff's NPR Briefing Package for additional information on the RFA.

entities. The IRFA must describe the impact of the proposed rule on small entities and identify significant alternatives that accomplish the statutory objectives and minimize any significant economic impact of the proposed rule on small entities. 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
- identification, to the extent possible, of all relevant federal rules that may duplicate, overlap, or conflict with the proposed rule.

Additionally, the IRFA must describe any significant alternatives to the proposed rule that accomplish the stated objectives of applicable statutes and minimize any significant economic impact of the proposed rule on small entities. CPSC staff prepared an IRFA for this rulemaking which appears at Tab F of the Staff's NPR Briefing Package. We provide a summary of the IRFA below.

### B. Agency Action, NPR Objectives, Product Description, and Market Description

An explanation of why the agency is considering issuing a mandatory rule for crib mattresses and a statement of the objectives of, and legal basis for, the proposed rule, are set forth in section I of this preamble. Section II of this preamble describes the types of crib mattresses within the scope of the NPR, the market for crib mattresses, and the use of crib mattresses in the United States.

C. Small Entities to Which the NPR Would Apply

Manufacturers of crib mattresses are typically categorized under the NAICS category 337910 (Mattress Manufacturing). The Small Business Administration (SBA) guidelines consider mattress manufacturing establishments to be small if they have fewer than 1,000 employees.<sup>59</sup> Importers of crib mattresses are typically categorized under NAICS code 423210 (Furniture Merchant Wholesalers) and SBA guidelines would consider them small if they have fewer than 100 employees.

Staff identified 26 manufacturers and importers of full-size and non-full-size crib mattresses, and after-market play yard mattresses. A majority of the 26 firms have under 50 employees. Most of the firms are domestic manufacturers (14) or domestic importers (8). Four firms are foreign. Sixteen of these 26 firms meet the SBA criteria for small businesses, and 10 firms would be considered large according to the SBA criteria.<sup>60</sup> Among the 16 small domestic firms identified by staff, 9 were manufacturers and 7 were importers. Staff observes that annual revenue varies among small domestic firms, as median annual revenue is estimated at \$6,740,000, but average annual revenue is higher at \$46,037,100.

Online registries are widely available for new crib mattresses. Producers supply crib mattresses to the U.S. market via electronic commerce websites, such as Amazon.com, Buy Buy Baby, Hayneedle, KOHL'S, Overstock, Walmart, and Wayfair. According to a 2017 Statista survey of baby products, the majority (59 percent) of respondents indicated they buy baby products mainly or exclusively online.<sup>61</sup> Staff expects that consumers of crib mattresses that do not buy online, purchase their mattresses in retail stores.

<sup>&</sup>lt;sup>59</sup> The size guidelines are established by the U.S. Small Business Administration (SBA).

<sup>&</sup>lt;sup>60</sup> Based on size and revenue data from Reference USA and firm financial reports, websites, and press releases.

<sup>&</sup>lt;sup>61</sup> Statista Survey of Baby Products in the U.S., 2017.

The majority of crib mattresses on the market are full-size crib mattresses. Staff estimates that 40 percent of crib mattresses on the market are coil/innerspring mattresses, and approximately 60 percent of crib mattresses are foam-core mattresses.<sup>62</sup> Among small domestic manufacturers, approximately 45 percent of available crib mattresses are coil mattresses. Among small importers, just 25 percent of available crib mattresses are composed of a coil core. Seventy-five percent of crib mattresses supplied by small domestic importers of crib mattresses consist of a foam core. Staff identified at least three small firms that only produce foam-core mattresses, while the majority of small entities produce a combination of both coil and foam-core crib mattresses.

## D. Impact of the Proposed Rule on Small Manufacturers and Importers

Of the 16 small manufacturers and importers identified by staff, 12 (8 manufacturers and 4 importers) are members of the JPMA, but staff cannot determine how many crib mattresses are currently certified to ASTM F2933-19. Many of the firms that would be subject to the draft proposed rule are known to produce a variety of children's products that are already subject to CPSC children's product safety rules, and therefore, are familiar with such requirements.<sup>63</sup> Additionally, two firms that are not JPMA members supply products that claim to meet ASTM standards. The Commission seeks comments from small firms on the number of mattress models they would typically certify to the ASTM standard annually.

Manufacturers and importers of crib mattresses would be responsible for ensuring that their products comply with the requirements of the proposed rule. If a crib mattress does not comply with the requirements, the manufacturers or importers will need to modify the product or cease manufacture or importation. Importers might be able to work with their manufacturers to supply

<sup>&</sup>lt;sup>62</sup> Based on staff's compiled search results of data available on the Internet found March through May 2020.

<sup>&</sup>lt;sup>63</sup> Crib mattresses listed for sale on a variety of online retail websites often include product descriptions indicating that the crib mattress product meets CPSC general safety standards, while not referencing any one specific CPSC safety standard.

compliant mattresses and could potentially switch suppliers if their current supplier is unwilling to supply current mattresses. Alternatively, importers might simply drop the noncompliant mattresses from their product lines.

Additionally, as required by section 14 of the CPSA and its implementing regulations, manufacturers and importers of crib mattresses would be required to certify that their crib mattresses comply with the requirements of a final rule, if issued, based on the results of third party testing by a CPSC-accepted third party conformity assessment body (*i.e.*, testing laboratory). Crib mattresses are already subject to third party testing requirements and adoption of the proposed rule would only augment existing testing requirements.<sup>64,65</sup>

1. Costs Associated with Modifying Products

The majority of crib mattresses currently available on the market will not require extensive modification to comply with the proposed rule. Staff reports that the majority of crib mattresses they tested already meet the performance requirements of the proposed rule. We do not know the exact costs of modifying crib mattresses to comply with the proposed rule, which would vary by product model. Modifying crib mattresses to comply with the compression standard could be as simple as adding a perimeter border wire to the mattress edge or an anti-sag weight distribution bar to the mattress structure. However, staff believes it possible that a required modification could be prohibitively expensive, and therefore, the proposed rule may result in the removal of certain crib mattresses from commerce.

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

<sup>&</sup>lt;sup>64</sup> Manufacturers and importers of children's products must certify compliance with applicable federal safety requirements in a Children's Product Certificate (CPC). In most instances, testing by a third party CPSC-accepted laboratory must serve as the basis for the production of the CPC.

<sup>&</sup>lt;sup>65</sup> Mattresses intended for children must be tested at a third party test laboratory or a fire-walled internal laboratory: <u>https://cpsc.gov/s3fs-public/pdfs/blk\_media\_mattress.pdf</u>. In either case, the lab would need to be CPSC-accepted to test to the standards since crib mattresses are considered to be primarily intended for children 12 and under.

content or formatting of the instructions to comply. Likewise, the cost of warning labels is generally low, especially if some warning labels are already present, and the product does not need to be modified to accommodate new labels.

# 2. Third Party Testing Costs

If issued, a final rule would require all manufacturers and importers of crib mattresses to meet additional third-party testing requirements under section 14 of the CPSA. Third-party testing requirements will include any physical and mechanical test requirements specified in the final crib mattress rule. Based on information from a testing laboratory, the cost of testing to the current version of ASTM F2933 is \$200 to \$250 per sample. The additional testing that would be required by the proposed rule would increase this cost by \$50 to \$75 per sample tested. Thus, the total cost of the third-party testing would be \$250 to \$325 per sample. Given that the average number of crib mattress models per firm is approximately 12, the cost of the third-party testing could be about \$3,000 to \$3,900, if only one model per sample were required to provide a high degree of assurance that the model complied with the requirements of the rule.

Additionally, according to conformity assessment bodies that staff contacted, for each mattress model to be tested, the firm will need to provide the crib or play yard equipment intended to be used with the mattress being tested. However, to comply with ASTM F2933-19 and other CPSC requirements for children's products, the costs of supplying a crib, crib mattress, or play yard to the conformity assessment body are already borne by the producer for testing under previously adopted rules and standards. Regardless, third-party testing facilities have indicated that they are unable to store equipment that will be needed or used during testing, such as cribs or play yards, for long periods of time. Therefore, ensuring that all crib equipment needed for testing arrives at the testing lab at the appropriate time may pose a logistical burden, even if there is no increase in monetary costs for freight or shipping.

Additional costs of the proposed testing would include the cost of the 100 percent cotton sheets used during testing.<sup>66,67</sup> These sheets would be used in the proposed "Compression Test" for full-size crib mattresses. While the number of times a sheet can be reused has not yet been determined, we assume one new sheet per test. The cost of one, 100 percent cotton, full-size crib mattress sheet is approximately \$10.<sup>68</sup> Staff estimates approximately 3 out of 4 crib mattresses on the market are full-size crib mattresses.<sup>69</sup> Therefore, for a typical manufacturer or importer with 12 crib mattress models, 9 might be full-size crib mattresses, and the additional cost of one fitted sheet per full-size mattress would be \$90, plus the testing costs charged by the conformity assessment body.

For a subset of mattresses, *i.e.*, metal coil spring crib mattresses, the proposed rule would include cyclic impact testing called the "Cyclic Load Test." During the Cyclic Load Test, an impactor weighing 30 pounds shall be dropped repetitively from above the mattress surface, and across four different locations on the mattress. As a result of the Cyclic Load Test, the mattress product is rendered unusable for either of the proposed mattress firmness or compression tests. Under cyclic load testing, the mattress product could be misshapen, deformed, or otherwise destroyed, and wire coils may protrude from the mattress surface. Approximately 40 percent of crib mattresses available for sale are metal spring coil mattresses. The average cost of a crib mattress available for sale in the United States is \$150,<sup>70</sup> and on average, the typical manufacturer or importer of crib mattresses tests 12 models annually. Therefore, the cost to the typical small firm of the destroyed mattresses would amount to 40 percent of \$1,800 (12 models x \$150), or approximately \$720, as a result of the proposed Cyclic Load Test.

<sup>&</sup>lt;sup>66</sup> The proposed test includes measuring the mattress without a fitted sheet and with a twice-washed fitted sheet.

<sup>&</sup>lt;sup>67</sup> With input from the ASTM standards organization, CPSC staff will determine the number of times a sheet can be reused.

<sup>&</sup>lt;sup>68</sup> Based on compiled search results of data available on the Internet.

<sup>&</sup>lt;sup>69</sup> Based on a review of over 300 mattress models available for sale on the Internet.

<sup>&</sup>lt;sup>70</sup> Price estimated from data available on the Internet, collected between January 2020 and June 2020.

Based on the foregoing, for a typical manufacturer or importer with 12 crib mattress models that requires only one test per model to provide a high degree of assurance, the full cost of third party testing will be approximately \$3,000 to \$3,900, plus \$90 in costs for fitted-sheet testing materials, and \$720 for the cost of used test mattresses, for a total of \$3,810 to \$4,710 or an average of \$318 to \$393 per model.

3. Summary of Impacts

Generally, based on Small Business Administration guidelines, CPSC considers impacts that exceed one percent of a firm's revenue to be *potentially* significant. The lowest reported annual revenue for any small domestic firm producing fewer than four crib mattress models was \$1.36 million. One percent of annual revenue for the firm is \$13,600 (\$1,360,000 x 0.01). Consequently, if the costs of modifying their mattresses to comply with the standard exceeded \$13,600, the rule could have a significant impact on some small firms. This would include the costs of modifying noncompliant mattresses to comply with the requirements, the loss of revenue that results from removing noncompliant mattresses from their product line, and the cost of third-party testing. For manufacturers or importers with greater revenue, the impact of the proposed would have to be higher than this for the impact to be considered significant.

Given that a substantial number of mattresses already comply with the requirements of the proposed rule, and some of the testing costs are already being borne by firms that certify to the current voluntary standard, the Commission considers it unlikely that the rule would have a significant impact on a substantial number of small entities. However, we request comments on the costs of the proposed rule, or impediments to modifying existing crib mattress products to conform to the proposed rule, especially those that would result in the removal of the mattress product from the market and other impacts of the draft proposed rule on small manufacturers and importers.

# *E.* Other Federal Rules that May Duplicate, Overlap, or Conflict with the Draft Proposed Rule

CPSC staff did not identify any other federal rules that duplicate, overlap, or conflict with the proposed rule.

### F. Alternatives Considered to Reduce the Impact on Small Entities

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

### 1. Adopt ASTM F2933-19 without modification

The Commission considered proposing to incorporate by reference ASTM F2933-19, without any modifications, and to direct staff to work with ASTM to improve test methods and the firmness of crib mattresses in a future revision of the voluntary standard. This alternative could reduce the impact of the rule on small businesses, but, according to CPSC staff, the reduction would not be expected to be very significant. As discussed in the IRFA analysis in Tab F of Staff's NPR Briefing Package, and in this preamble, many crib mattresses probably already comply with the proposed standard. The additional testing costs associated with the modifications to ASTM F2933-19 in the proposed rule would only increase the testing costs by \$50 to \$75 per sample. Moreover, adopting ASTM F2933-19 without modification would not address all of the identified hazard patterns associated with crib mattresses.

# 2. Small Batch Exemption

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 Consumer Product Safety Improvement Act of 2008. Consequently, the Commission cannot create a small batch exemption absent a statutory change.

# 3. Delay the Effective Date of the Requirements

Typically, the Commission proposes 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 or toddler product rule, unless specific circumstances evince the need for a longer effective date. Additionally, 6 months from the change in a voluntary standard is the time frame that JPMA uses for its certification program, so compliant manufacturers are used to a 6-month time frame to comply with a modified standard. The Commission proposes a 6-month effective date for a final rule on crib mattresses.

One alternative the Commission will consider to reduce the impact of a mandatory rule on small firms is to set an effective date later than 6 months. Implementing a later effective date could mitigate the effects of the rule on small businesses. For businesses that would choose to exit the crib mattress market, or discontinue certain crib mattress models currently in production (rather than produce conforming products), such a delay might provide them with more time to adjust marketing towards other product offerings, sell inventory, or consider alternative business opportunities. The Commission requests comments on the proposed 6-month effective date.

### 4. Not Issue a Mandatory Standard

Another option available to the Commission that would reduce the burden on small firms is not to adopt a mandatory standard for crib mattresses. Although this option would eliminate the cost impacts of complying with the proposed rule, failure to issue a mandatory standard for crib mattresses would not adequately address the hazard patterns for crib mattresses, especially for hazard patterns that are not adequately addressed in the voluntary standard.

## G. IRFA Conclusion

CPSC staff evaluated the possible impacts of the proposed rule on small entities, as required by the RFA. Staff identified 26 manufacturers and importers of mattress products, 16 of which

would be considered small businesses (9 manufacturers and 7 importers). The potential impacts include the costs of modifying mattresses to conform to the requirements, the lost revenue if some models are discontinued, and the costs associated with the third-party testing. The Commission believes it possible that the proposed rule could have a significant impact on some small firms, but cannot estimate how many. However, the Commission believes it unlikely that the proposed rule would have a significant impact on a substantial number of small entities. The Commission considered several staff-identified alternatives to the proposed rule, to reduce any adverse impact on small firms. The Commission concludes that each of these alternatives would provide limited relief, or is not available due to statutory limitations. The Commission invites comments, particularly from small businesses, on the cost of making necessary modifications to noncomplying crib mattress models to comply with the proposed rule, and alternatives that could reduce the burden on small businesses.

### XIII. Environmental Considerations

The Commission's regulations address whether the agency is required to 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 NPR for crib mattresses falls within the categorical exclusion.

# XIV. Paperwork Reduction Act

This proposed rule for crib mattresses 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 Mattresses

*Description*: The proposed rule would require each crib mattress within the scope of the rule to comply with ASTM F2933-19, *Standard Consumer Safety Specification for Crib Mattresses*, including the proposed additional requirements summarized in section VII of this preamble. Section 7 of ASTM F2933-19, and a proposed new section 8 in the NPR, contain requirements for marking, labeling, and 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 mattresses.

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

16 CFR	Number of	Frequency	Total	Hours per	Total				
Section	Respondents	of	Annual	Response	Burden				
		Responses	Responses	-	Hours				
1241.2(a), (b)	26	12	312	1	312				

 Table 8 – Estimated Annual Reporting Burden

Our estimate is based on the following:

The Commission proposes in the NPR modifications to section 7 of ASTM 2933-19, and a new section 8 on instructional literature, to bring the standard into alignment with other safety standards for durable infant or toddler products. For example, in addition to improved warning format and content, proposed modifications to section 7.1.1 of ASTM F2933-19 would require that the name and the place of business (city, state, and mailing address, including zip code) or telephone number of the manufacturer, distributor, or seller be marked clearly and legibly on each product and its retail package. Proposed modifications to section 7.1.2 of ASTM F2933-19 would also require a code mark or other means that identifies the date (month and year, as a minimum) of manufacture. Proposed modifications to section 7.2 of ASTM F2933-19 would require marking and labeling on the product to be permanent.

Twenty-six known entities supply crib mattresses to the U.S. market and these entities may need to make some modifications to existing product labels. We estimate that the time required to make these modifications is about 1 hour per model. Based on an evaluation of supplier product lines, each entity supplies an average of 12 models of crib mattresses;<sup>71</sup> therefore, the estimated burden associated with labels is 1 hour per model x 26 entities x 12 models per entity = 312 hours. We estimate the hourly compensation for the time required to create and update labels is \$32.74 (U.S. Bureau of Labor Statistics, "Employer Costs for Employee Compensation," March 2020, total compensation for all sales and office workers in goods-producing private industries: http://www.bls.gov/ncs/). Therefore, the estimated annual cost to industry associated with the labeling requirements is \$10,214.88 (\$32.74 per hour x 312 hours = \$10,214.88). No operating, maintenance, or capital costs are associated with the collection.

<sup>&</sup>lt;sup>71</sup> This number was derived during the market research phase of the initial regulatory flexibility analysis by dividing the total number of crib mattresses supplied by all crib mattress suppliers by the total number of crib mattress suppliers.

The NPR also proposes a new section 8 that would require instructions to be supplied with the crib mattress. The instructions would be required to: (a) be easy to read and understand; (b) include information regarding assembly, maintenance, cleaning, and use, where applicable; and (c) 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. 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." Based on staff's review of product information online, approximately 80 percent of firms that supply cribs to the crib mattress market already provide instructional literature to consumers for products intended for use by children. All of the firms which supply crib mattresses already provide customer support for use of their children's products. Therefore, we tentatively estimate that no burden hours are associated with the proposed section 8 of ASTM F2933-19, because any burden associated with supplying instructions with crib mattresses would be "usual and customary" and not within the definition of "burden" under the OMB's regulations.

Based on this analysis, the proposed standard for crib mattresses would impose a burden to industry of 312 hours at a cost of \$10,214.88 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:

- 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; and
- the estimated burden hours associated with label modification, including any alternative estimates.

### **XV.** Preemption

Section 26(a) of the CPSA, 15 U.S.C. 2075(a), states 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.
## **XVI.** Request for Comments

This Commission proposes a rule under section 104(b) of the CPSIA to issue a consumer product safety standard for crib mattresses, to amend part 1112 to add crib mattresses 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 mattresses as a durable infant or toddler product subject to CPSC consumer registration requirements. The Commission requests comments on the proposal to incorporate by reference ASTM F2933-19, with modifications to address mattress firmness, mattress compression, lacerations from coils and springs, dimensional requirements for non-full-size cribs, and improve warnings and instructions. The Commission also requests comments on the proposed effective date; the costs of compliance with, and testing to, the proposed Safety Standard for Crib Mattresses; and any aspect of this proposal. During the comment period, the ASTM F2933-19 Standard Consumer Safety Specification for Crib Mattresses, 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 1241

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

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

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

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

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

2. Amend § 1112.15 by adding paragraph (b)(51) 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) \* \* \*

(51) 16 CFR part 1241, Safety Standard for Crib Mattresses.

\* \* \* \* \*

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

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

4. Amend § 1130.2 by adding paragraph (a)(19) to read as follows:

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

# § 1130.2 Definitions.

\* \* \* \* \* \* (a) \* \* \*

(19) Crib mattresses.

\* \* \* \* \*

5. Add part 1241 to read as follows:

## PART 1241-SAFETY STANDARD FOR CRIB MATTRESSES

Sec.

1241.1 Scope.

1241.2 Requirements for crib mattresses.

Authority: Sec. 104, Pub. L. 110-314, 122 Stat. 3016 (15 U.S.C. 2056a); Sec. 3, Pub. L. 112-28, 125 Stat. 273.

## § 1241.1 Scope.

This part establishes a consumer product safety standard for crib mattresses. The scope of this standard for crib mattresses includes all crib mattresses within the scope of ASTM F2933, *Standard Consumer Safety Specification for Crib Mattresses*, including: full-size crib mattresses, non-full-size crib mattresses, and after-market mattresses for play yards and non-full-size cribs.

## § 1241.2 Requirements for crib mattresses.

(a) Except as provided in paragraph (b) of this section, each crib mattress must comply with all applicable provisions of ASTM F2933-19, Standard Consumer Safety Specification for Crib Mattresses (approved on June 15, 2019). 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; <u>http://www.astm.org/cpsc.htm</u>. Once incorporated by reference, you may review a read-only copy of ASTM F2933-19 at <u>http://www.astm.org/READINGROOM/</u>. You may also 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, call 202-741-6030, or go to:

http://www.archives.gov/federal register/code of federal regulations/ibr locations.html.

(b) Comply with ASTM F2933-19 with the following additions or exclusions:

(1) Instead of complying with section 3.1.2 of ASTM F2933-19, comply with the following:

(i) 3.1.2 *conspicuous*, adj—visible while the mattress is being placed in its intended use position.

(ii) [Reserved]

(2) Add the following paragraph to section 3.1 of ASTM F2933-19:

(i) 3.1.11 *sleep surface* - The product component, or group of components, providing the horizontal plane, or nearly horizontal plane ( $\leq 10^\circ$ ), intended to support an infant during sleep.

(ii) [Reserved]

(3) Instead of complying with section 5.7.1.1 of ASTM F2933-19, comply with the following:

(i) 5.7.1.1 *Mattress Size*-The dimensions of a full-size crib mattress shall measure at least  $27\frac{1}{4}$  in. (690 mm) wide and  $51\frac{5}{8}$  in. (1310 mm) long. When the mattress is placed against the perimeter and in the corner of the crib, the corner gap shall not exceed 1.75 in. (44.5 mm). Dimensions shall be tested in accordance with 6.2.

(ii) [Reserved]

(4) Instead of complying with section 5.7.2.1 and 5.7.2.2 of ASTM F2933-19, comply with the following:

(i) 5.7.2.1 *Mattress supplied with a non-full-size crib*: shall meet the specifications of *Mattresses for Rigid sided products* of Consumer Safety Specification ASTM F406 when tested with the non-full-size crib product with which it is supplied.

(ii) 5.7.2.2 *After-market mattresses for non-full-size cribs:* shall be treated as though the mattresses were "the mattress supplied with a non-full-size crib" and shall meet the specifications of *Mattresses for Rigid sided products* in Consumer Safety Specification ASTM F406, when tested to the equivalent interior dimension of the product for which it is intended to be used.

(5) In section 5.9 of ASTM F2933-19, remove the term "and Non-Full Size Crib."

(6) In section 5.9.1 of ASTM F2933-19, replace the term "For Mesh/Fabric Sided Products and Rigid Sided Non-Rectangular Products" with "For Mesh/Fabric Sided Play Yard Products."

(7) In section 5.9.1.2 of ASTM F2933-19, remove the term "Mattresses for Rigid sided products;".

(8) In section 5.9.1.3 of ASTM F2933-19, replace the term "replacement" with "aftermarket."

(9) Add the following paragraphs to section 5 of ASTM F2933-19:

(i) 5.10 Mattress Firmness

(ii) 5.10.1 All crib mattresses within the scope of this standard, when tested in accordance with 6.3, the feeler arm shall not contact the sleep surface of the crib mattress.

(iii) 5.11 Coil Springs

(iv) 5.11.1 When tested in accordance with 6.4, there shall be no exposed coil springs or metal wires.

The requirements in this section only pertain to crib mattresses with coil springs.

(10) Renumber section 6.2.2 of ASTM F2933-19 to 6.2.3.

(11) Add the following paragraph to section 6.2.2 of ASTM F2933-19:

(i) 6.2.2 Test Equipment-Mattress Sheet:

(ii) [Reserved]

(12) Renumber section 6.2.2.1 of ASTM F2933-19 to 6.2.3.1.

(13) Add the following paragraph to section 6.2.2.1 of ASTM F2933-19:

(i) 6.2.2.1 The mattress sheet shall be 100% cotton and fitted for the mattress to be tested.

(ii) [Reserved]

(14) Renumber section 6.2.2.2 of ASTM F2933-19 to 6.2.3.2.

(15) Add the following paragraph to section 6.2.2.2 of ASTM F2933-19:

(i) 6.2.2.2 The mattress sheet shall be washed in hot water (50° C [122° F] or higher) and dried a minimum of two times on the highest setting using household textile laundering units. This shall be the test mattress sheet.

(ii) [Reserved]

(16) Renumber section 6.2.2.3 of ASTM F2933-19 to 6.2.3.3.

(17) Renumber section 6.2.2.4 of ASTM F2933-19 to 6.2.3.4.

(18) Add the following paragraphs to section 6.2.3 of ASTM F2933-19:

(i) 6.2.3.5 Measure the shortest gap between the mattress and the mattress measuring box at the corner adjoining Walls C and D after the dimensions of the mattress have been recorded. The mattress shall not be moved before or during measurement. This shall be the corner gap measurement.

(ii) 6.2.3.6 Rotate the mattress 180° such that the opposing corner is adjacent to Walls C and D, then repeat 6.2.3.2 and 6.2.3.5.

(iii) 6.2.3.7 The test mattress sheet shall be placed on the mattress such that each sheet edge is wrapped fully around and under the mattress.

(iv) 6.2.3.8 The mattress with test mattress sheet shall be measured following steps 6.2.3.1 through 6.2.3.6. The mattress dimensions shall meet the requirements in 5.7.

(19) Add the following paragraphs as section 6.3 of ASTM F2933-19

(i) 6.3 Mattress Firmness

(ii) 6.3.1 Test Fixture

(iii) 6.3.1.1 The fixture, as shown in Fig. 2, shall be a rigid, robust object with a round footprint of diameter  $203 \pm 1$  mm, and an overall mass of  $5200 \pm 20$  g. The lower edge of the fixture shall have a radius not larger than 1 mm. Overhanging the footprint by  $40 \pm 2$  mm shall be a flexible, flat bar of width  $12 \pm 0.2$  mm with square-cut ends. This bar may be fashioned from a shortened hacksaw blade. The bar shall rest parallel to the bottom surface of the fixture and shall be positioned at a height of  $15 \pm 0.2$  mm above the bottom surface of the fixture. The bar shall lay directly over a radial axis of the footprint (i.e. such that a longitudinal centerline of the bar would pass over the center of the footprint).

(iv) 6.3.1.2 Included on the fixture, but not overhanging the footprint, shall be a linear level that is positioned on a plane parallel to the bar, and in a direction parallel to the bar.

(v) 6.3.1.3 Other parts of the fixture, including any handle arrangement and any clamping arrangement for the bar, shall not comprise more that 30% of the total mass of the fixture, and shall be mounted as concentric and as low as possible.

(vi) 6.3.2 Test Method:

(vii) 6.3.2.1 Mattresses that are supplied with a product shall be tested when positioned on that product. Mattresses sold independent of a product, shall be tested on a flat, rigid, horizontal support. After-market mattresses for play yards and non-full-size cribs shall be tested with each brand and model of product it is intended to replace.

(viii) 6.3.2.2 Where a user of a mattress could possibly position either side face up, even if this is not an intended use, then both sides of the mattress shall be tested.

(ix) 6.3.2.3 Before testing each mattress, the following steps shall be followed:

(1) Verify there is no excess moisture in the mattress, beyond reasonable laboratory humidity levels.

(2) Allow sufficient time per the manufacturer's instructions to fully inflate, if shipped in a vacuum sealed package.

(3) Shake and or agitate the mattress in order to fully aerate and distribute all internal components evenly.

(4) Place the mattress in the manufacturer's recommended use position if there is one, in the supplied product, or on a flat, rigid, horizontal support.

(5) Let the mattress rest for at least 5 minutes.

(6) Mark a longitudinal centerline on the mattress sleep surface, and divide this line in half. This point will be the first test location. Then further divide the two lines on either side of the first test location into halves. These will be the second and third test locations.

(x) 6.3.2.4

(1) Position the test fixture on each of the test locations, with the footprint of the fixture centered on the location, with the bar extending over the centerline and always pointing at the same end of the mattress sleep surface.

(2) At each test location in turn, rotate the bar to point in the required direction, and gently set the fixture down on the mattress sleep surface, ensuring that the footprint of the fixture does not extend beyond the edge of the mattress. The fixture shall be placed as horizontal as possible, using the level to verify. If the bar makes contact with the top of the mattress sleep surface, even slightly, the mattress is considered to have failed the test.

(3) Repeat Steps (1) and (2) and at the remaining locations identified in 6.3.2.1(6).

(4) Repeat Steps (1) and (2) at a location away from the centerline most likely to fail(e.g. a very soft spot on the sleep surface or at a raised portion of the sleep surface). In

the case of testing a raised portion of a sleep surface, position center of the fixture such that the bar is over the raised portion, to simulate the position of an infant's nose.

(5) In the event that the fixture is not resting in a nearly horizontal orientation, repeat the test procedure at that location by beginning again from Step (1) above. However, if the test produces a fail even with the device tilted back away from the bar so as to raise it, then a fail can be recorded.

(20) Add the following paragraphs as section 6.4 of ASTM F2933-19:

(i) 6.4 Coil Spring Test

(ii) 6.4.1 General—This test consists of dropping a specified weight repeatedly onto the -

mattress. The test assists in evaluating the structural integrity of a mattress with coil springs.

(iii) 6.4.2 Test Fixture:

(iv) 6.4.2.1 A guided free-fall impacting system machine (which keeps the upper surface of the impact mass parallel to the horizontal surface on which the crib is secured) (See Fig. 3)

(v) 6.4.2.2 A 30-lb (13.6-kg) impact mass (see Fig. 4 and Fig.5).

(vi) 6.4.2.3 A 6-in. (150-mm) long gauge.

(vii) 6.4.2.4 An enclosed frame measuring 29 inches by 53 inches (737 mm by 1346 mm) for the purpose of restricting mattress movement. When testing full-size mattresses, a full-size crib meeting the requirements of ASTM F1169-19 would suffice.

(viii) 6.4.2.5 a <sup>3</sup>/<sub>4</sub>" piece of plywood or OSB that is rigidly supported along the perimeter.

(ix) 6.4.3 Test Method:

(x) 6.4.3.1 Place the mattress on the wooden support and inside the enclosed frame.

(xi) 6.4.3.2 Position geometric center of the impact mass above the geometric center of the test mattress.

(xii) 6.4.3.3 Adjust the distance between the top surface of the mattress and bottom surface of the impact mass to 6 in. (150 mm) (using the 6-in. (150-mm) long gauge, per 6.4.2.3) when the impact mass is in its highest position. Lock the impactor mechanism at this height and do not adjust the height during impacting to compensate for any change in distance as a result of the mattress compressing or the mattress support deforming or moving during impacting.

(xiii) 6.4.3.4 Allow the 30-lb (13.6-kg) impact mass to fall freely 250 times at the rate of one impact every 4 s. Load retraction shall not begin until at least 2 s after the start of the drop.

(xiv) 6.4.3.5 Repeat the step described in 6.4.3.4 at the other test locations shown in Fig.6.

(21) Add the following Figures to section 6 of ASTM F2933-19:

(i) Figure 2.



Figure 2. Mattress Firmness Test Fixture

(ii) Figure 3.



Figure 3. Typical free fall impacting system<sup>72</sup>

(iii) Figure 4.



Figure 4. Profile of Impact mass<sup>72</sup>

<sup>&</sup>lt;sup>72</sup> Reprinted, with permission, from ASTM F1169-19 Standard Consumer Safety Specification for Full-Size Baby Cribs, copyright ASTM International, 100 Barr Harbor Drive, West Conshohocken, PA 19428. A copy of the complete standard may be obtained from ASTM International, <u>www.astm.org</u>.

(iv) Figure 5.



Figure 5. Photo of typical impact mass<sup>72</sup>





(22) Instead of complying with sections 7.1 and 7.2 of ASTM F2933-19, comply with the following:

(i) 7.1 Each mattress and its retail package shall be marked or labeled clearly and legibly to indicate the following:

(ii) 7.1.1 The name, place of business (city, state, and mailing address, including zip code), and telephone number of the manufacturer, distributor, or seller.

(iii) 7.1.2 A code mark or other means that identifies the date (month and year at a minimum) of manufacture.

(iv) 7.2 The marking and labeling on the product shall be permanent.



(23) Do not comply with sections 7.2.1, 7.2.2, 7.2.2.1, 7.2.2.2, and 7.2.2.3 of ASTM F2933-19.

(24) Instead of complying with sections 7.3, 7.3.1, 7.3.2, and 7.3.3 of ASTM F2933-19, comply with the following:

(i) 7.3 Any upholstery labeling required by law shall not be used to meet the requirements of this section.

(ii) [Reserved]

(25) Instead of complying with sections 7.4 and 7.4.1 of ASTM F2933-19, comply with the following:

(i) 7.4 Warning Design for Mattresses

(ii) 7.4.1 The warnings shall be easy to read and understand and be in the English language at a minimum.

(iii) 7.4.2 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.

(iv) 7.4.3 The warnings shall be conspicuous and permanent.

(v) 7.4.4 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.

(vi) 7.4.4.1 In sections 6.2.2, 7.3, 7.5, and 8.1.2, replace "should" with "shall."

(vii) 7.4.4.2 In section 7.6.3, replace "should (when feasible)" with "shall."

(viii) 7.4.4.3 Strike the word "safety" when used immediately before a color (*e.g.*, replace "safety white" with "white").

(ix) NOTE 3—For reference, ANSI Z535.1 provides a system for specifying safety colors.

(x) 7.4.5 The safety alert symbol "[Safety Alert Symbol]" and the signal word "WARNING" shall be at least 0.2 in. (5 mm) high. The remainder of the text shall be in characters whose upper case shall be at least 0.1 in. (2.5 mm), except where otherwise specified.

(xi) NOTE 4—For improved warning readability, typefaces with large height-to-width ratios, which are commonly identified as "condensed," "compressed," "narrow," or similar should be avoided.

(xii) 7.4.6 Message Panel Text Layout

(xiii) 7.4.6.1 The text shall be left aligned, ragged right for all but one-line text messages, which can be left aligned or centered.

(xiv) NOTE 5—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. 7 for examples of left aligned text.

(xv) 7.4.6.2 The text in each column needs to 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.

(xvi) 7.4.7 Example warnings in the format described in this section are shown in FIGS. 8,9, and 10.

(26) Instead of complying with sections 7.5, 7.5.1, 7.5.2, 7.5.3, 7.5.3.1, and 7.5.3.2 of ASTM F2933-19, comply with the following:

(i) 7.5 Warning Statements - Each mattress shall have warning statements to address the following, at a minimum, unless otherwise specified. The blank in the mattress fit statement beginning with "If a gap is larger than," needs to be filled with "1<sup>3</sup>/<sub>8</sub> in. (3.5 cm)" for full-size crib mattresses and "1 in. (2.5 cm)" for all other mattresses.

(ii) NOTE 6—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.

## SIDS AND SUFFOCATION HAZARDS

ALWAYS place baby on back to sleep to reduce the risks of SIDS and suffocation.

## **Babies have suffocated:**

• on pillows, comforters, and extra padding

• in gaps between a wrong-size mattress, or extra padding, and side walls of product.

**NEVER** add soft bedding, padding, or an extra mattress.

**USE ONLY** one mattress at a time.

DO NOT cover the faces or heads of babies with a blanket or over-bundle them.

Overheating can increase the risk of SIDS.

ALWAYS check mattress fit every time you change the sheets, by pushing mattress

tight to one corner. Look for any gaps between the mattress and the side walls. If a gap is larger

than \_\_\_\_, the mattress does not fit – **do not** use it.

(iii) Renumber section 7.3.1 of ASTM F2933-19 to section 7.5.1.

(iv) In section 7.5.1, replace the reference to "7.3" with a reference to "7.5."

(v) In section 7.5.1, replace the term "Only use" with the term "USE ONLY."

(vi) Renumber section 7.3.2 of ASTM F2933-19 to section 7.5.2.

(vii) In section 7.5.2, replace the term "For non-full-size crib mattresses" with the term "For

non-full-size crib mattresses and after-market mattresses for play yards and non-full-size cribs."

(viii) In section 7.5.2, replace the reference to "7.3" with a reference to "7.5."

(ix) In section 7.5.2, replace the term "Only use" with the term "USE ONLY."

(x) Renumber section 7.3.3 of ASTM F2933-19 to section 7.5.3.

(xi) In section 7.5.3, replace the term "Additional manufacturers warnings may be included between the warnings specified in 7.3 and 7.4 if desired" with "Manufacturers are permitted to include additional warnings between the warnings specified in 7.5 and 7.6 if desired."

(27) Instead of complying with sections 7.6, 7.6.1, 7.6.1.1, 7.6.1.2, or 7.7 of ASTM F 2933-19, comply with the following:

(i) 7.6 The following warning statement shall be included exactly as stated below and shall be located at the bottom of the warnings on each mattress:

**DO NOT** remove these important safety warnings.

(ii) 7.7 Additional Marking and Warnings for After-Market Mattresses for Play Yards and Non-Full-Size Cribs—The mattress shall have:

(iii) 7.7.1 All warnings added by the original manufacturer which are in addition to those required by this standard.

(iv) 7.7.2 Assembly/attachment instructions that were provided on the original mattress.

(v) 7.7.3 The specific brand(s) and model(s) number(s) of the product(s) in which it is intended to be used.

(vi) 7.7.4 *For Rigid Sided Rectangular Products*—the following statement shall appear exactly as stated below (the blanks are to be filled in as appropriate).

This mattress measures \_\_\_\_\_ long, \_\_\_\_\_ wide, and \_\_\_\_\_ thick when measured from seam to seam.

(28) Add the following paragraphs as section 7.8 of ASTM F2933-19:

(i) 7.8 Package Warnings

(ii) 7.8.1 The warnings and statements are not required on the retail package if they are on the mattress and are visible in their entirety through the retail package. Cartons and other materials used exclusively for shipping the mattress are not considered retail packaging.

(iii) 7.8.2 Warning Statements—Each mattress' retail package shall have statements to

address the following, at a minimum.

(iv) 7.8.2.1 All warnings included in section 7.5, as applicable.

- (v) 7.8.2.2 All additional markings and warnings included in section 7.7, as applicable.
- (29) Add the following figures to section 7 of ASTM F2933-19:

(i) Figure 7.



## Figure 7. Examples of Left Aligned Text.

(ii) Figure 8.



Figure 8. Example of warning label for Full-Size Crib Mattress.

(iii) Figure 9.



Figure 9. Example of warning label for After-Market Mattress for Mesh/Fabric Sided Products and Rigid Sided Non-Rectangular Products. Items italicized in brackets are to be added as appropriate.

(iv) Figure 10.



Figure 10. Example of warning label for After-Market Mattress for Rigid Sided Rectangular Products.

Items italicized in brackets, and blanks, are to be added or filled in as appropriate.

(30) Renumber section 8 of ASTM F2933-19 to section 9.

(31) Add the following paragraphs to section 8 of ASTM F2933-19:

## (i) 8. Instructional Literature

(ii) 8.1 Instructions shall be provided with the mattress and shall be easy to read and

understand, and shall be in the English language, at a minimum. These instructions shall include

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

(iii) 8.2 The instructions shall have statements to address the following, at a minimum.

(iv) 8.2.1 All warnings included in section 7.5, as applicable.

(v) 8.2.2 All additional markings and warnings included in section 7.7, as applicable.

(vi) 8.3 The warnings in the instructions shall meet the requirements specified in 7.4.4,

7.4.5, and 7.4.6, 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 cautions and warnings shall contrast with the background of the instructional literature.

(vii) NOTE 7—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.

(viii) 8.4 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.

(ix) NOTE 8—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**

Draft Notice of Proposed Rulemaking for Crib Mattresses<sup>1</sup> Under the Danny Keysar Child Product Safety Notification Act

September 30, 2020

CPSC Hotline: 1-800-638-CPSC(2772) CPSC's Web Site: http://www.cpsc.gov

<sup>&</sup>lt;sup>1</sup> As well as supplemental and after-market mattresses used in play yards and portable cribs.

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# **Briefing Memorandum**



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

## Memorandum

Date: September 30, 2020

TO:	The Commission Alberta E. Mills, Secretary
THROUGH:	John. G. Mullan, General Counsel Mary T. Boyle, Executive Director
FROM:	Duane Boniface, Assistant Executive Director Office of Hazard Identification and Reduction
	Hope E J. Nesteruk, Project Manager Directorate for Engineering Sciences
SUBJECT:	Staff's Draft Notice of Proposed Rulemaking for Crib Mattresses 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 durable infant or toddler products, and (2) promulgate mandatory consumer product safety standards that are substantially the same as, 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." Section 104(f)(2) sets forth a non-exhaustive list of durable infant or toddler products. The list of products in section 104(f)(2) does not include crib mattresses, but it does include infant sleep products that are used with crib mattresses, such as full-size cribs, nonfull-size cribs, and bassinets.

On June 16, 2015, the president of Keeping Babies Safe (KBS) and the mother of a child who died in an incident involving an after-market mattress, petitioned the CPSC requesting a ban on supplemental mattresses for play yards with non-rigid sides (petition CP 15-2). The petitioner alleged that "thicker mattresses create a suffocation hazard because they create a gap between the mattress pad sides and the side of the portable crib where a baby can suffocate when the baby's head falls in such gap while lying in the prone position." Furthermore, the petitioner asserted that "no feasible consumer product safety standard would adequately protect babies from the

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unreasonable risk of injury and death associated with the product." CPSC staff prepared a briefing package for the petition, recommending that the Commission defer whether to grant or deny the petition, so that staff could work on voluntary standards for crib mattresses and play yards to address the hazards identified in the petition. Staff noted that any work on the play yard voluntary standard could become a mandatory standard through the P.L. 112-28 update process, as the Commission has an existing mandatory standard for play yards (16 CFR part 1221), but that any changes to the crib mattress voluntary standard would remain a voluntary standard, because the Commission does not have a mandatory rule for crib mattresses. In response to the petition request for a product ban, and the staff's recommendation to defer the petition, the Commission voted<sup>2</sup> (3-2) to "take other action," granted the petition, and directed staff to initiate a rulemaking under section 104 of the CPSA to promulgate a mandatory consumer product safety standard to address the risk of injury associated with the use of crib mattresses. The Commission directed that the scope of the rule "shall include crib mattresses, as well as supplemental and after-market<sup>3</sup> mattresses used in play yards and portable cribs." The Commission further directed staff to amend the product registration card rule, 16 CFR part 1130, to add "crib mattresses" to the list of "durable infant or toddler products" that require a registration card. Consequently, this draft notice of proposed rulemaking (NPR) under section 104 of the CPSIA is intended to create a new mandatory standard for crib mattresses, and to update part 1130 to add "crib mattresses" to the list of durable infant or toddler products that require a product registration card.<sup>4</sup>

Section 104 of the CPSIA requires that, in consultation with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts, the Commission must examine and assess the effectiveness of any voluntary consumer product safety standards for durable infant or toddler products. CPSC staff regularly participates in the juvenile products subcommittee meetings of ASTM International (ASTM). ASTM subcommittees consist of members who represent producers, users, consumers, government, and academia.<sup>5</sup> The consultation process for this crib mattress rulemaking commenced during the ASTM subcommittee meeting in May 2018, when staff presented its initial recommendations for updating the crib mattress voluntary standard to address the incident data. Since then, staff has actively participated with the ASTM F15.66 subcommittee for Crib Mattresses, to address the associated hazards.

<sup>&</sup>lt;sup>2</sup> <u>https://www.cpsc.gov/s3fs-public/RCA-Petition CP 15-2 Requesting Ban on Supplemental Mattresses</u> for\_Play\_Yards\_with\_Non-Rigid\_Sides\_052517.pdf

<sup>&</sup>lt;sup>3</sup> "Supplemental" is a use pattern of using an after-market mattress on top of the supplied mattress in a play yard. <sup>4</sup> CPSC already has a mandatory standard for play yards, codified at 16 CFR part 1221, which regulates play yard mattresses sold with the product. The play yard standard, which is based on ASTM's voluntary standard F406, currently requires that mattresses sold with a play yard to be no more than 1.5 inches thick, to prevent infants from suffocating in a hazardous gap between the play yard mattress and the side or bottom of a play yard. Staff actively participates with the F15.18 subcommittee for play yards. The F15.18 subcommittee is currently considering the safety of allowing thicker mattresses for play yards, to address perceived comfort issues that may lead caregivers to use an after-market mattress. Should ASTM F406 be revised to address play yard mattresses greater than 1.5 inches, the update provisions of P.L.-112-28 require ASTM to notify the Commission of the revision, and allow the Commission to evaluate the safety of the proposed revision, before such revision would become part of the mandatory standard for play yards.

<sup>&</sup>lt;sup>5</sup> ASTM International website: <u>www.astm.org</u>, About ASTM International.

This staff briefing package recommends that the Commission issue an NPR to create a mandatory standard for crib mattresses that would address the hazards associated with full-size crib mattresses, non-full-size crib mattresses, and after-market mattresses for play yards and non-full-size cribs, incorporating by reference ASTM F2933 – 19, with additional requirements to make the standard more stringent. Specifically, to further reduce the risk of injury associated with the use of crib mattresses, staff recommends that the Commission include the following additional requirements to address:

- Suffocation hazards due to overly soft crib mattresses, by adding a test for mattress firmness based on sections 6 and 8 of AS/NZS 8811.1:2013 Methods of testing infant products Method 1: Sleep Surfaces Test (AS/NZS 8811.1);
- Entrapment hazards
  - Full-size crib mattresses due to poor mattress fit from compression by sheets, by repeating the dimensional conformity test and measuring for corner gaps, after installing a shrunken (by washing twice) cotton sheet;
  - After-market non-full-size crib mattresses due to lack of dimensional requirements for rectangular-shaped products, by extending the dimensional requirements in ASTM F2933-19 section 5.7.2 to all non-full-size crib mattresses, regardless of mattress shape, and regardless of whether the mattress is sold with a non-full-size crib or as an after-market mattress;
- Laceration hazards due to coils and springs breaking and poking through mattresses, by adding a cyclic impact test for mattresses that use coil springs; and
- Marking, labeling, and instructional literature improvements to clarify for manufacturers and test labs, and to communicate better to consumers the risks of SIDS and suffocation related to infant positioning, soft bedding, and gap entrapment.

Staff also recommends updating 16 CFR part 1130 to include "crib mattresses" as a durable infant or toddler product that requires a product registration card, and updating 16 CFR part 1112 to include a Notice of Requirements (NOR) for crib mattresses.

This briefing package: (1) reviews the incident data; (2) assesses the effectiveness of the current voluntary standard for crib mattresses; (3) examines recent recalls associated with crib mattresses; (4) discusses the impact of a rule on small businesses; and (5) provides staff's recommendations to the Commission.

## II. Background

## A. Product Review

The draft NPR proposes creating a mandatory standard for crib mattresses, incorporating by reference ASTM F2933 – 19, with additional modifications to further reduce the risk of injury. ASTM F2933 – 19 provides performance and labeling standards for mattresses intended for full-size cribs, non-full-size cribs, after-market mattresses for play yards, and after-market mattresses for non-full-size cribs. ASTM F2933 – 19 defines "mattress" as "ticking filled with a resilient material used alone or in combination with other products intended or promoted for sleeping on it", and the standard defines an "after-market mattress for play yard or non-full-size crib" as a "a

mattress sold or distributed for a play yard or non-full-sized crib" (§ 3.1.5 and 3.1.1, respectively). In addition, "crib" is defined as a "bed that is designed to provide sleeping accommodations for an infant which have specific interior dimensions as determined by it being either a full size or non-full size crib" (§ 3.1.4).

Full-size cribs are typically sold separately from crib mattresses. Full-size crib mattresses generally are referred to by industry as "standard" crib mattresses. Full-size crib mattresses are also used for toddler beds, meaning that one crib mattress may be used from birth through the toddler years. Non-full-size cribs, on the other hand, are cribs that differ in dimension or shape from full-size cribs, that is, non-full-size cribs can be rigid products smaller or larger than full-size cribs or non-rectangular in shape. Consistent with ASTM F2933 – 19, the draft NPR defines "crib mattresses" to include full-size crib mattresses, non-full-size crib mattresses, and aftermarket mattresses for play yards and non-full-size cribs, as in ASTM F2933 – 19, and consistent with Commission direction to include "crib mattresses, as well as after-market mattresses for play yards and portable cribs." "Portable crib" is a term that is used colloquially to refer to a product that would generally fall under the non-full-size crib category as a smaller than full-size crib. <sup>6</sup>

Crib mattresses come in a variety of designs and are made of a broad array of materials. Crib mattresses typically have a fabric or vinyl ticking, which covers inner-spring coils or foam. Inner-spring mattresses often have a layer of foam or batting between the springs and the ticking.

Section 5.7 of ASTM F2933 – 19 states that the dimensions of a full-size crib mattress shall measure at least 27 <sup>1</sup>/<sub>4</sub> in. wide and 51 <sup>5</sup>/<sub>8</sub> in. long. The interior dimensions of full-size cribs are  $28 \pm \frac{5}{8}$  in. (710 ± 16 mm) wide and 52 <sup>3</sup>/<sub>8</sub> ± <sup>5</sup>/<sub>8</sub> in. (1330 ± 16 mm) long. Non-full-size crib mattresses do not have defined dimensions, except for the minimum effective crib-side height and side-gap requirement. ASTM F2933 – 19 requires that the dimensions of a mattress supplied with a non-full-size baby crib shall be such that the mattress, when inserted in the center of the crib, in a non-compressed state, shall not leave a gap of more than <sup>1</sup>/<sub>2</sub> in. at any point between the perimeter of the mattress and the perimeter of the crib.

Section 5.9 of ASTM F2933 – 19 requires that after-market mattresses for play yards and non-full-size cribs shall have the same (within  $\frac{1}{4}$  in.) thickness, floor support structure, and attachment method as the mattresses they are intended to replace.

## **B.** Market Description

Crib mattresses range in price from \$20 to \$500, with the more expensive crib mattresses typically being full-size crib mattresses made using a firm coil or high-end foam core. Crib mattresses are sometimes sold with waterproof covers specifically designed to be used with the mattress. While some manufacturers produce a large variety of crib mattress models, others produce only a small selection. Many crib mattresses are GreenGuard Certified, which is a UL-sponsored standard intended to reduce the emissions of volatile organic compounds from

<sup>&</sup>lt;sup>6</sup> Some consumers may also refer to a play yard as a crib.

products.<sup>7</sup> Additionally, many full-size crib mattresses are advertised online as meeting the CPSC mattress and mattress pad flammability requirements.<sup>8</sup> Crib mattresses are defined as children's products and are already subject to other federal safety rules, such as lead and phthalate testing.

## III. Incident Data (Tab A)

## Injuries

1. NEISS Injury Estimates

CPSC staff reviewed injury estimates from the National Electronic Injury Surveillance System (NEISS), a statistically valid injury surveillance system. NEISS injury data are gathered from emergency departments (EDs) of hospitals selected as a probability sample of all the U.S. hospitals with EDs. CPSC staff found 21 NEISS cases, including 19 injuries and 2 fatalities, associated with a crib mattress (meaning full-size, non-full-size, play yard, and after-market crib mattresses) from January 1, 2010 through March 31, 2020. Because the data did not meet the minimum criteria for reporting an estimate,<sup>9</sup> staff includes these cases with the rest of the reported incident data described below.

## 2. Reported Incidents

In addition to NEISS data, CPSC staff also reviewed incident data associated with crib mattresses as reported through the Consumer Product Safety Risk Management System (CPSRMS).<sup>10</sup> Reviewing combined NEISS and CPSRMS data, CPSC staff is aware of 439 reports associated with a crib mattress. Of the 439 incident reports, 116 reports (26 percent) involved a fatality; 15 reports (3 percent) required an infant to receive treatment in the emergency room, and 4 reports (1 percent) required hospital admission. Staff found that 199 reports (45 percent) described an incident that resulted in no injury, and 16 reports (4 percent) stated that no actual incident and no injury occurred. In the reports with no injuries reported, staff found that caretakers generally undertook intervention measures once they identified a problem with the crib mattress, and the mattress was no longer used after the caretaker identified a hazard. Reports indicated that the level of care and treatment for the infant following an incident was not known in 66 reports (15 percent), and 13 reports (3 percent) stated it is unknown whether an injury occurred.

<sup>&</sup>lt;sup>7</sup> <u>https://www.ul.com/resources/ul-greenguard-certification-program.</u>

<sup>&</sup>lt;sup>8</sup> Review of manufacturers' websites, product labels, and materials.

<sup>&</sup>lt;sup>9</sup> NEISS estimates are reportable, provided the sample count is greater than 20, the national estimate is 1,200, or greater, and the coefficient of variation (CV) is less than 0.33.

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

## **Fatalities**

CPSC staff is aware of 116 reported deaths associated with crib mattresses that were reported to have occurred during the period January 1, 2010 through March 31, 2020. Figure 1 contains a description of the 114 reported fatalities associated with crib mattresses (excluding 2 fatalities associated with full-size crib mattresses used in a play yard, which are out of scope for crib mattresses and after-market play yard mattresses) by age and hazard category.







## **Hazard Patterns**

Table 1 contains a breakdown of incidents by hazard pattern, with fatal hazard patterns bolded and italicized. CPSC staff's recommendations for the draft NPR focus on addressing the primary hazard patterns associated with fatalities, nonfatal hazard patterns with similarities to fatal hazard patterns (*i.e.*, softness), and hazard patterns that compose a large portion of the nonfatal incidents (e.g., "coil or spring" at 38% of nonfatal).

Hazard Category	Fatal Reports	Nonfatal Reports	<b>Total Reports</b>
Chemical/Flammability	0	23	23
Coil or Spring	0	124	124
Crib Mattress Used in a Play Yard	2	1	3
Expand or Inflate	0	6	6
Face in Mattress	13	1	14
Fit Issues	20	88	108
Found Prone	66	3	69
Mattress Falls Apart	0	18	18
Softness	0	36	36
Multiple Contributing Factors	15	17	32
Other	0	6	6
Total	116	323	439

Table 1. Fatal and Nonfatal Reports Associated with Crib Mattresses by Hazard Category, January 1, 2010 –March 31, 2020

Source: CPSRMS and NEISS databases

Reporting is ongoing. Staff considers 2018–2020 incomplete.

- 1. *Chemical/Flammability*: Seven percent (23 out of 323) of the nonfatal incidents reported a crib mattress having a chemical odor (5), causing rashes (7), or not meeting mandatory federal flammability standards (11). Infants were reported to have suffered from rashes and upper respiratory issues.
- 2. *Coil or spring*: Thirty-eight percent (124 out of 323) of nonfatal incidents involved a coil or spring found protruding through the crib mattress. A 2-year-old received two stitches in the hospital ED for a laceration injury. Another 2-year-old with a toe laceration was treated and released from the hospital ED.
- 3. *Crib mattress used in a play yard*: Less than 1 percent (1 out of 323) of nonfatal incidents involved protruding coils or springs of a crib mattress used in a play yard scratching an infant's back. Two percent of the fatalities involved using a crib mattress in a play yard (2 out of 116). Reports state that infants were found wedged between the crib mattress and the mesh of the play yard, due to the crib mattress not fitting snugly within the play yard.
- 4. *Expand or inflate*: Two percent (6 out of 323) of nonfatal incidents involved a crib mattress that failed to expand or inflate properly. Staff identified related hazards, including fit issues with gaps appearing around the crib mattress causing entrapment or wedging, and an uneven crib mattress that may cause an infant to roll over.
- 5. *Face in mattress*: Eleven percent (13 out of 116) of fatalities were associated with the face of an infant reportedly in contact with a crib mattress or crib sheet covering the crib mattress. Based on the available information about each fatality, bedding was present in the sleeping environment in some of these reports, but bedding was not touching the infant; nor did staff determine that the bedding was a contributing factor in the death.

Less than 1 percent (1 out of 323) of reported nonfatal incidents involved an infant found limp, pale, and with blue around the lips while face down in contact with a crib mattress.

- 6. *Fit Issues*: Seventeen percent (20 out of 116) of fatalities involved issues with the fit of a crib mattress in the sleeping environment. In all of these fatalities, the infant became wedged in gaps between at least one of the sides of a crib mattress and the crib rails or play yard mesh. Twenty-seven percent (88 out of 323) of nonfatal incidents involved issues with the fit of a crib mattress in the sleeping environment. In all of these reports, staff determined that gaps were present on one or more sides around the perimeter of a crib mattress, creating a wedging or entrapment hazard between the crib mattress and the crib rails or play yard mesh.
- 7. *Found Prone*: Fifty-seven percent (66 out of 116) of fatalities involved an infant found in a prone position with no mention of whether the face of the child was in contact with the crib mattress or crib sheet, and no mention of the face being obstructed by other crib bedding or other items in the sleep environment. Given the available information about each fatality, bedding was present in the sleeping environment in some of these reports, but staff did not determine that bedding was a contributing factor in the deaths. One percent (3 out of 323) of nonfatal incidents involved an infant found in a prone position without any mention of the face being in contact with the mattress or crib sheet, and no mention of the face being obstructed by other crib bedding or other items in the sleep environment. Staff found no other details about the sleep environment in any of these three reported incidents.
- 8. *Mattress Falls Apart*: Six percent (18 out of 323) of nonfatal incidents involved part of a crib mattress coming apart. In most of these reports, the seams of the mattress unraveled, creating a strangulation hazard due to the stitching of the mattress being exposed, or a choking or ingestion hazard due to the inner filling coming out of the mattress in small pieces and remaining in the sleep environment.
- 9. Softness: Eleven percent (36 out of 323) of nonfatal incidents involved a crib mattress's inner cushioning being reportedly too soft. Staff found 17 reports of depressions or indentations in the crib mattress, accompanied by the following descriptions: "bunches up/squishy"; "depression/dips/indentation/sinks in/sunken"; and "deflates/like an air mattress not fully inflated." Twelve reports described a crib sheet being placed on a crib mattress and causing the mattress to bend or bow; causing a gap or fit issue between the mattress is not breathable. Three reports allege that the crib's mattress is too thin and that the inner cushioning is too soft.
- 10. *Multiple Contributing Factors (MCF)*: Thirteen percent (15 out of 116) of fatalities involved multiple factors that potentially played a role in the fatality, and the crib mattress was likely one of the contributing factors. Examples of other contributing factors included the following: entrapment between the mattress and bumper pads; entrapment between the mattress and a crib rail with limb entrapment; use of a swaddle; sharing the sleep environment with another infant; and congenital or recent health

conditions. Of nonfatal incidents, 17 out of 323 (5%) reported multiple contributing factors.

11. *Other*: Two percent (6 out of 323) of nonfatal incidents involved miscellaneous other issues associated with a crib mattress. Reports in this category included: a blade found in a crib mattress; an infant's arm "tangled in a crib mattress"; an infant "slipped on a crib mattress," causing a slat entrapment; an infant's arm "stuck on a crib mattress"; a crib mattress with a loose plastic bag for a cover; and concern about crib mattresses not having proper warning labels to direct caregivers to position infants on their back when placing them in a crib.

## IV. Voluntary Standard - ASTM F2933 - 19

## A. History of the ASTM Voluntary Standard (Tab B)

The ASTM Committee F15 on Consumer Products first published the voluntary standard for crib mattresses in 2013, as ASTM F2933 – 13, *Standard Consumer Safety Specification for Crib Mattresses*. The first publication established requirements for the standard and addressed the following issues:

- Sharp points,
- Small parts,
- Lead and other toxic substances in paints,
- Finger entrapment,
- Mattress dimension conformity,
- Mattress thickness, and
- Marking and labeling.

Since 2013, ASTM has revised and updated the voluntary standard three times to address safety issues, as outlined below:

ASTM F2933 – 16 (approved 12/1/2016):

• Revised warning label permanency requirements in 5.6.1, to include requirement that "Non-coated paper warning label shall not be applied on either side of sleeping surface." Added a note under this section, stating that non-coated paper label may absorb water and can deteriorate.

ASTM F2933 – 18 (approved 8/15/2018):

- Revised scope to include a new section 1.5, stating that the standard was developed in accordance with internationally recognized principles on standardization.
- Added to section 3, Terminology, a definition of "after-market mattress for play yard or non-full-size crib."

- Added a new requirement for after-market mattresses for play yards and non-full-size crib mattresses in section 5, General Requirements, stating that after-market mattresses for soft-sided (*i.e.*, play yards) and non-rectangular rigid-sided products (*i.e.*, non-full-size cribs):
  - Shall have the same thickness, floor support structure, and attachment method as the mattress it is intended to replace, and
  - Shall meet the specifications of Mattress Vertical Displacement test from ASTM F406 – 19, Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards.
- Added the following marking and labeling requirements for after-market mattresses in sections 7.5 to 7.7:
  - After-market mattresses and their retail packaging shall include specified suffocation warning language related to hazardous gaps and stacked mattresses.
  - Requirements that distinguish between types of products.
  - After-market mattresses shall have all the warnings that the original manufacturer had and provide instructions that are on the original mattress, and both the after-market mattress and the retail packaging shall identify the brand and model numbers of products in which it is intended to be used.
- Rigid-sided rectangular products, including after-market mattresses and their retail packaging, shall have a specified statement regarding mattress dimensions and fit.

ASTM F2933 – 19 (approved 6/15/2019):

• Added a new requirement for mattress seam stitching in section 5, General Requirements, requiring that all seam stitching that is accessible to the occupant be lock stitching.

## Provisions in ASTM F2933 – 19 (Tab B)

ASTM F2933 – 19 contains general requirements typically found in other ASTM juvenile product standards, such as requirements for openings, label permanency, and the prohibition of sharp points/edges, small parts, and lead in paints. Section 5 of ASTM F2933 – 19 contains the following four additional requirements that apply specifically to mattresses for cribs, non-full-size-cribs, and after-market mattresses for non-full-size cribs and play yards:

- § 5.7 Mattress Dimensions: This section describes the dimensional requirements for fullsize and for non-full-size crib mattresses that are supplied with a non-full-size crib, to prevent an infant from becoming wedged in a gap caused by too small a crib mattress. To ensure the crib mattress dimensions are within the allowable range, the test requires a mattress to be placed in a test box and pushed against the side of the box with a force prescribed in the test method.
- § 5.7.2.2 *Mattress Thickness*: This requirement only applies to non-full-size crib mattresses, to prevent occupants from falling out of the product. The requirement states that a mattress supplied with a non-full-size crib shall have a thickness that will provide a minimum effective crib-side height dimension of at least 20 inches when the crib side is

in its highest adjustable position, and the mattress support is in its lowest adjustable position. Additionally, the mattress shall have a thickness that will provide a minimum effective crib-side height dimension of at least 3 inches when the crib side is in its lowest adjustable position, and the mattress support is in its highest adjustable position.

- § 5.8 Mattress Seam Stitching: This requirement applies to all crib mattresses within the scope of the standard, and states that all seam stitching that is accessible to the occupant must be lock stitching, to prevent accessible stitching from becoming loose and creating a small part or strangulation hazard.
- § 5.9 After-Market Mattress for Play Yard and Non-Full-Size Cribs: This requirement is for after-market mattresses for play yards and non-full-size cribs, and states that after-market mattresses for soft-sided and non-rectangular, rigid-sided products must have the same thickness, floor support structure, and attachment method as the mattress it is intended to replace. Accordingly, after-market mattresses must be identical to the original equipment manufacturer (OEM) mattress. Requirements for OEM mattresses sold with play yards and non-full-size cribs are codified at 16 CFR parts 1220 (non-full-size cribs) and 1221 (play yards), which incorporate by reference ASTM F406, *Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards* (ASTM F406). After-market mattresses must also meet the Mattress Vertical Displacement test in ASTM F406.<sup>11</sup>

Tab B contains a more detailed discussion of these provisions in the voluntary standard.

## Adequacy of ASTM F2933 – 19 Requirements (Tabs B, C, and E)

ASTM developed ASTM F2933 to mitigate the risk of injury by addressing the hazard patterns associated with the use of crib mattresses. Hazard mitigation strategies include performance requirements and instructions and on-product warnings to help inform caretakers of the primary hazards during use of the product. Based on the Engineering (Tab B), Human Factors (Tab C), and Health Sciences (Tab E) assessments, staff concludes that the requirements in the current voluntary standard, ASTM F2933 – 19, adequately addresses the hazard patterns related to expanding or inflating crib mattresses, mattresses falling apart, and most addressable hazards associated with multiple contributing factors, or other hazards. However, ASTM F2933 – 19 does not adequately address the most prevalent or severe identified hazards associated with the use of crib mattresses, such as coil spring issues, face in mattress, fit issues, found prone, and softness) are also inadequate. Accordingly, staff proposes additional requirements in the draft NPR to make the standard more stringent, to further reduce the risks of death and injury from these hazard patterns. Table 2 summarizes staff's assessment of the adequacy of ASTM F2933 – 19 in addressing the hazard patterns.

<sup>&</sup>lt;sup>11</sup> The purpose of requiring after-market mattresses to be identical to OEM mattresses is to reduce the risk of infant entrapment and suffocation associated with after-market mattresses that are too thick, or that do not fit correctly or attach to a play yard or non-full-size crib. ASTM developed this requirement in collaboration with CPSC staff and the ASTM Play Yard Vertical Displacement Task Group and the Play Yard Mattress Fit and Thickness Task Group.

Identified Hazard Pattern (potential injury)	Applicable Mattresses	How addressed in ASTM F2933 – 19	Staff assessment of adequacy	Staff Comments
Chemical/Flammability Hazards (odors, rash)	All	16 CFR part 1303 Ban of Lead- Containing Paint 16 CFR part 1500 Hazardous Substances Act Regulations (Sections 5.1 and 5.4) 16 CFR part 1632 Standard for the Flammability of Mattresses and Mattress Pads 16 CFR part 1633 Standard for the Flammability (Open Flame) of Mattress Sets	Adequate	See LSM memo (Tab B).
Coil or Spring (laceration)	Coil or spring mattresses (primarily full-size)	Prohibition of sharp points (Section 5.2)	Inadequate	Recommend additional cyclic testing to identify potential for springs to break through surface during foreseeable use and misuse. See also LSM memo (Tab B).
Crib Mattress Used in a Play Yard (suffocation due to ill- fitting mattress)	Aftermarket play yard mattresses	Labeling requirements, requirements for after-market mattresses. Testing requirements harmonized with ASTM F406. (Section 7.5)	Adequate	See LSM & ESHF memo (Tabs B & C).
Expand or Inflate (suffocation due to ill- fitting mattress that does not expand or inflate properly)	Foam products, typically full-size and shipped as "bed in a box"	Dimensional conformity, mattress thickness, and labeling requirements (Section 5.7)	Adequate	See LSM memo (Tab B).
Face in Mattress (suffocation)	All	Labeling requirements (Section 7.3)	Inadequate	Recommend a test based on sections 6 and 8 of AS/NZS

## Table 2. Adequacy of ASTM F2933 – 19 in Addressing the Hazard Patterns

Identified Hazard Pattern (potential injury)	Applicable Mattresses	How addressed in ASTM F2933 – 19	Staff assessment of adequacy	Staff Comments
				8811.1 firmness test. See also ESHF memo (Tab C).
Fit Issues (suffocation due to ill- fitting mattress)	All	Dimensional conformity and after-market mattress requirements (Sections 5.7 and 5.9)	Inadequate	Recommend additional fitted sheet compression test for full- size crib mattresses and extending dimensional requirements in section 5.7 to all after-market, non-full-size crib mattresses. See also LSM memo (Tab B).
Found Prone (suffocation due to prone position)	All	Labeling requirements (Section 7.3)	Inadequate	Recommend a test based on sections 6 and 8 of AS/NZS 8811.1 firmness test and strengthening warning label requirements. See LSM memo (Tab B) and ESHF memo (Tab C)
Mattress Falls Apart (choking/ingestion)	All	Mattress seam stitching requirement and small parts prohibition (Sections 5.3 and 5.8)	Adequate	See LSM memo (Tab B).
Softness (suffocation due to soft surface)	All	Not addressed	Inadequate	Recommend a test based on sections 6 and 8 of AS/NZS 8811.1 firmness test. See also LSM memo (Tab B)
Multiple Contributing Factors ( <i>e.g.</i> , entrapment in bumper pads, limb entrapment, crib sharing with another infant, existing health condition)	All	General requirements and warning labels (Sections 5.7 and 7.3)	Inadequate	Some of these contributing factors are addressed by staff's recommended additional requirements described above, while others are related to another product use or other factors out of the scope of the crib mattresses standard.

## a. Coil or Spring

Laceration hazards due to an exposed coil or spring accounted for 124 of the 440 incident reports (38% of nonfatal incidents). Currently, ASTM F2933-19 does not address this hazard. A cyclic test could address this hazard, by loading and unloading any mattress that contains coils or springs for a set number of cycles, to exercise metal coil springs and identify springs that cannot withstand normal use without breaking, or that may otherwise break the surface of the mattress.
The Crib Mattress Cyclic Testing task group discussed a cyclic impact test based on the Mattress Support Vertical Impact Test from section 7.4 of ASTM F1169 – 19 (the standard for full-size cribs) in their task group meeting in July 2018. At the F15.66 Crib Mattress subcommittee meeting held in October 2018, the subcommittee discussed both the Mattress Support Vertical Impact Test and the Mattress Durability Roller Testing for spring/coil mattresses, based on ASTM F1566, *Standard Test Methods for Evaluation of Innersprings, Boxsprings, Mattresses or Mattress Sets*, section 7, as possible cycle loading tests. In the following months, CPSC staff and other members of the Crib Mattress Cyclic Testing task group performed variations of the Mattress Support Vertical Impact Test to determine a test that would be most applicable to crib mattresses with coil springs.

On April 29, 2019, staff sent a letter to the subcommittee chair in response to ballot F15 (19-04), stating staff's initial test results. In the task group meeting in July 2019, staff and one manufacturer discussed the results of their continued testing and refined the requirements. The task group focused testing on the Mattress Support Vertical Impact Test because it uses the same equipment employed in full-size crib testing. After replicating the full-size crib impact test (45 pounds dropped 750 times), staff assessed that the test was too onerous. During task group discussions, consensus was to lower the weight to 30 pounds and increase the number of cycles to 1,000. ASTM has not held additional task group meetings or issued ballots on this issue since the July 2019 task group meeting. Staff's recommended requirement is based on the last work of the task group, which is a test that drops a 30-pound impactor, similar to the full-size crib standard, on a mattress in four specified locations for a total of 1000 impacts. Tab B provides additional details of the recommended requirements.

### b. Fit Issues

Fit issues are associated with 108 of 439 incidents; 20 were fatal, and 88 were nonfatal. In these reports, gaps between the crib mattress and the crib rail or play yard mesh, on one or more areas around the perimeter of a crib mattress, created a wedging or entrapment hazard. Reports of mattresses that fail to expand, compress, or buckle, indicate the potential to form hazardous gaps between the corner of a crib and the corner of the mattress. This hazard can also arise when a fitted sheet is placed on the mattress, creating large corner gaps that could lead to entrapment.

Staff initially brought this concern to ASTM in April 2018. ASTM F2933 – 19 contains a mattress dimensional conformity test intended to addresses this hazard. However, staff testing found that tight-fitting sheets over crib mattresses can create gaps between the corners of the mattress and the interior corner of the crib, creating an entrapment hazard. Accordingly, staff concludes that ASTM F2933 – 19 does not adequately addresses entrapment hazards between the crib mattress and the side or corner of a crib.

For further examination, staff obtained 11 full-size crib mattresses and eight 100 percent cotton full-size crib mattress sheets to investigate this reported hazard pattern. Staff washed four sets of sheets twice in hot water then dried them at the highest temperature setting; staff did not wash the remaining four sheet sets. Staff measured the length and width of two corner seams of the eight mattress sheets with the corner seams straightened. Staff measured length and width by holding the innermost ends of two adjacent corner seams, separating them until a straight edge

was formed, and measuring the straight edge. Staff set aside for mattress testing the smallest sheet of each group, as determined by the smallest length and width dimensions. The sheets were then fitted on the mattresses to determine the change in dimensions and whether any potentially hazardous gaps were created. Staff shared the test results, detailed in Tab B, with the subcommittee chair on March 20, 2020, but there have been no subcommittee or task group meetings since then, due to the COVID-19 pandemic. To strengthen the standard, staff recommends adding a test, discussed in detail in Tab B, to the draft NPR to address the fit issues with full-size crib mattresses caused by a tight-fitting sheet. This additional test may also help with complaints around mattresses inflating or expanding, because it will repeat the dimensional conformity test.

Staff is not currently recommending adding the fitted sheet test as a requirement for non-full-size crib mattresses, but invites comment on whether the same compression issues arise with non-full-size and play yard mattresses.

Additionally, staff notes that section 5.9 of ASTM F2933 – 19 currently includes provisions to address fit issues with after-market mattresses for play yards and non-full-size cribs. These provisions require that play yards and non-rectangular rigid-sided products have the same, within 0.25 inch, thickness floor support structure and attachment method as the mattress it is intended to replace and that the after-market mattress meet the specifications of the *Mattress, Mattresses for Rigid-Sided Products and Mattress Vertical Displacement* sections of ASTM F406.

As detailed in section IV.D below, the dimensional requirements for after-market non-full-size crib mattresses in section 5.9 of ASTM F2933 – 19 currently only apply to non-rectangular, non-full-size crib mattresses, and the dimensional requirements in section 5.7 of the standard only apply to OEM non-full-size crib mattresses. Although labeling requirements in section 7 of the standard apply to all non-full-size crib mattresses, regardless of shape or whether they are after-market or OEM, ASTM F2933 – 19 contains no dimensional requirements that apply to after-market rectangular, non-full-size crib mattresses. For the draft NPR, to address this gap in the standard, and to further reduce the risk of injury associated with after-market rectangular-shaped, non-full-size crib mattresses, staff recommends modifying section 5.7 to expand the dimensional requirements to all after-market, non-full-size crib mattresses, regardless of shape. Staff also recommends modifying section 5.9 of ASTM F2933-19, to remove non-full-size crib mattresses from that section, and to clarify requirements for after-market play yard mattresses.

### c. Found Prone, Face into Mattress, and Softness

Although staff separated the hazard patterns for found prone, face into mattress, and softness in the incident review, due to available details in each incident, CPSC staff considers these hazard patterns to be related. Accordingly, staff's recommended changes in the draft NPR related to each hazard pattern may address incidents associated with all three hazard patterns.

Staff found that in 57 percent (66 out of 116) of the reported fatalities and three reported nonfatal incidents (1%), the infant was found in a prone position (face down) with no mention of whether the face of the child was in contact with the crib mattress or crib sheet, and no mention of whether the face was obstructed by other crib bedding or other items in the sleep environment.

However, in 11 percent (13 out of 116) of fatalities, when discovered, the child was found prone and the report specifically indicated the face of the child was in contact with a crib mattress or crib sheet covering the crib mattress. Based on the available information about each fatality, staff found that some reports indicate that bedding was present in the sleeping environment, but bedding was not touching the infant or did not appear to be a contributing factor in the death. Additionally, staff found that in 11 percent (36 out of 323) of the nonfatal incidents, the report stated that a crib mattress inner cushioning was too soft. Although these incidents did not involve a fatality, soft bedding, such as pillows and comforters, is associated with infant fatalities, and staff deduces that an excessively soft mattress (*i.e.*, one that may mold around or otherwise occlude an infant's airway), such as mattresses made of memory foam,<sup>12</sup> could present the same hazard.

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. A crib mattress must be sufficiently firm to prevent a child's nose and mouth from being obstructed by a mattress that is too soft and pillow-like. Prone positioning is a known risk factor for sudden unexpected infant death (SUID), and may be related to limited physical and developmental capabilities of infants, who may not arouse themselves in a low-oxygen situation. Suffocation-type asphyxial deaths (*e.g.*, smothering) involve occlusion of airways and can occur when an infant is placed to sleep or rolls into a prone position on a surface capable of conforming to the body or face of an infant, such that the mouth and nose are physically blocked, preventing air passage. Suffocation is discussed further in Tab E.

Other than through warnings, ASTM F2933 – 19 does not address mattress firmness or softness hazards potentially related to prone and face into mattress incidents. ASTM F2933 – 19 contains warning requirements regarding prone positioning; however, as discussed in Tab C, staff concludes that the warnings are inadequate and recommends modifications for the draft NPR.

Currently, ASTM F2933-19 addresses prone position through a warning that states:

To prevent deaths, the U.S. Consumer Product Safety Commission (CPSC), the American Academy of Pediatrics (AAP), and the National Institute of Child Health and Human Development (NICHD) recommend the following:

To reduce the risk of Sudden Infant Death Syndrome (SIDS) and suffocation, pediatricians recommend healthy infants be placed on their backs to sleep, unless otherwise advised by your physician.

This warning statement includes, and is presented after, a significant amount of unnecessary text. Given the large number of deaths involving prone positioning, staff concludes that this warning must be as clear and direct as possible. Staff also concludes that the warnings pertaining to soft bedding contain unnecessary wording and finds that the warnings are not organized clearly. Numerous incident reports indicate that caregivers added soft bedding to the sleep area. Survey and focus group feedback (see Tab C) also demonstrate common consumer use of soft bedding

<sup>&</sup>lt;sup>12</sup> Memory foam is a viscoelastic-foam product that is sensitive to pressure and temperature and intended to conform to the body.

in infant sleep areas. As advocated in numerous public awareness efforts by health and safety professionals, warnings regarding soft bedding must be communicated effectively.

Staff recommends modifying the warning content regarding soft bedding, and staff recommends formatting changes to increase the readability and directness of the warnings. These recommendations are reflected on the right in Figure 2, page 19. Discussed in Tab C, section D and its Appendix, staff recommends modifying this warning statement and its placement on the warning label, to increase the likelihood of consumers reading, understanding, and heeding the hazard concerning prone sleep. Staff's recommendations are also shown in the example label on the right in Figure 2, page 19.

In addition to strengthening the warning label to reduce fatalities associated with an infant's face in a soft mattress, which may also address some prone-positioning deaths<sup>13</sup>–in which it was not clear that that face was *in* the mattress–staff recommends a performance requirement to measure mattress firmness. Staff's view is supported by published guidance from the American Academy of Pediatrics (AAP), which states: "A soft sleeping surface (*e.g.*, memory foam) can increase the risk of rebreathing or suffocation"<sup>14</sup>; and "Soft mattresses, including those made from memory foam, could create a pocket (or indentation) and increase the chance of rebreathing or suffocation if the infant is placed in or rolls over to the prone position."<sup>15</sup>

In a letter to the subcommittee chair for crib mattresses, dated December 11, 2019, staff recommended that the subcommittee continue their previous work on mattress firmness. The firmness task group met on January 8, 2020, to discuss this recommendation. In a task group meeting held on February 13, 2020, staff verbally shared the results of staff's testing to AS/NZS 8811.1:2013 and a draft test method in ISO/CD 23767, although most members had yet to perform any testing. Staff also shared testing results in a letter to the subcommittee and task group chair on March 20, 2020. The task group planned to discuss CPSC testing results at the April subcommittee meeting, which was canceled due to the COVID-19 pandemic. CPSC staff's testing, detailed in Tab B, found few failures with either test method, based on 11 sample mattresses available from big box retail stores.

After evaluating the hazards associated with soft surfaces, CPSC staff recommends additional requirements in the draft NPR, to make the standard more stringent, to further reduce the risk of death and injury associated with mattresses that are too soft and have the ability to conform to an infant's face. Although the warning label change and the firmness test will not make prone sleeping safe, they may help to reduce the instances in which an infant maneuvers into a prone position with its face *in* the mattress that could have been mitigated with a firmer surface. CPSC staff determined that the AS/NZS 8811.1:2103 is more repeatable and more stringent than the draft test in ISO/CD 23767. CPSC staff recommends proposing a mattress firmness test for all

<sup>&</sup>lt;sup>13</sup> Many factors contribute to prone positioning deaths, and suffocation face down in a soft mattress is just one possible factor. Staff could not definitively associate soft mattresses with specific incidents. However, staff did not associate incidents with firm mattresses, and staff is aware of deaths associated with other products with conforming surfaces (*e.g.*, pillows, blankets).

<sup>&</sup>lt;sup>14</sup> <u>https://www.aafp.org/afp/2017/0615/p806.html.</u>

<sup>&</sup>lt;sup>15</sup> https://pediatrics.aappublications.org/content/138/5/e20162938#ref-19.

crib mattresses within the scope of the standard that is based on sections 6 and 8 of AS/NZS 8811.1:2013.<sup>16</sup> Tab B contains additional details regarding staff's testing of mattress firmness and the rationale for recommending the addition of the performance test based on AS/NZS 8811.1:2013.

# d. General Assessment of Warnings and Instructions in ASTM F2933 – 19 (See Tab C)

Warning about a hazard is viewed universally as less effective at addressing hazards than either designing the hazard out of a product, or guarding the consumer from the hazard. The use of warnings is lower in the hazard-control hierarchy than design-based approaches because the effectiveness depends on persuading consumers to alter their behavior in some way to avoid hazards, rather than eliminating hazards or inhibiting exposure to hazards. Therefore, when a standard relies on warnings to address a hazard, warning statements must be as strong as possible; *i.e.*, the warnings must be noticeable, understandable, and motivating. 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*, recommends that on-product warnings include content that addresses the following three elements:<sup>17</sup>

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

Although the ASTM standard contains warnings pertaining to infant positioning, soft bedding, and gap entrapment, staff concludes that the wording and formatting of the warning messages must be improved to communicate the hazards more effectively to consumers. Figure 2 shows the current ASTM warning label and staff's recommended warning label for full-size crib mattresses (see the Appendix in Tab C for examples of recommended warning labels for other types of crib mattresses).

<sup>&</sup>lt;sup>16</sup> A test based on AS/NZS 8811.1:2013 was also used to address a smothering-type suffocation hazard presented by crib bumpers separating from the crib or otherwise protruding into the sleep area and getting underneath an infant. In these situations, the crib bumper behaves like a quilt or soft bedding that is able to conform to, and occlude, airway openings. Extending the requirement to the mattress will similarly reduce the risk of suffocation posed by soft depressions or indentations in crib mattresses.

<sup>&</sup>lt;sup>17</sup> All three elements may not be necessary in some cases, such as if certain information is open and obvious or can be readily inferred by consumers; however, people often overestimate the obviousness of such information to consumers.

Current warning in ASTM F2933 – 19

### **A**WARNING

Failure to follow these warnings could result in serious injury or death.

To prevent deaths, the U.S. Consumer Product Safety Commission (CPSC), the American Academy of Pediatrics (AAP), and the National Institute of Child Health and Human Development (NICHD) recommend the following:

To reduce the risk of Sudden Infant Death Syndrome (SIDS) and suffocation, pediatricians recommend healthy infants be placed on their backs to sleep, unless

otherwise advised by your physician. • Infants can suffocate on soft bedding. Never place a pillow or comforter under sleeping infant for additional padding or as a mattress substitute.

Do not cover the heads of babies with a blanket or over bundle them in clothing and blankets. Overheating can lead to SIDS.
Do not use this mattress in a crib having

interior dimensions that exceed  $28_{5\%}$  by 53 in. (73 by 135 cm) as measured from the innermost surfaces of the crib.

• Only use sheets and mattress pads designed specifically for crib mattresses.

DO NOT remove these important safety instructions.

Staff's recommended warning

### 

### SIDS AND SUFFOCATION HAZARDS

**ALWAYS** place baby on back to sleep to reduce the risks of SIDS and suffocation.

Babies have suffocated:

- on pillows, comforters, and extra padding
- in gaps between a wrong-size mattress, or extra padding, and side walls of product.

**NEVER** add soft bedding, padding, or an extra mattress.

**USE ONLY** one mattress at a time.

**DO NOT** cover the faces or heads of babies with a blanket or over-bundle them. Overheating can increase the risk of SIDS.

**ALWAYS** check mattress fit **every time you change the sheets,** by pushing mattress tight to one corner. Look for any gaps between the mattress and the side walls. If a gap is larger than  $1^{3}/_{8}$  in. (3.5 cm), the mattress does not fit – **do not** use it.

**DO NOT** use this mattress in a crib having interior dimensions that exceed  $28\frac{5}{8}$  by 53 in. (73 by 135 cm) as measured from the innermost surfaces of the crib.

**USE ONLY** sheets and mattress pads designed specifically for crib mattresses.

DO NOT remove these important safety warnings.

Figure 2. Current (left) and recommended (right) example warning labels for full-size crib mattresses.

Staff has additional concerns with the safety information requirements in ASTM F2933 - 19. These concerns include, but are not limited to,

- the definition of "conspicuous" in Section 3 is ambiguous;
- the warning labels do not have a clear and comprehensive hazard identifier;
- the packaging requirements for marking and labeling are limited and exclude full-size crib mattresses;
- there are no requirements for warnings in instructional literature;
- the warning message includes a significant amount of superfluous text, resulting in warning labels that are more difficult to understand and are less likely to be read in their entirety; and

• the requirements in section 7 are worded and organized poorly, which may lead to confusion among manufacturers, test labs, and others viewing the standard.

The Appendix to Tab C contains a significant number of specific staff-recommended requirements for safety information to address the listed concerns. Many of the changes incorporate efforts to align with recommendations from ASTM F15 Ad Hoc Language Task group (*i.e.*, addressing numerous warning format issues related to capturing consumer attention, improving readability, and increasing hazard perception and avoidance behavior).<sup>18</sup>

### Staff Recommended Modifications to Requirements for After-Market Non-Full-Size Crib Mattresses

ASTM F2933-19 addresses dimensional requirements for non-full-size crib mattresses in two places: section 5.7, which addresses mattresses "supplied with" a non-full-size crib (meaning OEM mattresses), and section 5.9, which addresses after-market mattresses for non-full-size cribs (meaning mattresses purchased separately from a crib, which are not intended by the OEM as a replacement mattress). Dimensional requirements for non-full-size crib mattresses are a key requirement in ASTM F2933 – 19, because size requirements prevent hazardous gaps from forming between the edge of a mattress and the side of the crib, where infants can become entrapped and suffocate. Staff identified a gap in the dimensional requirements for after-market non-full-size crib mattresses in section 5.9 ASTM F2933 – 19, which does not appear to have a performance requirement for the dimensions of an after-market, rectangular-shaped, non-full-size crib mattress. As explained below, to address this safety gap, staff recommends expanding the non-full-size crib mattress requirements in 5.7.2, which currently only apply to OEM mattresses, to apply to all non-full-size crib mattresses. Staff also recommends two additional modifications in sections 5.7 and 5.9 of ASTM F2933-19, to clarify ambiguities in the performance requirements for mattresses in the standard.

1. Dimension requirements for all after-market, non-full-size crib mattresses

Although the after-market requirements in section 5.9 are purportedly intended to apply to *"After-market mattress for play yard and non-full size crib,"* the requirements in section 5.9.1 are limited to "mesh/fabric sided products" (meaning play yards) and "rigid sided non-rectangular products" (meaning non-rectangular non-full-size cribs). Because section 5.7 of ASTM F2933-19 only applies to OEM mattresses ("supplied with a non-full-size crib"), staff found no performance requirements in the standard that apply to after-market, rectangular-shaped, non-full-size crib mattresses. Staff reviewed the rationales for changes to the after-market requirements for crib mattresses in the ASTM standards. Staff understands that the ASTM subcommittee intentionally decided to limit performance requirements in section 5.9.1 by omitting rectangular mattresses for rigid-sided products (*i.e.*, rectangular non-full-size cribs). Staff reviewed ASTM minutes and ballot F15 (17-02), which implemented this requirement in

<sup>&</sup>lt;sup>18</sup> The "Recommended Language Approved by Ad Hoc Task Group Revision E," dated May 28, 2019, documents recommendations from the ASTM Ad Hoc Language task group for ASTM juvenile products standards.

F2933; however, staff could not determine the rationale for limiting the requirements to *non-rectangular* products.<sup>19</sup>

Although ASTM F2933 – 19 contains no dimension requirements for after-market, rectangularshaped, non-full-size crib mattresses, the standard does contain warning requirements pertaining to the size of after-market mattresses for rectangular non-full-size cribs. Per section 7.6, these mattresses and their retail packaging must include the following statement:

Check for proper fit of the mattress. This mattress measures \_\_\_\_\_ long, \_\_\_\_\_ wide, and \_\_\_\_\_ thick when measured from seam to seam. (The blank is to be filled in.)

Warnings in section 7.7 pertaining to gap entrapment also apply to these mattresses, and specify that no gaps between the mattress and the side walls should be greater than 1 inch when the mattress is pushed tight to one corner.

Additionally, per 16 CFR part 1221, the mandatory standard for non-full-size cribs, which incorporates by reference ASTM F406 – 19, the on-product warning for non-full-size cribs that have a non-rectangular, removable mattress, *i.e.*, a mattress that could be replaced, requires the statement:

Check proper fit of mattress. Should be not more than \_\_\_ in. thick. The maximum gap between mattress and inside of crib border (or edge) should be no more than 1 in.

Rectangular, removable non-full-size crib mattresses must include the statement:

Use ONLY mattress/pad provided by manufacturer (which must be at least \_\_\_\_\_in. long by \_\_\_\_\_in. wide and not more than in. thick).

This warning puts the onus on the consumer to only use a mattress from the OEM.

Staff concludes that warnings alone are insufficient to address the hazards associated with illfitting, after-market, non-full-size crib mattresses. Accordingly, to ensure that all after-market mattresses for non-full-size crib are subject to a dimensional performance requirement, staff recommends that the current performance requirements for OEM non-full-size crib mattresses in section 5.7.2 of ASTM F2933 – 19 be modified to apply to all non-full-size crib mattresses, regardless of whether the mattress is sold with a crib, and regardless of the shape of the mattress. Accordingly, staff also recommends removing references to after-market non-full-size crib mattresses from section 5.9 of ASTM F2933 – 19. Staff recommends that section 5.9 focus solely upon after-market play yard mattresses.

<sup>&</sup>lt;sup>19</sup> CPSC staff spoke to the ASTM subcommittee chair on September 18, 2020, to discuss the rationale for excluding rectangular after-market non-full-size crib mattresses from dimension requirements. The ASTM subcommittee chair agreed that there appeared to be a gap in the standard for some after-market non-full-size crib mattresses, and agreed this issue should be taken up by the ASTM subcommittee at the next meeting scheduled for November 10, 2020.

Currently, the size and thickness requirements for OEM non-full-size crib mattresses in section 5.7.2 of ASTM F2933 – 19 repeat the requirements for non-full-size crib mattresses in section 5.17 of ASTM F406. To preclude the size requirements in each standard from unintentionally diverging in the future, staff also recommends modifying section 5.7.2 to refer to the requirements for non-full-size crib mattresses in F406, rather than repeating the same requirements in F2933.

Appendix B to Tab B contains a redline of staff's proposed changes to sections 5.7.2 and 5.9 of ASTM F2933-19.

Staff invites comments on this proposal and will continue to work with ASTM to address concerns with exempting after-market, rectangular-shaped, non-full-size crib mattresses from performance requirements.

2. Clarification regarding "replacement mattress" in section 5.9.1.3 of ASTM F2933-19

Finally, staff notes an inconsistency in the language of ASTM F2933 – 19 section 5.9.1.3, which requires that a "replacement mattress" for a play yard bassinet with a bassinet attachment meet certain specifications in ASTM F2194, when tested with each brand and model it is intended to replace. This requirement for bassinet mattresses appears in the section for "after-market" mattresses. Section 3.1.1 of ASTM F2933 – 19 specifically exempts "replacement" mattresses from the term "after-market," because "replacement" mattresses are supplied by an OEM and are equivalent to the original mattress. Staff recommends clarifying that the requirements in section 5.9.1.3 apply to after-market mattresses, by replacing the term "replacement," with the word "after-market."

### **International Standards (Tab B)**

Staff identified two international voluntary standards pertaining to crib mattresses, AS/NZS 8811.1:2013 and BS EN 16890:2017. Additionally, staff found a draft standard, ISO 23767 Children's furniture – Mattresses for cots and cribs – Safety requirements and test methods, which is under consideration and not yet published. Although ISO 23767 is a draft document and not yet an official standard, staff reviewed it and found that it is nearly identical to BS EN 16890.

With the exception of mattress firmness, CPSC staff concludes that ASTM F2933 – 19 is equivalent to, or more stringent than, the international standards described above. Compared to these international standards, ASTM F2933 – 19 is more comprehensive because it also addresses non-full-size crib mattresses and after-market mattresses for play yards and portable cribs. Additionally, except for mattress firmness, which staff recommends adding to the draft NPR, ASTM more fully addresses the hazard patterns identified by staff in the incident data reported to the CPSC. Furthermore, ASTM F2933 – 19 was developed through collaboration between CPSC staff and stakeholders, and has been revised three times in the attempt to address incident data provided by CPSC staff. Therefore, staff concludes that ASTM F2933 combined with a test based on sections 6 and 8 of AS/NZS 8811.1:2013 is more appropriate than other international standards to address hazard patterns associated with crib mattresses.

### V. Discussion

### **Compliance Recalls (Tab D)**

Compliance staff reviewed recalls of crib mattresses that occurred from June 1, 2010 to June 1, 2020. During that period, CPSC's Office of Compliance negotiated five consumer-level recalls involving crib mattresses. Crib mattress recalls were conducted to mitigate against risks of flammability and suffocation. Four crib mattress recalls (including approximately 80,000 units) involved noncompliance with mandatory federal flammability requirements. Staff is unable to calculate an exact number of units, due to a lack of differentiation between crib and adult mattress populations in recalls that included both. Another crib mattress recall (including approximately 300,000 units) involved a dimensional issue, where the crib mattress models were ill-fitting to cribs, creating dangerous gaps between the mattress and the side of a crib, which poses a suffocation hazard to an infant.

### Assessment of Small Business Impact of the Draft Proposed Rule (Tab F)

CPSC staff believes that most crib mattresses currently available on the market comply with the requirements of the draft proposed rule, or they could easily come into compliance with the draft proposed rule, by making modifications, such as adding a perimeter border wire to the mattress edge, or an anti-sag weight distribution bar to the mattress structure. However, based on a review of more than 300 crib mattress products available for purchase in the United States, staff concludes that a few unique mattress models may fail the test requirements in the draft proposed rule, and that some of these models may be removed from the market without modification. As noted in Tab F, the cost of the third party testing that manufacturers and importers would require to certify compliance with the rule is not likely to be significant, because any additional third party testing costs would likely amount to less than 1 percent of annual revenues for even the smallest suppliers. Consequently, it seems unlikely that the proposed rule will result in a significant impact on a substantial number of small entities. We invite comments, particularly from small businesses, on the cost of making necessary modifications to noncomplying crib mattress models to comply with the draft proposed rule and alternatives that could reduce the burden on small businesses.

### **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 for a final rule on crib mattresses. Barring evidence to the contrary, staff generally considers 6 months 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 the Juvenile Products Manufacturers Association (JPMA) typically allows for products in their certification program to shift to a new standard once that new standard is published. Therefore, juvenile product manufacturers are accustomed to adjusting to new standards within this time. Staff notes that the recommended draft NPR contains additional testing requirements and labeling changes, and that the current global COVID-19 pandemic has affected supply chains. Staff invites comments, particularly from small businesses, regarding the amount of time they will need to come into compliance.

### **VI. Other Recommended Amendments**

### A. Notice of Requirements

Section 14(a) of the 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 children's product safety rules. 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 to which a children's product is subject. A proposed rule for crib mattresses, 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. 16 CFR part 1112 (78 *Fed. Reg.* 15,836 (March 12, 2013)) (referred to here as part 1112). Part 1112, which took effect on June 10, 2013, establishes the requirements for accreditation of third party testing laboratories to test for compliance with a children's product safety rule. Part 1112 also codifies all of 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 mattresses, 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 mattresses in the list of children's product safety rules for which the CPSC has issued NORs.

### **B.** 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 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.

In 2009, the Commission issued a rule, referred to as the "product registration card rule," as required under section 104 (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 mattresses were not included in the statutory list, nor were they included in the Commission's revised list of "durable infant or toddler products" in the 2009 rule. However, the preamble to the product registration card rule stated that the specified statutory categories of durable infant or toddler products are not exhaustive, and that the Commission will explicitly identify the product categories that are covered under the definition of "durable infant or toddler product." 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 *Fed. Reg.* 68,668 (Dec. 29, 2009).

As stated in section I of this memorandum, the president of Keeping Babies Safe (KBS) and the mother of a child who died in an incident involving an after-market mattress, petitioned (CP 15-2) the CPSC, requesting a ban on supplemental mattresses for play yards with non-rigid sides, which are currently marketed to be used with non-full-size cribs, play yards, portable cribs, and play pens. In response to this petition, the Commission directed staff to initiate a 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 crib mattresses, and to amend the consumer registration rule accordingly. The Commission further clarified that the scope of the mandatory rule should include crib mattresses, as well as supplemental and after-market mattresses used in play yards and portable cribs.

In the draft NPR, staff adds "crib mattresses," which includes all mattresses within the scope of ASTM F2933 – 19, including after-market mattresses for play yards and non-full-size cribs, as a

durable infant and toddler product listed in part 1130.<sup>20</sup> Section 104(f)(2) lists 12 categories of products that are included within the definition of "durable infant or toddler product," including four types of infant sleep products: "(A) full-size cribs and non-full-size cribs, (B) toddler beds..., [and] (F) play yards."<sup>21</sup> These four products are all intended for infants and toddlers, used for unsupervised sleep, and are covered by the consumer registration rule. When a mattress is sold with one of these sleep-related products, such as the mattresses required to be sold with a play yard or non-full-size crib, the mattress is subject to a mandatory standard and to the consumer registration rule. However, currently, when a mattress is sold separately from a crib, toddler bed, non-full-size crib, or play yard, the mattress is not subject to a mandatory standard nor to the consumer registration rule, even though it is used in conjunction with a covered product. Updating part 1130 to include crib mattresses will address this inconsistency and address the identified hazards associated with crib mattresses used in regulated infant sleep products.

### VII. Staff Conclusion and Recommendations

Staff recommends that the Commission issue a proposed mandatory rule for crib mattresses, which includes regulations for after-market mattresses for play yards and portable cribs, by incorporating by reference ASTM F2933 – 19, *Standard Consumer Safety Specification for Crib Mattresses*, with modifications to further reduce the risk of injury. Staff recommends that the Commission include the following additional requirements to address:

- Suffocation hazards due to overly soft crib mattresses, by adding a test for mattress firmness based on sections 6 and 8 of AS/NZS 8811.1:2013 Methods of testing infant products Method 1: Sleep Surfaces Test (AS/NZS 8811.1);
- Entrapment hazards
  - Full-size crib mattresses due to poor mattress fit from compression by sheets, by repeating the dimensional conformity test and measuring for corner gaps, after installing a shrunken (by washing twice) cotton sheet;
  - After-market non-full-size crib mattresses due to lack of dimensional requirements for rectangular-shaped products, by extending the dimensional requirements in ASTM F2933-19 section 5.7.2 to all non-full-size crib mattresses, regardless of mattress shape, and regardless of whether the mattress is sold with a non-full-size crib, or as an after-market mattress;
- Laceration hazards due to coils and springs breaking and poking through mattresses, by adding a cyclic test for mattresses that use coil springs; and

<sup>&</sup>lt;sup>20</sup> As discussed in the briefing package for petition CP 15-2, "supplemental mattress" is a term that invites confusion. The term refers to the use-pattern of a product, which could be "supplementing" an existing mattress or "supplementing" the play yard itself. Staff believes that "supplemental" is more descriptive of the use-pattern; whereas, "after-market" is more descriptive of how the mattress is sold, *i.e.*, independent of the play yard or crib in which it is used. In addition, cribs can be either full-size or non-full-size, and either size could be made portable. Therefore, staff concludes that the term "after-market mattress" more clearly indicates any mattress sold independently from a play yard or crib that can be used as a sleeping surface inside the play yard or crib, whether used alone or with the original mattress. In addition, "after-market mattress" is the term defined in ASTM F2933-19 to include mattresses that are sold independently of play yards or non-full-size cribs.

<sup>&</sup>lt;sup>21</sup> Section 104(f)(2)(H) of the CPSIA.

• Marking, labeling, and instructional literature improvements - to provide clarity to manufacturers, test labs, and to better communicate to consumers the risks of SIDS and suffocation related to infant positioning, soft bedding, and gap entrapment.

Staff also recommends updating 16 CFR part 1130 to include "crib mattresses" as a durable infant or toddler product that requires a product registration card, and updating 16 CFR part 1112 to include a Notice of Requirements (NOR) for crib mattresses.

Finally, staff recommends an effective date of 6 months after publication of the final rule to allow time for manufacturers to bring their products into compliance and to arrange for third party testing. CPSC staff continues to work with ASTM to further address all four recommendations in the voluntary standard, and staff requests comments on these issues.

TAB A: Crib Mattress and After-Market Play Yard Mattress-Associated Deaths, and Nonfatal Incidents and Concerns Reported to CPSC (January 1, 2010–March 31, 2020).



#### Memorandum

To:

		Date:	September 30, 2020
To:	Hope Nesteruk, Project Manager, Crib Mattress Team Division of Mechanical and Combustic Directorate for Engineering Sciences	on Engineering,	•
Through:	Stephen Hanway Associate Executive Director, Directorate for Epidemiology		
	Risana Chowdhury Division Director, Division of Hazard Directorate for Epidemiology	Analysis,	
From:	Adam Suchy Mathematical Statistician Division of Hazard Analysis		
Subject:	Crib Mattress and After-Market Play Y	ard Mattress-A	ssociated Deaths, and

Subje Nonfatal Incidents and Concerns Reported to CPSC (January 1, 2010–March 31, 2020).

#### I. Introduction

This memorandum characterizes the number of reported fatalities, and nonfatal incidents and concerns, associated with crib mattresses and after-market play yard mattresses received by CPSC staff. For this memorandum, staff considered reports where: infants were found with their face reportedly in contact with a crib mattress or the crib sheet covering the crib mattress; infants were found in a prone position on a crib mattress, with no mention of the face being obstructed by the mattress or other crib bedding<sup>22</sup>; a crib mattress had fit issues (such as being too small or shrinkage, causing an entrapment hazard); a crib mattress had material, structural integrity, or quality issues (e.g., chemical odor, causing rashes, protruding coils, falling apart, or too soft or flimsy); and a few other miscellaneous issues associated with crib mattresses. All reports include mention of a crib mattress being used in a sleeping environment, such as a crib, play yard, or toddler bed. For the rest of this memorandum, all crib mattresses and after-market play yard mattresses will be collectively referred to as "crib mattresses."

<sup>&</sup>lt;sup>22</sup> Examples of other crib bedding not obstructing the face of an infant in the sleep environment include: bumper pads, blankets, dolls, pillows, sleep positioners, and other unsafe sleep environment factors.

CPSC Hotline: 1-800-638-CPSC(2772) CPSC's Web Site: http://www.cpsc.gov

### **II.** Incident Data<sup>23</sup>

Staff of CPSC's Directorate for Epidemiology, Division of Hazard Analysis (EPHA), searched the Consumer Product Safety Risk Management System<sup>24</sup> (CPSRMS) and the National Electronic Injury Surveillance System (NEISS) for fatalities, incidents, and concerns associated with crib mattresses, reported to have occurred between January 1, 2010 and March 31, 2020. Some of the nonfatal reports described concerns about potential hazards associated with a crib mattress, without an actual incident occurring. Staff initially extracted incident reports and NEISS injury cases using nine product codes, with no other restrictions on the extraction criteria. Staff then reviewed each record to determine whether a report was associated with a crib mattress. Staff searched the following product codes: *playpens and play yards* (1513), *portable cribs* (1529), *bassinets or cradles* (1537), *baby mattresses or pads* (1542), *cribs, nonportable* (1543), *cribs, not specified* (1545), *mattresses, not specified* (4010), *toddler beds* (4082), and a catch-all product code 9101.

Staff identified 21 NEISS cases associated with a crib mattress between January 1, 2010 and March 31, 2020. Because the data did not meet the minimum criteria for reporting an estimate,<sup>25</sup> staff included the 19 NEISS injuries and two NEISS fatalities with the rest of the reported incident data described in this memorandum.

None of the fatal incident reports stated that the fatality had a witness; consequently, each case involves some degree of speculation as to how the incident occurred. Staff found that the incident details are often vague concerning how the infant was positioned when initially found and which additional items present in the crib environment may have been a contributing cause of the fatality. Additionally, staff found that some incidents have conflicting reports from multiple sources describing the details of the fatality. Generally, the cause of death in reports describing a fatal incident were stated as asphyxia, suffocation, or SIDS. CPSC staff categorized the fatal and nonfatal reports into hazard scenarios based on the best available account information.

### III. Results<sup>26</sup>

CPSC staff is aware of 439 reports associated with a crib mattress.<sup>27</sup> Table 1 presents the severity of the reported cases, in order of severity. Of the 439 reports, 116 reports (26 percent) involved a fatality; 15 reports (3 percent) required an infant to receive treatment in the emergency room; and 4 reports (1 percent) required hospital admission. In 199 reports (45

<sup>&</sup>lt;sup>23</sup> Incidents presented in this memorandum represent a minimum for the number of incidents that have occurred during the given timeframe.

<sup>&</sup>lt;sup>24</sup> CPSRMS is the epidemiological database that houses all anecdotal reports of incidents received by CPSC, "external cause"-based death certificates purchased by CPSC, all in-depth investigations of these anecdotal reports, as well as investigations of select NEISS injuries. Examples of documents in CPSRMS are: hotline reports, Internet reports, news reports, medical examiner's reports, death certificates, retailer/manufacturer reports, and documents sent by state/local authorities, among others.

<sup>&</sup>lt;sup>25</sup> NEISS estimates are reportable, provided the sample count is greater than 20, the national estimate is 1,200 or greater, and the coefficient of variation (CV) is less than 0.33.

<sup>&</sup>lt;sup>26</sup> Percentages in tables may not sum to 100 percent due to rounding.

<sup>&</sup>lt;sup>27</sup> Of the 439 reports, 21 were from the NEISS.

percent), there were incidents that resulted in no injuries; and in 16 reports (4 percent), there were no actual incidents or injuries. In the incident reports with no injuries reported, staff observed that, generally, caregivers intervened once they identified a problem with the crib mattress, and the mattress was no longer used after the caregiver identified the hazard. Staff does not know the level of care infants received in 66 reports (15 percent), and staff does not know whether an injury occurred in 13 reports (3 percent).

Severity	Number of Reports	%
Fatalities	116	26%
Emergency Department Treatment Received	15	3%
Hospital Admission	4	1%
Seen by Medical Professional	1	<1%
First Aid Received by Non-Medical Professional	1	<1%
Level of care not known	66	15%
Incident, No Injury	199	45%
No First Aid or Medical Attention Received	8	2%
No Incident, No Injury	16	4%
Unspecified	13	3%
Total	439	100%

 Table 1: Reports Associated with Crib Mattresses by Severity

 January 1, 2010–March 31, 2020

Source: CPSRMS and NEISS databases

Reporting is ongoing; 2018–2020 are considered incomplete.

CPSC staff is aware of 116 reported deaths and 323 nonfatal incidents and concerns associated with crib mattresses that were reported to have occurred between January 1, 2010 and March 31, 2020. Table 2 presents hazard categories, which are further defined in the *Fatal Reports* and *Reported Nonfatal Incidents and Concerns* sections below.

Table 2: Fatal and Nonfatal Reports Associated with Crib Mattresses by Hazard Category
January 1, 2010–March 31, 2020

Hazard Category	Fatal Reports	Nonfatal Reports	Total Reports
Chemical/Flammability	0	23	23
Coil or Spring	0	124	124
Crib Mattress Used in a Play Yard	2	1	3
Expand or Inflate	0	6	6
Face in Mattress	13	1	14
Fit Issues	20	88	108
Found Prone	66	3	69
Mattress Falls Apart	0	18	18
Softness	0	36	36
Multiple Contributing Factors (MCF)	15	17	32
Other	0	6	6
Total	116	323	439

*Source:* CPSRMS and NEISS databases Reporting is ongoing; 2018–2020 are considered incomplete.

### A. Fatal Reports

CPSC staff is aware of 116 reported deaths associated with crib mattresses that were reported to have occurred between January 1, 2010 and March 31, 2020. Table 3 presents hazard categories.

 Table 3: Reported Fatalities Associated with Crib Mattresses by Hazard Category

 January 1, 2010–March 31, 2020

Hazard Category	Reported Deaths	%
Crib Mattress Used in a Play Yard	2	2%
Face in Mattress	13	11%
Fit Issues	20	17%
Found Prone	66	57%
Multiple Contributing Factors (MCF)	15	13%
Total	116	100%

Source: CPSRMS and NEISS databases

Reporting is ongoing; 2018–2020 are considered incomplete.

- 1. *Crib Mattress Used in a Play Yard*: Two percent of the fatalities involved use of a crib mattress in a play yard (2 out of 116). Reports state that infants were found wedged between the crib mattress and the mesh of the play yard, due to the crib mattress not fitting snugly in the play yard.
- 2. *Face in Mattress*: Eleven percent (13 out of 116) of fatalities were associated with the face of an infant, when found, reportedly in contact with a crib mattress or crib sheet covering the crib mattress. Based on the available information about each fatality, bedding was present in the sleeping environment in some of these reports, but bedding was not touching the infant, nor did staff determine that the bedding was a contributing factor in the death.
- 3. *Fit Issues*: Seventeen percent (20 out of 116) of fatalities involved issues with the fit of a crib mattress in the sleeping environment. In all of these fatalities, the infants became wedged in gaps between at least one of the sides of a crib mattress and the crib rails or play yard mesh.
- 4. *Found Prone*: Fifty-seven percent (66 out of 116) of fatalities involved an infant found in a prone position with no mention of whether the face of the child was in contact with the crib mattress or crib sheet, and no mention of the face being obstructed by other crib bedding, or other items in the sleep environment. Given the available information about each fatality, bedding was present in the sleeping environment in some of these reports, but staff did not determine that bedding was a contributing factor in the deaths.
- 5. *Multiple Contributing Factors (MCF)*: Thirteen percent (15 out of 116) of fatalities involved multiple factors that potentially played a role in the fatality, and the crib mattress was likely one of the contributing factors. Examples of other contributing factors are entrapment between the mattress and bumper pads, entrapment between the mattress

and a crib rail with limb entrapment, usage of a swaddle, sharing of the sleep environment with another infant, and congenital or recent health conditions.

Figure 1 displays the ages, in months, of reported deaths associated with crib mattresses for each hazard category. The oldest fatalities were: one, 3-year-old, and two, 2-year-old children. Staff observed considerably more reported prone fatalities between the ages of 1 and 5-months-old, and most of the deaths in the fit, face in mattress, and MCF hazard categories involved infants between the ages of 1 and 8-months-old, compared to other ages.



### Figure 1: Reported Fatalities Associated with Crib Mattresses by Age and Hazard Category

Source: CPSRMS and NEISS databases Reporting is ongoing; 2018–2020 are considered incomplete.

Of the 116 reported fatalities associated with crib mattresses, 74 deaths (64 percent) were male and 42 deaths (36 percent) were female. Staff identified the age and gender of the infant in every reported fatality.

### **B.** Nonfatal Incidents and Concerns

CPSC staff is aware of 323 reported nonfatal incidents and concerns associated with crib mattresses that were reported to have occurred between January 1, 2010 and March 31, 2020. Table 4 presents the hazard categories associated with nonfatal crib mattress reports.

Hazard Category	Nonfatal Reports	%				
Chemical/Flammability	23	7%				
Coil or Spring	124	38%				
Crib Mattress Used in a Play Yard	1	<1%				
Expand or Inflate	6	2%				
Face in Mattress	1	<1%				
Fit Issues	88	27%				
Found Prone	3	1%				
Mattress Falls Apart	18	6%				
Softness	36	11%				
Multiple Contributing Factors (MCF)	17	5%				
Other	6	2%				
Total	323	100%				

 Table 4: Nonfatal Reports Associated with Crib Mattresses by Hazard Category

 January 1, 2010 – March 31, 2020

Source: CPSRMS and NEISS databases

Reporting is ongoing; 2018–2020 are considered incomplete.

- 1. *Chemical/Flammability*: Seven percent (23 out of 323) of the nonfatal incidents reported a crib mattress having a chemical odor (5), causing rashes (7), or not meeting mandatory federal flammability standards (11). Infants were reported to have suffered from rashes and upper respiratory issues.
- 2. *Coil or Spring*: Thirty-eight percent (124 out of 323) of nonfatal incidents involved a coil or spring found protruding through the crib mattress. A 2-year-old received two stitches in the hospital emergency department for a laceration injury. Another 2-year-old with a toe laceration was treated and released from the hospital emergency department.
- 3. *Crib Mattress Used in a Play Yard*: Less than 1 percent (1 out of 323) of nonfatal incidents involved an infant's back being scratched by protruding coils or springs of a crib mattress being used in a play yard.
- 4. *Expand or Inflate*: Two percent (6 out of 323) of nonfatal incidents involved a crib mattress that failed to expand or inflate properly. Staff identified related hazards, including fit issues with gaps appearing around the crib mattress causing entrapment or wedging, and an uneven crib mattress that may cause an infant to roll over.
- 5. *Face in Mattress*: Less than 1 percent (1 out of 323) of nonfatal incidents involved an infant found limp, pale, and with blue around the lips while face down in contact with a crib mattress. Staff found no other details about the sleep environment in this incident. The 1-month-old infant was admitted to the hospital.
- 6. *Fit Issue*: Twenty-seven percent (88 out of 323) of nonfatal incidents involved issues with the fit of a crib mattress in the sleeping environment. In all of these reports, staff determined that gaps were present on one or more sides around the perimeter of a crib

mattress, creating wedging or entrapment hazard between the crib mattress and the crib rails or play yard mesh. A 3-month-old went into cardiac arrest and was admitted to the hospital after being found between a crib mattress and a crib frame. Six children between the ages of 6 months old and 2 years old, and a 10-year-old with Rett syndrome,<sup>28</sup> were treated and released from the hospital emergency department due to entrapment between a crib mattress and crib rails, and sustaining injuries, such as: an arm or leg fracture, a mid-back injury, a foot injury, lip hematoma, and a nursemaid's elbow.

- 7. *Found Prone*: One percent (3 out of 323) of nonfatal incidents involved an infant found in a prone position without any mention of the face being in contact with the mattress or crib sheet, and no mention of the face being obstructed by other crib bedding or other items in the sleep environment. Staff found no other details about the sleep environment in any of these three reported incidents. Among these three infants, an 8-month-old was admitted to the hospital after being found breathing poorly; and two infants received treatment in the emergency department: a 4-month-old was found breathing poorly, and a 1-month-old was found not breathing, while vomiting and choking.
- 8. *Mattress Falls Apart*: Six percent (18 out of 323) of nonfatal incidents involved part of a crib mattress coming apart. In most of these reports, the seams of the mattress unraveled, causing: a strangulation hazard due to the stitching of the mattress being exposed; and a choking or ingestion hazard due to the inner filling coming out of the mattress in small pieces and into the sleep environment. Examples of reported small pieces of a crib mattress filling that came apart are fibers, string, or wool. Staff found that in six incidents, string from crib mattress seams or piping was found wrapped around the neck of the infant, which could have led to a serious outcome if the child was not found in time. One incident involved an infant choking on a plastic piece of 'shredded' crib mattress, and 1 incident involved a 2-year-old who was treated and released from the hospital emergency department due to ingesting plastic pieces of a crib mattress.
- 9. *Softness*: Eleven percent (36 out of 323) of nonfatal incidents involved a crib mattress inner cushioning that was reportedly too soft. Staff found 17 reports of depressions or indentations in the crib mattress, accompanied by the following descriptions: "bunches up/squishy," "depression/dips/indentation/sinks in/sunken," and "deflates/like an air mattress not fully inflated." Twelve reports describe a crib sheet being placed on a crib mattress and causing the mattress to bend or bow, resulting in a gap or fit issue between the mattress and crib rails, creating an entrapment hazard. Four reports claim that a crib mattress is not breathable. Three reports allege that a crib mattress is too thin and that the inner cushioning is too soft.
- 10. *Multiple Contributing Factors (MCF)*: Five percent (17 out of 323) of nonfatal incidents involved multiple factors that played a role, of which the crib mattress was likely one

<sup>&</sup>lt;sup>28</sup> According to https://www.rettsyndrome.org, "Rett syndrome is a rare genetic neurological disorder that occurs almost exclusively in girls and leads to severe impairments, affecting nearly every aspect of the child's life: their ability to speak, walk, eat, and even breathe easily. The hallmark of Rett syndrome is near constant repetitive hand movements. Rett syndrome is usually recognized in children between 6 to 18 months as they begin to miss developmental milestones or lose abilities they had gained."

factor. Staff found that in 10 reports, an infant was found wedged between a crib mattress and the crib rail, while an arm, leg, or foot was caught in between the slats of the crib. Additionally, one infant in a sleep sack was found face down while reportedly attempting to turn over, and another child was found face down in a crib while having a seizure. Among the most serious injuries reported were two children who were treated and released from the hospital emergency department: a 5-month-old received a leg fracture after becoming entrapped under a crib mattress while also having an arm caught between the slats of the crib, and an 18-month-old was found face down on a crib mattress while having a seizure.

11. Other: Two percent (6 out of 323) of nonfatal incidents involved miscellaneous other issues associated with a crib mattress. Reports in this category include: a blade found in a crib mattress; an infant's arm was "tangled in a crib mattress"; an infant "slipped on a crib mattress," causing a slat entrapment; an infant's arm became "stuck on a crib mattress"; a crib mattress had a loose plastic bag for a cover; and a concern about crib mattresses not having proper warning labels to direct caregivers to place infants on their backs when putting them down in a crib. The 7-month-old infant who was "tangled in a crib mattress" was admitted to the hospital due to a leg fracture. The 9-month-old who was "stuck on a crib mattress" was treated and released from the hospital emergency department due to a nursemaid's elbow.

The hazard categories with the most reported nonfatal incidents associated with crib mattresses are issues with coils or springs, and crib mattresses that do not fit properly in the sleep environment. Figure 2 presents the number of reported nonfatal incidents from each year. In the most recent 2 years, from January 2018 to March 2020, staff observed fewer nonfatal reports of coil or spring issues associated with crib mattresses, compared to years 2014–2017. Eighty-nine percent (78 out of 88 nonfatal reports) of nonfatal reports involving fit issues occurred between 2010 and 2015.





*Source:* CPSRMS and NEISS databases Reporting is ongoing; 2018–2020 are considered incomplete. TAB B: Mechanical Engineering Assessment of the Adequacy of ASTM F2933-19 to Address Hazards Associated with Crib Mattresses Intended for Full-Size Cribs, Non-Full-Size Cribs, and After-Market Mattresses for Play Yards and Non-Full-Size Cribs

## T A B B



UNITED STATES CONSUMER PRODUCT SAFETY COMMISSION 4330 East West Highway Bethesda, Maryland 20814

### Memorandum

DATE: September 30, 2020

- TO: Hope E J. Nesteruk Crib Mattress 104 Project Manager Directorate for Engineering Sciences
- THROUGH: Andrew Stadnik Associate Executive Director, Directorate for Laboratory Sciences

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

FROM: Maxwell Sanborn Mechanical Engineer Directorate for Laboratory Sciences

> Daniel Taxier Mechanical Engineer Directorate for Engineering Sciences

SUBJECT: Mechanical Engineering Assessment of the Adequacy of ASTM F2933-19 to Address Hazards Associated with Crib Mattresses Intended for Full-Size Cribs, Non-Full-Size Cribs, and After-Market Mattresses for Play Yards and Non-Full-Size Cribs

### I. INTRODUCTION

Pursuant to section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), staff of the U.S. Consumer Product Safety Commission (CPSC, or Commission) is preparing a briefing packaging recommending that the Commission issue a notice of proposed rulemaking (NPR) to establish a mandatory standard for crib mattresses, including crib mattresses intended for use with full-size cribs, non-full-size cribs, and after-market mattresses for play yards and non-full-size cribs (collectively crib mattresses). This memorandum assesses the effectiveness of ASTM F2933-19, *Standard Consumer Safety Specification for Crib Mattresses* (ASTM F2933-19) to address hazards associated with crib mattresses, and recommends that the Commission issue an NPR proposing to incorporate by reference the voluntary standard ASTM F2933-19 as

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the mandatory standard, with the addition of tests to address entrapment hazards, excessive surface softness, and laceration hazards due to exposure to coil springs, and modifications to ensure that all non-full-size crib mattresses are subject to a dimensional performance requirement.

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 list of products in section 104(f)(2) does not include crib mattresses (16 CFR § 1130.2(a)(5)). However, in response to petition CP 15-2: petition requesting rulemaking on supplemental mattresses for play yards with non-rigid sides, the Commission voted<sup>29</sup> to "Take Other Action," granting the petition, and directing staff to being a rulemaking under section 104 of the CPSIA for crib mattresses, as well as for supplemental and after-market mattresses used in play yards and portable cribs.

To examine and assess the effectiveness of the relevant voluntary standards, 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. CPSC staff regularly participates in the juvenile products subcommittee meetings of ASTM International (ASTM). ASTM subcommittees consist of members who represent producers, users, consumers, government, and academia. <sup>30</sup> The consultation process for this rulemaking commenced during the ASTM subcommittee meeting in May 2018, when staff presented their initial recommendations for updating the crib mattress voluntary standard to address the incident data. Since then, staff has actively participated with the ASTM F15.66 subcommittee for Crib Mattresses in revising ASTM F2933-19 to address the associated hazards.

Staff recommends incorporating by reference the voluntary standard ASTM F2933-19 as the mandatory standard for crib mattresses, with modifications. To further reduce the risk of injury associated with crib mattresses, staff recommends that the draft NPR include the following additional tests to address entrapment hazards, excessive surface softness, and laceration hazards due to exposure to coil springs:

- Compression Test: This test involves placing a fitted sheet on a full-size crib mattress and measuring the gap between its corners and the walls of a test fixture box. This test would address hazardous gaps created between the edge of a crib and a full-size crib mattress due to mattress compression; when mattresses are too soft, compression, such as from a crib mattress sheet, may create large corner gaps, posing an entrapment hazard.
- Firmness Test: The test addresses excessively soft mattress surfaces for all crib mattresses within the scope of the standard that could indent and conform to an infant's face and become an asphyxiation hazard. Staff proposed adding a test for mattress firmness based on sections 6 and 8 of Australian/New Zealand Standard 8811.1:2013 *Methods of testing infant products* (AS/NZS 8811.1:2013).

<sup>&</sup>lt;sup>29</sup> <u>https://www.cpsc.gov/s3fs-public/RCA-Petition\_CP\_15-</u>

<sup>2</sup> Requesting Ban on Supplemental Mattresses for Play Yards with Non-Rigid Sides 052517.pdf

<sup>&</sup>lt;sup>30</sup> ASTM International website: www.astm.org, About ASTM International.

• Cyclic Loading Test: This test addresses lacerations associated with exposed coil springs for all mattresses that use coil springs, by dropping a 30-lb test mass 250 times in each of four locations on a test mattress.

Additionally, staff recommends a modification so that the dimensional requirements for non-fullsize crib mattresses in section 5.7 of ASTM F2933-19 will apply to all non-full-size crib mattresses, regardless of whether the non-full-size crib mattress is sold as an as an original equipment manufacturer (OEM) mattress, or as an after-market mattress, and regardless of whether the mattress is rectangular or non-rectangular in shape.

### II. BACKGROUND ON ASTM F2933

### A. The Product

ASTM F2933-19 provides performance and labeling standards for mattresses intended for fullsize cribs, non-full-size cribs, and after-market mattresses for play yards and non-full-size cribs. Although non-full-size crib mattresses that are supplied with a non-full-size crib OEM have requirements in both ASTM F406 and ASTM F2933, OEM play yard mattresses are covered only in ASTM F406, and after-market play yard mattresses are covered only by ASTM F2933. Staff provides Chart 1 to illustrate the interrelationship of these standards with respect to mattresses for play yard and non-full-size cribs. Chart 1 presents the types of crib mattresses covered by the voluntary standard, the current dimensional requirements for each mattress type (marked with a "C"), and staff's recommended changes to dimensional requirements in ASTM F2933-19 (marked with an "N").

			Full- Size cribs	Play Yards Rectangular NFS cribs		Non-Rectangular NFS cribs			
			All	OEM*	After- market	OEM*	After- market	OEM*	After- market
ASTM F2933 - 19	Crib Mattresses	5.7.1.1	С						
NPR	Crib Mattresses	Sheet Compression Test	Ν						
16 CFR Part 1221/ASTM F406	Play Yards	5.16.2	-	С					
16 CFR Part 1220/ASTM F406	Non-Full- Size Cribs	5.17				С		С	
ASTM F2933 - 19	Crib Mattresses	5.7.2				С	Ν	С	Ν
ASTM F2933 - 19	Crib Mattresses	5.9.1			C**				С

# Chart 1: Dimensional Requirements for Mattresses Used in Full-Size Cribs, Play yard, Portable Cribs, and Other Non-Full-Size (NFS) Cribs

\* Includes "replacement mattresses," which are assumed to be sold by an original equipment manufacturer (OEM) and equivalent in dimension and specification to the original mattress (*see* ASTM F2933 – 19 section 3.1.1.1). \*\* After-market play yard mattresses that are also used in a bassinet attachment to that play yard must also meet ASTM F2194, for bassinets

ASTM F2933-19 defines a "mattress" as ticking filled with a resilient material used alone or in combination with other products intended or promoted for sleeping on it. ASTM F2933-19 also defines an "after-market mattress for play yard or non-full-size crib" as a mattress sold or distributed for a play yard or non-full-sized crib.

### B. Revision History of ASTM F2933, Standard Consumer Safety Specification for Crib Mattresses

The ASTM Committee F15 on Consumer Products first published the voluntary standard for crib mattresses in 2013, as ASTM F2933-13, *Standard Consumer Safety Specification for Crib Mattresses*. The first publication established requirements for the standard and addressed the following issues:

- Sharp points and sharp edges,<sup>31</sup>
- Small parts,
- Lead and other toxic substances in paints,
- Finger entrapment,
- Mattress dimension conformity,
- Mattress thickness, and
- Marking and labeling.

Since 2013, ASTM has revised and updated the voluntary standard three times to address safety issues, as outlined below:

### ASTM F2933-16 (approved 12/1/2016):

• Revised warning label permanency requirements in 5.6.1 to include requirement that "[n]on-coated paper warning label shall not be applied on either side of sleeping surface." Added a note under this section, stating that non-coated paper label may absorb water and can deteriorate.

ASTM F2933-18 (approved 8/15/2018):

- Revised scope to include a new section 1.5, stating the standard was developed in accordance with internationally recognized principles on standardization.
- Added definition of "after-market mattress for play yard or non-full-size crib," to section 3, Terminology.

<sup>&</sup>lt;sup>31</sup> Tapered ends that do not meet the requirements of 16 CFR § 1500.48 and metal or glass tapered surfaces that do not meet the requirements of 16 CFR § 1500.49

- Added a new requirement for after-market mattresses for play yards and non-full-size crib mattresses in section 5, General Requirements, stating that after-market mattresses for soft-sided and non-rectangular, rigid-sided products shall have the same thickness, floor support structure, and attachment method as the mattress it is intended to replace and shall meet the specifications of Mattress Vertical Displacement test from ASTM F406-19, *Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards*.
- Added additional marking and labeling requirements for after-market mattresses in sections 7.5 through 7.7. To comply with these sections, after-market mattresses and their retail packaging shall include specified suffocation warning language related to hazardous gaps and stacked mattresses. Sections 7.5 and 7.6 have additional requirements that distinguish between types of products. Section 7.5 has requirements specific to mesh/fabric-sided and rigid-sided, non-rectangular products, including as follows: after-market mattresses shall have all the warnings that the original manufacturer had and provide instructions that are on the original mattress, and both the after-market mattress and the retail packaging shall identify the brand and model numbers of products in which it is intended to be used. Section 7.6 has requirements specific to rigid sided rectangular products including as follows: after-market mattresses and their retail packaging shall have a specified statement regarding mattress dimensions and fit.

ASTM F2933-19 (approved 6/15/2019):

- Added a new requirement for mattress seam stitching in section 5, General Requirements, requiring that all seam stitching that is accessible to the occupant be lock stitching.
- C. ASTM F2933-19 Requirements

In addition to the general requirements typically found in other ASTM juvenile product standards, such as requirements for openings, label permanency, and the prohibition of sharp points/edges, small parts, and lead in paints, section 5 of ASTM F2933-19 contains the following four additional requirements that apply specifically to mattresses for cribs, non-full-size-cribs, and to after-market mattresses for non-full-size cribs and play yards:

- § 5.7 *Mattress Dimensions*: This section describes the dimensional requirements for fullsize crib mattresses, and for non-full-size crib mattresses that are supplied with a nonfull-size crib, to prevent an infant from becoming wedged in a gap caused by a too small crib mattress. To ensure the crib mattress dimensions are within the allowable range, the test requires a mattress to be placed in a test box and pushed against the side of the box with a force prescribed in the test method.
- § 5.7.2.2 Mattress Thickness: This requirement only applies to non-full-size crib mattresses supplied with a non-full-size crib, to prevent occupants from falling out of the product. The requirement states that a mattress supplied with a non-full-size crib shall have a thickness that will provide a minimum effective crib-side height dimension of at least 20 inches when the crib side is in its highest adjustable position and the mattress

support is in its lowest adjustable position. Additionally, the mattress shall have a thickness that will provide a minimum effective crib-side height dimension of at least 3 inches when the crib side is in its lowest adjustable position, and the mattress support is in its highest adjustable position.

- § 5.8 Mattress Seam Stitching: This requirement applies to all crib mattresses within the scope of the standard and states that all seam stitching that is accessible to the occupant be lock stitching to prevent accessible stitching from becoming loose and creating a small part or strangulation hazard.
- § 5.9 After-Market Mattress for Play Yards and Non-Full-Size Cribs: This requirement is for after-market mattresses for play yards and non-full-size cribs, stating that after-market mattresses for soft-sided and non-rectangular, rigid-sided products must have the same thickness, floor support structure, and attachment method as the mattress it is intended to replace. Accordingly, these after-market mattresses must be identical to the OEM mattress. Requirements for OEM mattresses sold with play yards and non-full-size cribs are codified at 16 CFR parts 1220 (non-full-size cribs) and 1221 (play yards), which incorporate by reference ASTM F406, *Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards* (ASTM F406). After-market mattresses must also meet the Mattress Vertical Displacement test in ASTM F406.<sup>32</sup>

### III. ADEQUACY OF ASTM F2933-19 REQUIREMENTS TO ADDRESS ASSOCIATED HAZARDS

Below staff evaluates whether and how ASTM F2933-19 addresses each identified hazard pattern. CPSC's Directorate for Epidemiology, Division of Hazard Analysis (EPHA) staff searched the Consumer Product Safety Risk Management System (CPSRMS) database and the National Electronic Injury Surveillance System (NEISS) database for reported fatalities, incidents, and concerns associated with crib mattresses that occurred between January 1, 2010 and March 31, 2020. Staff found 439 incidents reported during this time. From these incidents, staff identified a number of hazard patterns associated with crib mattresses. Table 1 summarizes the staff-identified hazard patterns and how ASTM F2933-19 addresses each.

<sup>&</sup>lt;sup>32</sup> The purpose of requiring after-market mattresses to be identical to OEM mattresses is to reduce the risk of infant entrapment and suffocation associated with after-market mattresses that are too thick, or that do not fit correctly or attach to a play yard or non-full-size crib. ASTM developed this requirement in collaboration with CPSC staff and the ASTM Play Yard Vertical Displacement Task Group and the Play Yard Mattress Fit and Thickness Task Group.

			Staff	
		How Addressed	assessment	
	Applicable	in ASTM F2933	of	
Hazard Pattern	Mattresses	- 19	adequacy	Staff Comments
Chemical/ Flammability Hazards (odors, rash)	All	16 CFR part 1303 Ban of Lead- Containing Paint 16 CFR part 1500 Hazardous Substances Act Regulations (Sections 5.1 and 5.4) 16 CFR part 1632 Standard for the Flammability of Mattresses and Mattress Pads 16 CFR part 1633 Standard for the Flammability (Open Flame) of Mattress Sets	Adequate	
Coil or Spring (laceration)	Coil or spring mattresses (primarily full-size)	Prohibition of sharp points (Section 5.2)	Inadequate	Recommend additional cyclic testing to identify potential for springs to break through surface during foreseeable use and misuse.
Crib Mattress Used in a Play Yard (suffocation due to ill-fitting mattress)	Aftermarket play yard mattresses	Labeling requirements, requirements for after-market mattresses. Testing requirements harmonized with ASTM F406. (Section 7.5)	Adequate	
Expand or Inflate (suffocation due to ill- fitting mattress that does not expand or inflate properly)	Foam products, typically full- size and shipped as "bed in a box"	Dimensional conformity, mattress thickness, and labeling requirements (Section 5.7)	Adequate	This hazard is adequately addressed with F2933's dimensional conformity and mattress thickness.

### Table 1. Staff Assessment of ASTM F2933-19 to Address Identified Hazard Patterns

	Applicable	How Addressed in ASTM F2933	Staff assessment of	
Hazard Pattern Face in Mattress (suffocation)	Mattresses All	- 19 Labeling requirements (Section 7.3)	adequacy Inadequate See also ESHF memo (Tab C)	Staff CommentsRecommend a testbased on sections 6and 8 of AS/NZS8811.1 firmness test.
Fit Issues (suffocation due to ill-fitting mattress)	All	Dimensional conformity and after-market mattress requirements (Sections 5.7 and 5.9)	Inadequate	Recommend additional fitted sheet compression test for full-size mattresses and extending dimensional requirements in section 5.7 to all after- market non-full-size crib mattresses.
Found Prone (suffocation due to prone position)	All	Labeling requirements (Section 7.3)	Inadequate See also ESHF memo (Tab C)	Recommend a test based on sections 6 and 8 of AS/NZS 8811.1 firmness test.
Mattress Falls Apart (choking/ingestion)	All	Mattress seam stitching requirement and small parts prohibition (Sections 5.3 and 5.8)	Adequate	
Softness (suffocation due to soft surface)	All	Not addressed	Inadequate	Recommend a test based on sections 6 and 8 of AS/NZS 8811.1 firmness test.
Multiple Contributing Factors (MCF) ( <i>e.g.</i> , entrapment in bumper pads, limb entrapment, crib sharing with another infant, existing health condition)	All	General requirements and warning labels (Sections 5.7 and 7.3)	Inadequate	Some of these contributing factors are addressed by staff's recommended additional requirements described above, while others are related to another product use or other factor out of the scope of the crib mattresses standard.

The following subsections discuss the hazards specific to crib mattresses within the scope of ASTM F2933-19.

### A. Hazard Pattern – Chemical/Flammability Hazards

Seven percent (23 out of 323) of the nonfatal incidents reported a crib mattress having a chemical odor (5), causing rashes (7), or not meeting mandatory federal flammability standards (11). Reports describe infants suffering from rashes and upper respiratory issues. ASTM F2933-19 general requirements section addresses these hazards with the inclusion of 16 CFR part 1632 *Standard for the Flammability of Mattresses and Mattress Pads*, 16 CFR part 1633 *Standard for the Flammability (Open Flame) of Mattress Sets*, and 16 CFR part 1303 *Ban of Lead-Containing Paint and Certain Consumer Products Bearing Lead-Containing Paint*.

### B. Hazard Pattern – Coil or Spring

Potential laceration hazards due to an exposed coil or spring account for 28 percent (124 of the 439) of the incident reports. ASTM F2933-19 addresses this hazard by prohibiting sharp points. However, due to the number of incidents (38% of nonfatal incidents), staff recommends strengthening the standard with a cyclic impact test, discussed in Section V of this memorandum, which entails dropping a 30-lb. test mass 250 times in four locations on a test mattress.

### C. Hazard Pattern – Crib Mattress Used in a Play yard

Two deaths and one nonfatal incident are associated with using a crib mattress in a play yard. The two reported deaths were associated with the use of a crib mattresses that did not fit properly in a play yard. ASTM F2933-19 addresses this hazard with warning label requirements, and additionally, newer requirements that after-market play yard mattresses must meet the same requirements as OEM mattresses. This requirement was approved by the ASTM Crib Mattress Subcommittee in August 2018, and ASTM published the revision in September 2018. Staff concludes that these additions will increase the availability of properly fitting, after-market mattresses, and reduce the likelihood of caregivers using an ill-fitting crib mattress in a play yard.

The nonfatal incident involved scratches on an infant's back caused by protruding coils or springs of the crib mattress. Staff recommends addressing the coil or spring hazard, as described in section B above.

### D. Hazard Pattern – Expand or Inflate

In six of the 439 reported incidents, a crib mattress failed to expand or inflate properly. This can happen when a mattress is tightly rolled up for shipping or packaging purposes, and then does not completely decompress. Related hazards include fit issues with gaps appearing around the crib mattress, causing entrapment or wedging, and an uneven crib mattress that may cause an infant to roll over. Although this hazard is adequately addressed with F2933's dimensional conformity and mattress thickness requirements, staff assesses that the additional proposed mattress compression test, detailed in Section V, will strengthen the proposed standard and further reduce injuries associated with the failure of a mattress to expand or inflate fully to prevent hazardous gaps.

### E. Hazard Pattern – Face in Mattress

Thirteen fatal and one nonfatal incident are associated with an infant found face down on a crib mattress. The nonfatal incident involved an infant found limp, pale, and with blue around the lips, while face down, reportedly in contact with a crib mattress. ASTM F2933 does not address this hazard pattern. The Human Factors assessment in Tab C provides strengthened warning label recommendations to address this hazard pattern.

### F. Hazard Pattern – Fit issues

Fit issues are associated with 108 of 439 reported incidents, 20 of which were fatal, and 88 were nonfatal. In these reports, gaps between the crib mattress and the crib rail or play yard mesh, on one or more sides around the perimeter of a crib mattress, created a wedging or entrapment hazard. ASTM F2933-19 contains a mattress dimensional conformity test intended to address this hazard. However, staff found from visual inspection and measurement of mattresses tested, that tight-fitting sheets over crib mattresses can create gaps between the corners of the mattress and the interior corner of the crib, creating an entrapment hazard, as seen in Photo 1. Accordingly, staff concludes that ASTM F2933-19 does not adequately address entrapment hazards between the crib mattress and the side of a crib or play yard. To strengthen the standard, staff proposes to add a test, discussed in Section V, to the draft proposed rule to address the fit issues caused by a tight-fitting sheet.



Photo 1. Reenactment of a head entrapment in a corner gap. Source: CPSC in-depth investigation

ASTM F2933-19 also includes provisions to address fit issues with after-market mattresses for play yards and non-rectangular, non-full-size cribs. These provisions require that products have the same, within 0.25 inch, thickness floor support structure and attachment method as the mattress it is intended to replace; and that the after-market mattress meet the specifications of the *Mattress, Mattresses for Rigid-Sided Products and Mattress Vertical Displacement* sections of ASTM F406.

As detailed in section VI below, the dimensional requirements for after-market non-full-size crib mattresses in section 5.9 of ASTM F2933 – 19 currently only apply to non-rectangular, non-full-size crib mattresses, and the dimensional requirements in section 5.7 of the standard only apply to OEM non-full-size crib mattresses. Although labeling requirements in section 7 of the standard apply to all non-full-size crib mattresses, regardless of shape or, whether they are aftermarket or OEM, ASTM F2933 – 19 contains no dimensional requirements that apply to aftermarket, rectangular, non-full-size crib mattresses. For the draft NPR, to address this gap in the standard, staff recommends modifying section 5.7 to expand the dimensional requirements to all after-market, non-full-size crib mattresses, regardless of shape. Staff also recommends modifying section 5.9 of ASTM F2933 – 19, to remove non-full-size cribs from that section, and to clarify requirements for after-market play yard mattresses.

### G. Hazard Pattern – Found Prone

Sixty-six fatal and three nonfatal incidents are associated with infants found in a prone position on a crib mattress, without any mention of the face being in contact with the mattress or crib sheet, and no mention of the face being obstructed by other crib bedding or other items in the sleep environment. ASTM F2933 – 19 does not address this hazard pattern with a performance test; however, it does address it with warning labels. The Human Factors assessment in Tab C provides warning label recommendations to strengthen the standard to address this hazard pattern.

### H. Hazard Pattern – Mattress Falling Apart

Eighteen nonfatal incidents are associated with mattresses falling apart. In most of these reports, the seams of the mattresses unraveled, causing a strangulation hazard because the thread or cord used for stitching the mattress was exposed. This failure also resulted in a choking or ingestion hazard because the inner filling came out of the mattress in small pieces and into the sleep environment of the crib. ASTM F2933 adequately addresses this hazard with a mattress seamstitching requirement and small parts prohibition.

### I. Hazard Pattern–Softness

Thirty-six nonfatal incidents are associated with mattress softness. Mattress softness hazards include depressions or indentations found in the crib mattress that could increase the risk of asphyxia. Eleven of these 36 incidents relate to bending, buckling, or mattress compression occurring when a crib sheet was placed on a mattress, shrinking the mattress, and creating an entrapment hazard. ASTM F2933-19 does not address firmness or softness hazards; nor does it address mattress buckling. However, other international standards, Australian/New Zealand Standard (AS/NZS) 8811.1:2013, and EN 16890, both address mattress firmness. Staff recommends adding a fitted-sheet test to the NPR that would address the bending or buckling incidents, as well as including a mattress firmness test, based on the AS/NZS 8811.1:2013 – Methods of testing infant products – Method 1: Sleep Surfaces – Test, to address mattress softness. Staff's recommended firmness test based on the AS/NZS standard addresses the hazard
using an internationally recognized standard and harmonizes with requirements proposed in the recent NPR for Crib Bumpers<sup>33</sup>.

#### J. Hazard Pattern – Multiple Contributing Factors

Multiple contributing factors accounted for 32 of the 439 incidents reported, including 15 fatal and 17 nonfatal incidents. Examples of contributing factors are: entrapment between the mattress and crib bumper pads, limb entrapment between the mattress and a crib rail, crib occupant usage of a swaddle, sharing of the crib with another infant, and congenital or recent health conditions of infants. ASTM F2933 adequately addresses these hazards in the general requirements sections. ASTM F2933 also addresses these hazards with safety requirements, but those are inadequate. Tab C outlines the human factors assessment of the requirements for safety information with staff-recommended modifications.

# IV. INTERNATIONAL STANDARDS

CPSC staff identified two international voluntary standards pertaining to crib mattresses:

- BS EN 16890:2017 Children's Furniture Mattresses for cots and cribs Safety requirements and test methods (BS EN 16890); and
- Australian/New Zealand Standard 8811.1:2013 Methods of testing infant products (AS/NZS 8811.1).

Additionally, staff found a draft standard, ISO 23767 *Children's furniture – Mattresses for cots and cribs – Safety requirements and test methods*, which is under consideration and not yet published. Although this draft document is not yet an official standard, staff reviewed it for relevancy and found that it is nearly identical to BS EN 16890.

Table 2 compares these international standards to ASTM F2933 regarding the previously discussed hazard patterns and other common hazards. The table describes which hazards are addressed by each standard and provides supplementary comments for each hazard.

<sup>&</sup>lt;sup>33</sup> A test based on AS/NZS 8811.1:2013 was used to address a smothering-type suffocation hazard presented by crib bumpers separating from the crib or otherwise protruding into the sleep area and getting underneath an infant. In these situations, the crib bumper behaves like a quilt or soft bedding that is able to conform to, and occlude, airway openings. Extending the requirement to the mattress will similarly reduce the risk of suffocation posed by soft depressions or indentations in crib mattresses.

# Table 2. Applicable Standards Comparison

Hazard Pattern	ASTM F2933	AS/NZS 8811.1	EN 16890	Comments
Chemical Hazards	16 CFR part 1303 Ban of Lead- Containing Paint 16 CFR part 1500 Hazardous Substances Act Regulations	Not addressed	Provision for specific controlled toxic substances	ASTM is adequate to address US incident data
Coil or Spring	Prohibition of sharp points	Not addressed	Prohibition of sharp points	CPSC staff recommends additional cyclic testing described in Section V
Crib Mattress Used in a Play Yard	Labeling requirements, requirements for after-market mattresses and required testing to ASTM F406 mattress requirements	Not addressed	Labeling requirements	ASTM more stringent
Expand or Inflate	Dimensional conformity, mattress thickness, and labeling requirements	Not addressed	Dimensional conformity, labeling requirements	ASTM more stringent
Face in Mattress	Labeling requirements	Firmness test	Firmness test	Recommend a test based on sections 6 and 8 of AS/NZS 8811.1 firmness test in addition to label requirements in ASTM F2933- 19
Fit Issues	Dimensional conformity and after-market mattress requirements	Not addressed	Dimensional conformity, conical probe test, cyclic test	Recommend additional fitted sheet compression test for full-size crib mattresses and extending dimensional requirements in section 5.7 to all after-market non- full-size crib mattresses

Hazard Pattern	ASTM F2933	AS/NZS 8811.1	EN 16890	Comments
Found Prone	Labeling requirements	Firmness test	Firmness test	Recommend a test based on sections 6 and 8 of AS/NZS 8811.1 firmness test in addition to label requirements in ASTM F2933- 19
Mattress Falls Apart	Mattress seam stitching requirement and small parts prohibition	Not addressed	Mattress seam stitching requirement and small parts prohibition	ASTM more stringent
Softness	Not addressed	Firmness test	Firmness test	Recommend a test based on sections 6 and 8 of AS/NZS 8811.1 firmness test
Multiple Contributing Factors (MCF)	General requirements and instructional literature	Not addressed	General requirements and instructional literature	ASTM General Requirements are adequate but safety info is inadequate
Small Parts	Prohibited per 16 CFR part 1501	Not addressed	Same as ASTM	ASTM is adequate to address U.S. incident data
Sharp Points/Edges	Prohibited per 16 CFR 1500	Not addressed	Prohibited but no performance requirements	ASTM is more stringent
Flammability	Prohibited per 16 CFR 1632 and 1633	Not addressed	Must comply with EN 71- 2:2011 and EN 597-1	ASTM is adequate to address U.S. incident data
Small Openings	Openings between 0.210" and 0.375" prohibited	Not addressed	Not addressed	ASTM is adequate and more stringent
Label Permanency	Must not detach with < 15-lb. pull force	Not addressed	Must not detach after 30 attempts to remove with feeler gauge	ASTM is adequate and more stringent
Dimensional Conformity	Must be at least 27.25" x 51.625" during application of forces	Not addressed	Must be within 10 mm of nominal dimensions	ASTM is adequate and more stringent
Entanglement	All accessible stitching must be lock stitching	Not addressed	Maximum free length of 220 mm	ASTM is adequate to address U.S. incident data

Hazard Pattern	ASTM F2933	AS/NZS 8811.1	EN 16890	Comments
Seam Stitching	All accessible stitching must be lock stitching	Not addressed	Seams must not be penetrated > 6 mm with 12 mm diameter probe	ASTM is adequate and more stringent
After-Market Mattresses	Mattresses shall have same thickness, floor support structure and attachment method as the mattress it is intended to replace	Not addressed	Not addressed	ASTM is more stringent; NPR proposes to extend dimension requirements in 5.7.2 to all after- market non-full- size crib mattresses
Warning Labels/Instructions	Warning labels required, instructions not required	Not addressed	Instructions required/warning labels do not address as many hazards	ASTM is inadequate. See human factors assessment in Tab C.

#### A. Chemical Hazards

The EN standard contains a comprehensive list of specific controlled toxic substances. The ASTM standard contains a requirement for compliance with 16 CFR part 1303 (lead content) and 16 CFR part 1500 (Hazardous Substances). The incident data reported to the CPSC do not indicate that the other substances listed in the EN standard are common causes of injury or hazard. Therefore, staff considers the ASTM standard adequate.

# B. Coil or Spring

Both the ASTM F2933-19 and EN 16890 standards address this hazard by prohibiting any sharp points. However, due to the number of incidents (38% of nonfatal incidents), staff recommends strengthening the standard with a cyclic impact test, discussed in Section V, which would address laceration hazards due to exposed coil springs after cyclic impact testing. AS/NZS 8811.1 does not address this hazard.

#### C. Crib Mattress Used in a Play Yard

ASTM F2933-19 requires labeling addressing this hazard, requirements for after-market mattresses, and required testing to ASTM F406 mattress requirements. The EN standard only addresses this hazard with requirements for language describing proper use of the mattress in the instructions. Staff concludes that the ASTM is more stringent because ASTM requires both on-product labeling and performance tests.

# D. Expand or Inflate

ASTM F2933-19 addresses this hazard with dimensional conformity, mattress thickness, and labeling requirements. AS/NZS 8811.1 does not address this hazard. EN 16890 has dimensional conformity and labeling requirements. ASTM requires minimum dimensions of 27.25 inches x 51.625 inches for full-size cribs, while EN 16890 requires that measured dimensions must be within 10 mm of nominal dimensions. Because EN 16890 does not specify nominal dimensions, staff concludes that the ASTM standard is more stringent because a crib mattress's nominal dimensions could be small enough to still allow hazardous gaps.

#### E. Face in Mattress/Found Prone

ASTM F2933-19 addresses this hazard with labeling requirements. Both EN 16890 and AS/NZS 8811.1 address this hazard with separate firmness tests; neither standard addresses this hazard with warning labels or instructions. Staff recommends adding a test based on AS/NZS 8811.1's firmness test because staff found it to be more stringent than EN 16890, as explained in section V of this memorandum.

F. Fit Issues

ASTM F2933-19 addresses this hazard by requiring full-size crib mattresses be at least 27.25" x 51.625" during application of forces and by requiring after-market mattresses to have the same thickness, floor support structure, and attachment method as the mattress it is intended to replace. AS/NZS 8811.1 does not address this hazard. EN 16890 addresses this hazard with dimensional conformity requirements, as described in section IV.D above. Because of the after-market mattress requirements, staff concludes that ASTM F2933-19 is more stringent and recommends the additional fitted-sheet compression test for full-size crib mattresses, and extending requirements for OEM non-full-size crib mattresses to all after-market non-full-size crib mattresses, discussed in Sections V and VI, to address U.S. incident data.

# G. Mattress Falls Apart

ASTM F2933-19 addresses this hazard with a mattress seam stitching requirement and small parts prohibition. AS/NZS 8811.1 does not address this hazard. EN 16890 addresses this hazard with small parts prohibition and a less stringent mattress seam-stitching requirement. While the EN standard requires a tight seam, it does not require that the seam be stitched in such a way that it could unravel. Accordingly, staff concludes that ASTM is more stringent.

#### H. Softness

ASTM F2933-19 does not address this hazard. Both EN 16890 and AS/NZS 8811.1 address this hazard with separate firmness tests. Staff tested mattresses for firmness using both test methods and found that AS/NZS 8811.1 is more stringent and simpler to perform repeatable tests.

The mattress firmness test in EN 16980 consists of placing a square template, which has a circular hole in the center, on the mattress surface. A weighted sphere, whose diameter is slightly larger than that of the circular hole, is then placed in the center of the hole, as shown in Photo 2. After 5 minutes, the sphere/template is observed to see whether the sphere has

sufficiently sunk into the mattress, such that it is resting on the template. Staff tested the samples on both sides of the mattresses, with one side being a firmer side for infants, and a softer side for toddlers. As seen in Table 4, one sample of the 11 samples tested did not meet the performance requirements of both AS/NZS 8811.1:2013 and the EN16890 section 8.2.3, test for firmness. However, that sample also did meet the requirements of EN 16890 section 8.2.3 when tested on the firm side, while that same firm side did not meet the performance requirements of AS/NZS 8811.1:2013.



Photo 2. EN 16890 firmness test fixture.<sup>34</sup>

Staff concludes that the AS/NZS 8811.1:2013 test for firmness is more stringent because more samples did not meet the performance requirements of AS/NZS 8811.1:2013 than the firmness test of EN16890. Additionally, staff found that AS/NZS 8811.1:2013 is more repeatable and is easier to discern when a mattress does not meet the performance requirements than the EN16980 method.

Accordingly, to address mattresses that are too soft, for the draft proposed rule, staff recommends adding a test based on AS/NZS 8811.1 mattress firmness test.

# I. Multiple Contributing Factors

ASTM F2933-19 addresses this hazard with general requirements, such as prohibitions on small parts, sharp points and sharp edges and requirements addressing chemical hazards, flammability, small openings and label permanency. ASTM F2933-19 also addresses this hazard with warning labels against suffocation, overheating, and entrapment. EN 16890 address this hazard with general requirements, such as prohibitions on small parts, sharp points and edges, and requirements addressing chemical hazards, flammability, small openings, and label permanency. Additionally, EN 16890 addresses this hazard with instructional literature that warns against entrapment and flammability. The AS/NZS 8811.1 standard does not address this hazard. Some of these contributing factors are addressed by staff's recommended requirements, while others are out of the scope of the ASTM crib mattresses standard, such as use of a swaddle, sharing the crib with another infant, and congenital or recent health conditions of infants. Staff concludes

<sup>&</sup>lt;sup>34</sup> Photo courtesy of https://catas.com/uploads/media/mterassieng.pdf.

that ASTM F2933-19 adequately addresses these hazards in the general requirements sections. ASTM F2933-19 also addresses these hazards with safety requirements, but those are inadequate. The requirements for safety information, with modifications recommended by staff, are outlined in the human factors assessment in Tab C.

#### J. Small Parts

ASTM F2933-19 prohibits small parts per 16 CFR part 1501, and EN 16890 uses similar test methods, so both are adequate to address U.S. incident data. AS/NZS 8811.1 does not address this hazard.

#### K. Sharp Points/Edges

ASTM F2933-19 prohibits sharp points and edges per 16 CFR part 1500. The AS/NZS 8811.1 standard does not address this hazard. EN 16890 prohibits sharp points and edges, but it does not have any performance requirements similar to those required by ASTM F2933-19. Staff concludes that ASTM F2933-19 is a more stringent standard than both AS/NZS 8811.1 and EN 16890 standards.

# L. Flammability

ASTM F2933-19 prohibits flammable material per 16 CFR parts 1632 and 1633. AS/NZS 8811.1 does not address this hazard. EN 16890 requires compliance with EN 71-2:2011 and EN 597-1. Incident data do not indicate a pattern of hazards associated with flammability; therefore, staff concludes that the ASTM standard is adequate to address U.S. incident data.

# M. Small Openings

ASTM F2933-19 prohibits openings between 0.210 inch and 0.375 inch. Neither EN 16890, nor AS/NZS 8811.1 address this hazard. Staff concludes that ASTM F2933-19 is more stringent.

# N. Label Permanency

ASTM F2933-19 requires that labels must not detach with less than a 15-lb. pull force. AS/NZS 8811.1 does not address this hazard. EN 16890 requires that labels must not detach after 30 attempts to remove with a feeler gauge. Since the ASTM standard has a force requirement, rather than the number of attempts to remove the label, staff concludes that the ASTM standard is more stringent than the EN standard.

#### O. Dimensional Conformity

ASTM F2933-19 requires that full-size crib mattresses must be at least 27.25" x 51.625" during application of forces. AS/NZS 8811.1 does not address this hazard. EN 16890 requires that measured dimensions must be within 10 mm of nominal dimensions. Because EN 16890 does

not specify nominal dimensions, staff concludes that the ASTM standard is more stringent because a crib mattress's nominal dimensions could be small enough to allow hazardous gaps,

# P. Entanglement

While ASTM F2933-19 does not have a requirement specific to cords and loops, it addresses entanglement of loose threading, by requiring that all accessible stitching must be lock stitching. AS/NZS 8811.1 does not address this hazard. EN 16980 requires that any cord or ribbon must have a maximum free length of 220 mm. The ASTM standard does not include similar provisions, but the incident data do not indicate a pattern of hazards associated with loose cords or ribbons. Therefore, staff concludes that the ASTM standard is adequate to address U.S. incident data.

# Q. Seam Stitching

ASTM F2933-19 requires that all accessible stitching must be lock stitching. AS/NZS 8811.1 does not address this hazard. EN 16980 requires that seams must not be penetrated greater than 6 mm with 12 mm diameter probe. While the EN standard requires a tight seam, it does not require that the seam be stitched in such a way that it could not unravel. Staff concludes that ASTM is more stringent.

# R. After-Market Mattresses

ASTM F2933-19 section 5.9 requires that after-market mattresses for play yards and nonrectangular, non-full-size cribs shall have the same thickness, floor support structure, and attachment method as the mattress it is intended to replace. Poorly fitting mattresses could create hazardous gaps that could lead to entrapment. EN 16890 and AS/NZS 8811.1 do not address this hazard. These requirements are critical because two deaths are associated with this hazard. Although staff is recommending changes to section 5.7, to extend dimensional requirements to all after-market non-full-size crib mattresses, regardless of shape, staff concludes that the ASTM standard is more stringent because it currently addresses hazards associated with ill-fitting aftermarket play yard and non-rectangular non-full-size crib mattresses with a performance requirement, and rectangular-shaped non-full-size cribs with labeling requirements.

# S. Warning Labels

ASTM F2933-19 requires that mattresses have warning labels, while EN 16890 and AS/NZS 8811.1 do not. CPSC Human Factors staff analyzed the warning labels requirements of ASTM F2933-19 and recommends additional language. See Tab C for a detailed discussion.

# T. Instructions

ASTM F2933-19 and AS/NZS 8811.1 standards do not require instructional literature. EN 16890 does require instructional literature. EN 16890 is the most stringent because it requires that crib mattresses include instructions. In Tab C, staff proposes safety instructions to be added to ASTM F2933-19.

#### **Summary of International Standards Comparison**

Compared to AS/NZS 8811.1 and EN 16890, ASTM F2933-19 is the most comprehensive standard to address incidents associated with the use of crib mattresses in the United States. Currently, however, the standard does not adequately address several hazards addressed in international standards. Accordingly, as outlined above, for the draft proposed rule, staff recommends including a staff-developed compression test, the surface firmness test described in AS/NZS 8811.1:2013, and a cyclic-loading test based on the Mattress Support Vertical Impact Test from section 7.4 of ASTM F1169-19.

EN 16890 is more robust than AS/NZS 88.1, because it addresses common hazards associated with durable nursery products, such as small parts, sharp points/edges, chemical hazards, flammability, and label permanency. The EN 16890 standard also addresses hazards that are not addressed in other applicable standards, specifically entanglement hazards caused by cords or ribbons, and asphyxiation hazards caused by soft surfaces. However, CPSC staff did not receive any incident reports of entanglements of cords or ribbons that involved loose threads. Additionally, staff did not observe cords or ribbons attached to any of the 11 crib mattress samples that staff tested. Accordingly, staff does not recommend including an entanglement requirement in the draft proposed rule. Other requirements in EN 16890, such as prohibitions on small parts, sharp points and edges, and requirements addressing chemical hazards, flammability, small openings and label permanency, are the same or less stringent than ASTM F2933 – 19.

#### V. STAFF-PROPOSED AMENDMENTS TO ASTM F2933-19 TO FURTHER REDUCE THE RISK OF INJURY ASSOCIATED WITH CRIB MATTRESSES

After analysis and testing crib mattress samples, staff developed the following list of recommended changes to ASTM F2933 – 19. Staff made these recommendations to the Subcommittee Co-Chairman for ASTM F15.66, Crib Mattresses, in a letter dated March 20, 2020. These recommendations address the hazard patterns identified with crib mattresses, including entrapment, suffocation, and lacerations. Appendix B details staff's recommended revisions to ASTM F2933 – 19.

#### A. Mattress Entrapment from Compression

# **1. Hazard Description**

CPSC staff is concerned about hazardous gaps that form between the corner of a crib and the corner of the mattress when a fitted sheet is placed on the mattress, compressing the corners and creating large corner gaps that could lead to entrapment.

# 2. Work with ASTM

Staff discussed this concern with ASTM on several occasions. For example, at ASTM F15.66 subcommittee meetings in April<sup>35</sup> and October 2018,<sup>36</sup> and during a task group meeting in July 2018.<sup>37</sup> CPSC staff discussed the incident reports regarding mattresses that compress and create gaps along the edge of the mattresses. Additionally, a CPSC staff member reported a similar issue to the crib mattress team. She observed that the same crib sheet applied by different users could result in significant variations in gap sizes between the crib mattress and crib sides. In May 2019, the ASTM task group discussed mattresses that compress when sheets are installed. CPSC staff sent a letter<sup>38</sup> to the ASTM Crib Mattress task group on December 11, 2019, outlining staff's concerns that the ASTM F2933-19 standard did not adequately address mattress compression. The letter cited recent consumer incident reports involving large corner gaps, and it described staff's in-depth investigation of one such mattress. On January 6, 2020, CPSC staff attended a meeting<sup>39</sup> with the ASTM crib mattress task group to answer the task group's questions about the December 11, 2019 letter. Staff shared preliminary results of staff's testing with the ASTM task group during meetings<sup>40</sup> held on January 29, 2020 and February 10, 2020. Staff shared the final test results<sup>41</sup> with the subcommittee chair on March 20, 2020, but no other subcommittee or task group meetings have occurred since then.

# 3. Test Results and Discussion

Staff testing found that mattress sheets washed twice were, on average, 2.5 inches (or approximately 4.7%) shorter in length than unwashed sheets. Staff selected the shortest sheet for mattress compression testing.

After installing each sample sheet set, all 11 mattresses staff tested met the dimensional requirements of ASTM F2933-19. Table 3 in Appendix A displays the mattress compression test results.

The tested mattresses fell into either of two categories when staff measured dimensional changes:

- 1. Compression of length and expansion of width.
- 2. Little change or expansion in length and width.

Mattresses consisting of foam cores (either a single core or 2 stage) exhibited the first type of behavior; innerspring mattresses or mattresses with a nonmetallic spring structure exhibited the second type of behavior. Staff sorted mattresses into groups based on their characteristics:

• Group 1 – Foam Mattresses

<sup>&</sup>lt;sup>35</sup> April 30, 2018, Meeting of the ASTM F15.66 Subcommittee.

<sup>&</sup>lt;sup>36</sup> October 15, 2018, Meeting of the ASTM F15.66 Subcommittee.

<sup>&</sup>lt;sup>37</sup> July 19, 2018, Meeting of the ASTM Crib Mattress Cyclic Testing task group.

<sup>&</sup>lt;sup>38</sup> December 11, 2019, letter to ASTM Subcommittee Chair of F15.66 on Crib Mattresses.

<sup>&</sup>lt;sup>39</sup> January 6, 2020, Meeting of the ASTM Crib Mattress Compression Task Group.

<sup>&</sup>lt;sup>40</sup> January 29, 2020, ASTM Subcommittee F15.66 on Crib Mattresses meeting.

<sup>&</sup>lt;sup>41</sup> March 20, 2020, Letter to ASTM Subcommittee Chair F15.66 on Crib Mattresses meeting.

• Group 2 – Innerspring and Other Mattresses

Group 1 – foam mattresses (n = 8), on average, compressed in length by about 1/8 in. when fitted with an unwashed sheet, and by almost  $\frac{1}{4}$  in. when fitted with a twice-washed sheet. The width, on average, had little observable expansion with an unwashed sheet, and increased by 1/10 in. with a twice-washed sheet. In contrast, Group 2 – innerspring or other mattresses (n = 3), on average, had no change in length and less than 1/10 in. expansion in width with an unwashed sheet.

Staff observed that when a fitted sheet is placed on the mattress, the length and width dimensional changes were small, compared to the gaps that formed between the corners of the mattress and the interior corner of the crib (*See* Figures 1 and 2 below). As shown in Table 3, both mattress groups had approximately the same average corner gap of 1 in. using the twice-washed sheet.<sup>42</sup>



Figure 1, Mattress Showing Corner Gap Locations

<sup>&</sup>lt;sup>42</sup> Staff observed other characteristics of mattresses tested as follows: Mattresses H and I were innerspring mattresses. Mattresses A, F, G, I, J, and K were two-stage mattresses. Two-stage mattresses can be used on either side, one side being firmer and intended for infants, while the other side is softer and intended for toddlers. Mattress K was a foam mattress with a unique (non-metal-coil) spring structure.



Figure 2, Detail View of Maximum Corner Gap Location and Measurement.

Large corner gaps, like gaps shown in Figure 1, can be a hazard to young infants whose heads become entrapped. Based on staff's review of anthropomorphic data, staff concludes that a gap of 1 in. between the corner of the mattress and adjacent side walls of the crib is acceptable, and is the maximum allowable gap in many durable children's nursery products. Based on these measurements, and assuming the nearest mattress surface to the corner occurs at a 45° angle, the maximum corner gap contribution from side gaps would be the square root of the sum of the two adjacent sidewall measurements, see Figure 2 above:

$$\sqrt{1^2 + 1^2} = \sqrt{2} \cong 1.41$$
 in.

According to anthropometric data,<sup>43</sup> the head breadth of fifth percentile 0 to 3-month-old infants is 3.66 in. Therefore, to prevent head entrapment in the largest corner gap, the opposite corner gap between the mattress and adjacent corner must be smaller than:

3.66 - 1.41 = 2.25 in.

<sup>&</sup>lt;sup>43</sup> According to Snyder (1975), the 5<sup>th</sup> percentile head breadth, *i.e.*, the maximum breadth of the head above and behind the ears, of children 0 to 3 months old is approximately 3.7 inches, which is more than twice as wide as the maximum allowable side gap between full-size cribs and full-size crib mattresses. ESHF staff selected head "breadth" as opposed to length or height, to err on the side of caution, as head breadth is the smallest of these three head dimensions that could cause a fatal entrapment.

To account for an increase in the corner gap caused by an infant laying in the gap and compressing the mattress, staff decreased the allowable gap by a 0.5 in. margin of safety. Therefore, the maximum allowable corner gap of a compressed mattress should be 1.75 in. (2.25 - 0.50), as measured in the corner of the mattress pushed into the corner of the testing apparatus. Staff shared this protocol and test results with the ASTM subcommittee chair on March 20, 2020, but there have been no discussions with the subcommittee or task group, because no ASTM meetings have occurred since March 2020.

#### 4. **Staff Recommendation**

Based on this testing, to further reduce the risk of injury associated with corner gap entrapment, staff recommends that the following new compression test be included in the draft proposed rule:

Mattress Sheet Fitted Test

- To condition the sheet for compression testing, a store-bought fitted mattress sheet intended for the tested mattress size, consisting of 100 percent cotton, shall be washed in hot water (50° C [122° F] or higher) and dried a minimum of two times on the highest setting, using household textile laundering units.
- 2. The shrunken fitted sheet shall be placed fully on the mattress, such that each sheet edge is wrapped fully around and under the mattress.
- 3. The mattress, with the shrunken sheet, shall meet the *Mattress Dimension* requirements in ASTM F2933-19.
  - 3.1. A full-size crib mattress shall be measured according to section 6.2 of the standard.
    - 3.1.1. After dimensional measurements are taken, while no force is being applied, measure the corner gap between the adjoining Walls C and D and the crib mattress. See Figure 1 for illustration. The gap shall not exceed 1.75 in.
      - 3.1.1.1. Corner gap measurements shall be repeated after rotating the mattress
         180° and repositioning it in the corner following sections 6.2.2.1 and 6.2.2.2 of
         ASTM F2933-19.

Currently, staff is not aware of incidents related to non-full-size crib mattresses compressing when sheets are installed. Therefore, at this time, staff is not recommending a similar sheet compression test for non-full-size crib mattresses. However, staff is still considering recommending that the Commission require the sheet compression test for non-full-size crib mattresses in a final rule. Accordingly, staff invites comments regarding the applicability of the sheet compression test for non-full-size crib mattresses and the use of sheets with non-full-size mattresses.

B. Mattress Firmness and Suffocation

# 1. Hazard Description

Based on the incident data, CPSC staff is concerned that some mattress surfaces may be too soft, and may allow depressions in the surface that conform to an infant's face and compromise an infant's ability to breathe.

# 2. Work with ASTM

Staff discussed this hazard pattern with ASTM on several occasions. For example, at the ASTM F15.66 subcommittee meetings in May 2018, CPSC staff identified mattress firmness as an issue seen in staff's incident analysis. Subsequent ASTM task group meetings on this topic resulted in the task group deciding to table the issue, based on task group members arguing that the incident did not definitively link mattress softness to deaths. CPSC staff remained concerned about this hazard pattern, given that prone positioning on soft surfaces is a known hazard pattern; and in a ballot response letter dated April 29, 2019,<sup>44</sup> staff urged the task group to remain active and continue to evaluate the need for performance requirements for mattress firmness.

In a December 11, 2019 letter from CPSC staff to the subcommittee chair for crib mattresses, staff recommended that the subcommittee continue their previous work on mattress firmness, or consider disallowing or developing requirements for visco-elastic (memory) foam for use in crib mattresses, due to its nature of conforming to the body when warm. The firmness task group met on January 8, 2020, to discuss this recommendation, and the group reached a consensus to explore a performance test requirement for mattress firmness, by testing mattresses using known firmness tests based on AS/NZS 8811.1 and the protocol in EN 16890, section 8.2.3.

The ASTM task group met again on February 13, 2020, to continue discussion on mattressfirmness testing. Staff verbally shared the test results with the ASTM subcommittee, and the group discussed each method. Subsequently, staff shared CPSC's mattress firmness test results in a letter to the subcommittee and task group chair on March 20, 2020. The task group planned to discuss the AS/NZS 8811.1:2013 test and staff's testing results at the April 2020 subcommittee meeting; however, the meeting was canceled due to the COVID-19 pandemic.

# **3.** Testing and Discussion

To address the incidents associated with mattress firmness, staff tested both sides of 11 full-size crib mattress samples to both AS/NZS 8811.1:2013 and EN 16890, section 8.2.3. Both test methods involve placing a test fixture of a specified shape and weight on the surface and using a gage to determine the deflection. Both tests have a pass/fail criteria. Table 4 in Appendix A displays the results from staff's firmness testing.

Only mattress F failed the firmness tests outlined in each standard. Mattress F was a two-stage mattress, indicating it had a firmer side intended for infants and a softer side intended for toddlers. Both sides of mattress F failed the AS/NZS protocol. The mattress failed the EN 16890 only on the "toddler" side, which is intentionally made softer.

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, address "good

<sup>&</sup>lt;sup>44</sup> April 29, 2019 staff letter to ASTM Subcommittee Chair of F15.66 on Crib Mattresses.

quality research" that "has pointed to an association between infant mortality and overly soft sleep surfaces." That research<sup>45</sup> 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 conventional bedding. In one study by Schlaud and colleagues,<sup>46</sup> researchers assessed sleep surface firmness by measuring deflection resulting from an applied weight: a 2 kg (4.4 lb) cylinder with a diameter of 6 cm (2.4 in) placed through a support gage on the sleep surface. For this test, 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<sup>47</sup> 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.

Figure 3 shows the firmness test apparatus based on AS/NZS 8811.1. 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 <sup>1</sup>/<sub>4</sub>, <sup>1</sup>/<sub>2</sub>, and <sup>3</sup>/<sub>4</sub> points along the medial line of the sleep surface, with the feeler arm aligned with the medial line. The test is conducted at a fourth location chosen using 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.

Staff concludes that the AS/NZS 8811.1:2013 test for firmness is more stringent because more samples did not meet the performance requirements of AS/NZS 8811.1:2013 than the firmness test of EN16890. Additionally, staff found that AS/NZS 8811.1:2013 is more repeatable and is easier to discern when a mattress does not meet the performance requirements than the EN16980 method.

Accordingly, to address mattresses that are too soft, for the draft proposed rule, staff adding a test for mattress firmness for all crib mattresses within the scope of the standard, based on sections 6 and 8 in AS/NZS 8811.1 mattress firmness test.

<sup>&</sup>lt;sup>45</sup> 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).

<sup>&</sup>lt;sup>46</sup> 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.

<sup>&</sup>lt;sup>47</sup> Australia and New Zealand's proposed new test for infant mattress firmness: A brief summary, August 2012



Australian/New Zealand Standard 8811.1:2013 test apparatus

# 4. Staff's Recommendation

To further reduce the risk of infant suffocation associated with surface softness in crib mattresses, staff recommends adding to the draft proposed rule for Crib Mattresses the following mattress firmness test summarized from a test based on section 8 of AS/NZS 8811.1:2013:

- 1. Mark three equidistant points along the longitudinal center line, with one at the center and the other two equidistantly between the center and the edge of the mattress. Choose one more "worst-case" scenario test location(s) where an infant's head might lay in a particularly soft spot, or an infant's nose or mouth might contact a protrusion above the sleep surface.
- 2. Hold the test fixture with its base horizontally, and rotate it so the feeler arm is aligned with the center line of the sleep surface, and pointing in the same direction for each test; then gently set down the fixture on one of the test locations, ensuring that the edge of the bottom disk does not extend beyond the edge of the sleep surface.
- 3. If the level indicates that the feeler arm is approximately level when resting the fixture is resting on the sleep surface, observe whether the feeler arm makes any contact with the top of the sleep surface or cover. If the feeler arm is not level, decompress the mattress, allow it to settle, and start again. If the feeler arm contacts the sleep surface even when the test fixture is tilted back so as to raise the feeler arm, assume that such contact would occur had the fixture come to rest horizontally.
- 4. Repeat steps at remaining locations.

# C. Lacerations from Exposed Coil Springs

# 1. Hazard Description

Staff found that 124 of the incident reports were associated with potential lacerations to infants from an exposed coil or spring.

# 2. Work with ASTM

The Crib Mattress Cyclic Testing task group discussed a cyclic impact test based on the Mattress Support Vertical Impact Test from section 7.4 of ASTM F1169-19 in their July 2018 task group meeting.<sup>48</sup> At the F15.66 Crib Mattress subcommittee meeting held in October 2018, the subcommittee discussed both the Mattress Support Vertical Impact Test and the Mattress Durability Roller Testing for spring/coil mattresses, based on ASTM F1566, *Standard Test Methods for Evaluation of Innersprings, Boxsprings, Mattresses or Mattress Sets*, section 7, as possible cycle loading tests. The meeting minutes from the meeting on October 23, 2018<sup>49</sup> state: "The subcommittee determined that impact testing would be the most representative of real world use."

In the following months, CPSC staff and other members of the Crib Mattress Cyclic Testing task group performed the Mattress Support Vertical Impact Test on crib mattresses on four samples, to determine what test would be most applicable to crib mattresses with coil springs.

On April 29, 2019, staff sent a letter to the subcommittee chair in response to ballot F15 (19-04), providing staff's initial test results. In the July 2019 task group meeting<sup>14</sup> staff and one manufacturer discussed the results of their continued testing and refined the requirements. The task group has not met since then.

# 3. Testing and Discussion

CPSC staff and other members of the Crib Mattress Cyclic Testing task group performed variations of the Mattress Support Vertical Impact Test to determine a test that would be most applicable to crib mattresses with coil springs. The test was designed to simulate wear and tear due to a child jumping up and down on the mattress. Staff's initial test used the Mattress Support Vertical Impact Test impactor with a weight of 45 lbs., as specified in F1169-19. Staff tested three separate mattresses, and in each test, the mass was dropped 200 times 6 inches above the mattress surface at four specified locations (shown in Figure 4) for a total of 800 impacts per mattress. Staff thought this test was too severe because all of the mattresses were forming holes from the 45-lb. impactor. Staff revised the test protocol by decreasing the impactor mass to 30 lbs., replacing the aluminum frame with support only along the perimeter of the board, and increasing the number of cycles to 250 per location for a total of 1,000. Staff observed no tears, perforations or other signs of damage, nor were there any exposed coil springs or wires. In the July 2019 task group meeting, staff and one manufacturer discussed the results of their continued testing and refined the requirements.

# 4. Staff's Recommendation

For the draft proposed rule, to further reduce the risk of infant lacerations from exposed coils and springs, staff recommends including a cyclic loading test, as follows:

<sup>&</sup>lt;sup>48</sup> July 19, 2019, Meeting of the ASTM Crib Mattress Cyclic Testing task group.

<sup>&</sup>lt;sup>49</sup> October 15, 2018, Meeting of the ASTM F15.66 Subcommittee.

- 1. Mattress shall be tested in an enclosed frame measuring 29 inches x 53 inches (737 mm by 1346 mm) for the purpose of restricting mattress movement. A crib meeting the requirements of ASTM F1169-19 would suffice.
- 2. The mattress can be placed on top of a <sup>3</sup>/<sub>4</sub>" piece of plywood or OSB, which is rigidly supported along the perimeter.
- 3. An impactor with the dimensions of the vertical impactor of ASTM F1169-19 weighing 30 lbs. shall be dropped from a height of 6 inches from the top of the mattress surface to the bottom of the impactor, 250 times in four locations (specified in Figure 4), for a total of 1,000 cycles. Cyclic loading rate shall be one drop every  $4 \pm 1$  seconds.
- 4. At the conclusion of the cyclic loading test, the mattress shall be removed from the test enclosure and visually inspected for exposed wires or coil springs.



Figure 4. Impact test locations.

# VI. STAFF RECOMMENDED MODIFICATIONS TO REQUIREMENTS FOR AFTER-MARKET NON-FULL-SIZE CRIB MATTRESSES

Dimensional requirements for non-full-size crib mattresses are a key requirement in ASTM F2933-19, because size requirements prevent hazardous gaps from forming between the edge of a mattress and the side of the crib, where infants can become entrapped and suffocate. Staff identified a gap in the dimensional requirements for after-market non-full-size cribs in section 5.9 ASTM F2933-19, which does not appear to have a performance requirement for the dimensions of an after-market, rectangular-shaped, non-full-size crib mattress. As explained below, to address this safety gap, staff recommends expanding the non-full-size crib mattress requirements in 5.7.2, which currently only apply to OEM mattresses, to apply to all non-full-size crib mattresses. Staff also recommends two additional modifications in sections 5.7 and 5.9 of ASTM F2933-19, to clarify ambiguities for performance requirements for mattresses in the standard.

#### A. Dimension requirements for all after-market non-full-size crib mattresses

Although the after-market requirements in section 5.9 are purportedly intended to apply to "*After-market mattress for play yard and non-full size crib*," the requirements in section 5.9.1 are limited to "mesh/fabric sided products" (meaning play yards) and "rigid sided non-rectangular products" (meaning non-rectangular non-full-size cribs). Because section 5.7 of ASTM F2933-19 only applies to OEM mattresses, staff found no performance requirements in the standard that apply to after-market, rectangular-shaped, non-full-size crib mattresses. Staff reviewed the rationales for changes to the after-market requirements for crib mattresses in the ASTM standards. Staff understands that the ASTM subcommittee consciously decided to limit performance requirements in section 5.9.1 by omitting rectangular mattresses for rigid-sided products (*i.e.*, rectangular non-full-size cribs). Staff reviewed ASTM minutes and ballot F15 (17-02), which implemented this requirement in F2933; however, staff could not determine the rationale for limiting the requirements to *non-rectangular* products.

While ASTM F2933 – 19 contains no dimension requirements for after-market, rectangularshaped, non-full-size crib mattresses, the standard does contain warning requirements pertaining to the size of after-market mattresses for rectangular non-full-size cribs. ESHF staff concludes in Tab C that warnings, alone, are insufficient to address the hazards associated with ill-fitting after-market non-full-size crib mattresses. Accordingly, to ensure that all after-market mattresses for non-full-size crib are subject to a dimensional performance requirement, staff recommends that the current performance requirements for OEM non-full-size crib mattresses in section 5.7.2 of ASTM F2933-19 be modified to apply to all non-full-size crib mattresses, regardless of whether the mattress is sold with a crib, and regardless of the shape of the mattress. Accordingly, staff also recommends removing references to after-market non-full-size cribs from section 5.9 of ASTM F2933-19. Staff recommends that section 5.9 focus solely upon aftermarket play yard mattresses.

Currently, the size and thickness requirements for OEM non-full-size crib mattresses in section 5.7.2 of ASTM F2933-19 repeat the requirements for non-full-size crib mattresses in section 5.17 of ASTM F406. To preclude the size requirements in each standard from unintentionally

diverging in the future, staff also recommends modifying section 5.7.2 to refer to the requirements for non-full-size crib mattresses in F406, rather than repeating the same requirements in F2933.

Appendix B contains a redline of staff's proposed changes to section 5.7.2 of ASTM F2933-19.

Staff invites comments on this proposal and will continue to work with ASTM to address concerns with exempting after-market, rectangular-shaped, non-full-size crib mattresses from performance requirements.

# B. Clarification regarding "replacement mattress" in section 5.9.1.3 of ASTM F2933-19

Finally, staff notes an inconsistency in the language of ASTM F2933-19 section 5.9.1.3, which requires that a "replacement mattress" for a play yard bassinet with a bassinet attachment meet certain specifications in ASTM F2194, when tested with each brand and model it is intended to replace. This requirement for bassinet mattresses appears in the section for "after-market" mattresses. Section 3.1.1 of ASTM F2933-19 specifically exempts "replacement" mattresses from the term "after-market," as "replacement" mattresses are supplied by an OEM and are equivalent to the original mattress. Staff recommends clarifying that the requirements in section 5.9.1.3 apply to after-market mattresses, by replacing the term "replacement" with "after-market." Tab B outlines the staff's proposed changes to section 5.9.

# VII. CONCLUSION

LSM staff reviewed the incident data and evaluated whether ASTM F2933-19, or other international standards, addressed the identified hazard patterns for crib mattresses, non-full-size crib mattresses, and play yard mattresses. Staff recommends that the draft proposed rule incorporate by reference ASTM F2933-19, with modifications, as a mandatory standard for crib mattresses. To further reduce the risk of injury associated with crib mattresses, staff recommends that the draft NPR include the three additional test methods discussed in Section V above, as part of the mandatory standard for crib mattresses. These three test methods are:

- 1. Mattress Compression Test, which involves placing a fitted sheet on a full-size crib mattress and measuring the gap between its corners and the walls of box. This test would address hazardous gaps created between the edge of a crib and the mattress.
- 2. Mattress Firmness Test, which addresses excessively soft mattress surfaces for all crib mattresses within the scope of the standard that could indent and become an asphyxiation hazard. This test is based on the method used in sections 6 and 8 of the Australian/New Zealand Standard 8811.1:2013 *Methods of testing infant products*.
- 3. Mattress Cyclic Loading Test, which addresses lacerations due to exposed coil springs.

Staff also recommends modifications to extend dimensional requirements to include all aftermarket non-full-size crib mattresses, and, as discussed in Tab C, modifications to the safety instructions.

# Appendix A: Test Result Tables

Mattress	Mattress	Base Dime	nsions	Mattress Sheet Dir	with Unwa nensions	shed	Unwashe Differenc	ed Sheet e	Mattress with Sheet Washed 2X Dimensions		Sheet Washed 2X Difference		Mattress Construction	
	Length (in)	Width (in)	Corner Gap (in)	Length (in)	Width (in)	Corner Gap (in)	Length (in)	Width (in)	Length (in)	Width (in)	Corner Gap (in)	Length (in)	Width (in)	
GROUP 1: FO	DAM MATT	RESSES												
А	52.500	27.875	0.500	52.250	27.875	0.875	-0.250	0.000	52.125	28.000	1.000	-0.375	0.125	2 Stage Foam
В	53.000	28.000	0.500	52.750	28.125	0.875	-0.250	0.125	52.625	28.250	1.000	-0.375	0.250	Foam
С	52.250	28.125	0.375	52.125	28.125	0.500	-0.125	0.000	52.125	28.125	1.000	-0.125	0.000	Foam
D	52.500	28.500	0.500	52.375	28.500	1.000	-0.125	0.000	52.250	28.625	1.250	-0.250	0.125	Foam
E	52.875	28.000	0.500	52.625	28.125	1.000	-0.250	0.125	52.500	28.125	1.125	-0.375	0.125	Foam
F	53.125	28.000	0.500	53.125	28.000	1.000	0.000	0.000	53.000	28.000	1.500	-0.125	0.000	2 Stage Foam
G	52.625	27.875	0.750	52.500	27.875	0.875	-0.125	0.000	52.500	28.000	1.250	-0.125	0.125	2 Stage Foam
J	52.625	27.875	0.500	52.625	27.875	0.625	0.000	0.000	52.500	28.000	0.625	-0.125	0.125	2 Stage Foam
Group 1 Avg.	52.688	28.031	0.516	52.547	28.063	0.844	-0.141	0.031	52.453	28.141	1.094	-0.234	0.109	
Group 1 St. Dev.	0.291	0.209	0.104	0.313	0.211	0.186	0.104	0.058	0.291	0.216	0.257	0.124	0.080	
GROUP 2: IN	INERSPRIN	G AND OTH	IER MATTR	ESSES										
Н	52.750	28.000	0.750	52.750	28.125	0.875	0.000	0.125	52.750	28.125	0.875	0.000	0.125	Innerspring
Ι	52.625	27.625	1.000	52.750	27.750	1.125	0.125	0.125	52.750	27.750	1.250	0.125	0.125	2 Stage Innerspring
К	52.250	28.000	0.500	52.125	28.000	0.250	-0.125	0.000	52.250	27.875	0.875	0.000	-0.125	2 Stage non- metal spring
Group 2 Avg.	52.542	27.875	0.750	52.542	27.958	0.750	0.000	0.083	52.583	27.917	1.000	0.042	0.042	
Group 2 St. Dev.	0.260	0.217	0.250	0.361	0.191	0.451	0.125	0.072	0.289	0.191	0.217	0.072	0.144	

Table 3. Mattress Sheet Compression Test Results

#### Table 4. Mattress Firmness Test Results

	Australian				ISO		
		Center	Center			Center	
Sample	Center	Left	Right	Corner	Center	Left	Corner
A-1	Р	Р	Р	Р	Р	Р	Р
A-2	Р	Р	Р	Р	Р	Р	Р
B-1	Р	Р	Р	Р	Р	Р	Р
B-2	Р	Р	Р	Р	Р	Р	Р
C-1	Р	Р	Р	Р	Р	Р	Р
C-2	Р	Р	Р	Р	Р	Р	Р
D-1	Р	Р	Р	Р	Р	Р	Р
D-2	Р	Р	Р	Р	Р	Р	Р
E-1	Р	Р	Р	Р	Р	Р	Р
E-2	Р	Р	Р	Р	Р	Р	Р
F-1	Р	Р	Р	F	Р	Р	Р
F-2	Р	Р	Р	F	F	F	F
G-1	Р	Р	Р	Р	Р	Р	Р

	Australian				ISO		
		Center	Center			Center	
Sample	Center	Left	Right	Corner	Center	Left	Corner
G-2	Р	Р	Р	Р	Р	Р	Р
H-1	Р	Р	Р	Р	Р	Р	Р
H-2	Р	Р	Р	Р	Р	Р	Р
I-1	Р	Р	Р	Р	Р	Р	Р
I-2	Р	Р	Р	Р	Р	Р	Р
J-1	Р	Р	Р	Р	Р	Р	Р
J-2	Р	Р	Р	Р	Р	Р	Р
K-1	Р	Р	Р	Р	Р	Р	Р
K-2	Р	Р	Р	Р	Р	Р	Р

Table 4 legend:

1 – For sample, indicates infant side, or the manufacturer's recommended-use side.
2 – For sample, indicates toddler side (if applicable), or the reverse side of the manufacturer's recommended-use side.

P – Pass.

F – Fail.

Appendix B: LSM Staff's Recommended Revisions to ASTM F2933 – 19<sup>50</sup> ASTM F2933 – 19, Section 3. Definitions

ASTM F2933 – 19	Staff's Recommended Revisions	Rationale Summary
	3.1.11 sleep surface - The product component, or	AS/NZS 8811.1:2013 defines sleep
	group of components, providing the horizontal plane,	surface for testing purposes. CPSC staff
	or nearly horizontal plane ( $\leq 10^\circ$ ), intended to support	developed this definition based on the
	an infant during sleep.	AS/NZS definition and current work on
		safe sleep.

#### ASTM F2933 – 19, Section 5. General Requirements

ASTM F2933 – 19	Staff's Recommended Revisions	Rationale Summary
5.7.1.1 <i>Mattress Size</i> -The dimensions	5.7.1.1 Mattress Size-The dimensions of a full-size	This test applies to full-size crib
of a full-size crib mattress shall	crib mattress shall measure at least 27 <sup>1</sup> / <sub>4</sub> in. (690 mm)	mattresses. Move "when tested in
measure at least 27 <sup>1</sup> / <sub>4</sub> in. (690 mm)	wide and 51 <sup>5</sup> / <sub>8</sub> in. (1310 mm) long when tested in	accordance with 6.2" to the end, which
wide and 51 <sup>5</sup> / <sub>8</sub> in. (1310 mm) long	accordance with 6.2. When the mattress is placed	clarified that both measures apply when
when tested in accordance with 6.2.	against the perimeter and in the corner of the crib, the	tested to 6.2, and add: "When the
	corner gap shall not exceed 1.75 in. (44.5 mm).	mattress is placed against the perimeter
	Dimensions shall be tested in accordance with 6.2.	and in the corner of the crib, the corner
		gap shall not exceed 1.75 in. (44.5 mm).
		Dimensions shall be tested in
		accordance with 6.2." This change will
		address staff's recommendation that the
		corner gap between a full-size crib and
		mattress should be no larger than 1.75
		in. (44.5 mm) when sheets are installed.

<sup>&</sup>lt;sup>50</sup> Recommended additions are underlined, and recommended deletions are single struck-through.

5.7.2 Non-Full-Size Crib Mattresses:	5.7.2 Non-Full-Size Crib Mattresses:	1.) The section should apply to all crib
5.7.2.1 <i>Mattress Size</i> -The dimensions	5.7.2.1 <i>Mattress supplied with a non-full-size crib:</i>	mattresses for non-full-size baby cribs,
of a mattress supplied with a non-	shall meet the specifications of Mattresses for Rigid	including both those supplied with a
full-size baby crib shall be such that	sided products of Consumer Safety Specification F406	non-full-size crib and an after-market
the mattress, when inserted in the	when tested with the non-full-size crib product with	mattress.
center of the crib, in a	which it is supplied. Noncompressed Mattress Size-	2.) Rather than repeat the text of ASTM
noncompressed state at any of the	The dimensions of a mattress supplied with a non-full-	F406 – 19 section 5.17, which contains
adjustable positions of the mattress	size baby crib shall be such that the mattress, when	requirements for mattress size and
support, shall not leave a gap of more	inserted in the center of the crib, in a noncompressed	mattress thickness, staff recommends
than <sup>1</sup> / <sub>2</sub> in. (12.7 mm) at any point	state at any of the adjustable positions of the mattress	referring to the dimension and thickness
between the perimeter of the mattress	support, shall not leave a gap of more than <sup>1</sup> / <sub>2</sub> in. (12.7	requirements in ASTM F406, reducing
and the perimeter of the crib. When	mm) at any point between the perimeter of the	the likelihood of the requirements
the mattress is placed against the	mattress and the perimeter of the crib. When the	becoming out of sync in the future.
perimeter of the crib, the resulting	mattress is placed against the perimeter of the crib, the	
gap shall not exceed 1.0 in. (25.4	resulting gap shall not exceed 1.0 in. (25.4 mm).	
mm).	5.7.2.2 <u>After-market mattresses for non-full-size cribs:</u>	
5.7.2.2 Mattress Thickness:	shall be treated as though the mattresses were "the	
(1) A mattress supplied with a non-	mattress supplied with a non-full-size crib" and shall	
full-size crib shall, in a	meet the specifications of Mattresses for Rigid sided	
noncompressed state, have a	products in Consumer Safety Specification F406,	
thickness that will provide a	when tested to the equivalent interior dimension of the	
minimum effective crib-side height	product for which it is intended to be used. Mattress	
dimension of at least 20 in. (508 mm)	Thickness:	
as measured from the upper surface	— (1) A mattress supplied with a non-full-size crib	
of the crib side or end panel. For this	shall, in a noncompressed state, have a thickness that	
measurement, the crib side shall be in	will provide a minimum effective crib-side height	
its lowest adjustable position.	dimension of at least 20 in. (508 mm) as measured	
(2) A mattress supplied with a non-	from the upper surface of the crib side or end panel.	
full-size crib shall, in a	For this measurement, the crib side shall be in its	
noncompressed state, have a	lowest adjustable position.	
thickness that will provide a	- (2) A mattress supplied with a non-full size crib	
minimum effective crib-side height	shall, in a noncompressed state, have a thickness that	
dimension of at least 3 in. (76 mm) as	will provide a minimum effective crib-side height	

ASTM F2933 – 19	Staff's Recommended Revisions	Rationale Summary
measured from the upper surface of	dimension of at least 3 in. (76 mm) as measured from	
the mattress to the upper surface of	the upper surface of the mattress to the upper surface	
the crib side or end panel. For this	of the crib side or end panel. For this measurement, the	
measurement, the crib side shall be in	crib side shall be in its lowest adjustable position and	
its lowest adjustable position and the	the mattress support in its highest adjustable position.	
mattress support in its highest		
adjustable position.		

5.9 After-Market Mattress for Play	5.9 After-Market Mattress for Play Yard and Non-Full	1.) Removed requirements for non-
Yard and Non-Full Size Crib:	<del>Size Crib:</del>	rectangular after-market non-full-size
5.9.1 For Mesh/Fabric Sided	5.9.1 For Mesh/Fabric Sided <u>Play Yard Products and</u>	crib mattresses, which are now
Products and Rigid Sided Non-	Rigid Sided Non-Rectangular Products:	addressed in proposed 5.7.2.2. Note
Rectangular Products:	5.9.1.1 The mattress shall have the same (within $\frac{1}{4}$ in.,	that the only requirement in 5.9 that was
5.9.1.1 The mattress shall have the	6.4 mm) thickness, floor support structure, and	relevant to non-full-size cribs was
same (within 1/4 in., 6.4 mm)	attachment method as the mattress it is intended to	"Mattresses for Rigid sided products,"
thickness, floor support structure and	replace.	which is ASTM F406 section 5.17, now
attachment method as the mattress it	5.9.1.2 The mattress shall meet the specifications of	included in 5.7.2.
is intended to replace.	the following sections of Consumer Safety	2.) Clarified that Mesh/Fabric sided
5.9.1.2 The mattress shall meet the	Specification F406 when tested with each brand and	products are commonly referred to as
specifications of the following	model of product it is intended to replace: Mattress,	play yards.
sections of Consumer Safety	Mattresses for Rigid sided products; Mattress Vertical	3.) In 5.9.1.3, the term "after-market" is
Specification F406 when tested with	Displacement.	defined in the standard, and it
each brand and model of product it is	5.9.1.3 If the replacement after-market mattress is	specifically exempts "replacement"
intended to replace: Mattress,	intended to be used in the bassinet of a play yard with	mattresses supplied by an OEM. It is
Mattresses for Rigid sided products;	a bassinet attachment, the mattress shall also meet the	not clear that the use of "replacement"
Mattress Vertical Displacement.	specifications of the following sections of Consumer	here refers only to after-market
5.9.1.3 If the replacement mattress is	Safety Specification F2194 when tested with each	mattresses. Staff concludes that using
intended to be used in the bassinet of	brand and model it is intended to replace: Pad	"after-market" will be clearer.
a play yard with a bassinet	Thickness for Fabric or Mesh Sided Products; Pad	
attachment, the mattress shall also	dimensions; Side Height; Bassinets with Segmented	
meet the specifications of the	Mattresses.	
following sections of Consumer	This section (5.9.1.3) applies only to a play yard	
Safety Specification F2194 when	mattress that is interchangeably used as a play yard	
tested with each brand and model it is	mattress and as a bassinet mattress / pad.	
intended to replace: Pad		
Thickness for Fabric or Mesh Sided		
Products; Pad dimensions; Side		
Height; Bassinets with Segmented		
Mattresses.		
This section $(5.9.1.3)$ applies only to		
a play yard mattress that is		

ASTM F2933 – 19	Staff's Recommended Revisions	Rationale Summary
interchangeably used as a play yard mattress and as a bassinet mattress /		
pad.		
	5.10 Mattress Firmness	Add a new section with a requirement for <i>Mattress Firmness</i> . This addition will address staff's recommendation that a crib mattress's surface firmness meets the requirements based on
	5 10 1 All crib mattresses within the scope of this	AS/INZS 8811.1.
	standard, when tested in accordance with 6.3, the	
	feeler arm shall not contact the sleep surface of the	
	crib mattress.	
	5.11 Coil Springs	Add a new section with a requirement for <i>Coil Springs</i> . This addition will address staff's recommendation that a crib mattress does not have any exposed springs or wires when subject to the cyclic testing as described.
	The requirements in this section only pertain to crib	
	mattresses with coil springs.	
	5.11.1 When tested in accordance with 6.4, there shall	
	be no exposed coil springs or metal wires.	

#### ASTM F2933 – 19, Section 6. Test Methods

ASTM F2933 – 19	Staff's Recommended Revisions	Rationale Summary
6.2.2 Test Method:	6.2.2 Test Method Test Equipment-Mattress	To accommodate sheet compression test, add
	Sheet:	new equipment to section 6.2.2: <u>Test Equipment-</u>
		Mattress Sheet, with specifications and

ASTM F2933 – 19	Staff's Recommended Revisions	Rationale Summary
	6.2.2.1 The mattress sheet shall be 100%	instructions in sections 6.2.2.1 and 6.2.2.2,
	cotton and fitted for the mattress to be tested.	respectively. Staff recommends the use of a
	6.2.2.2 The mattress sheet shall be washed in	washed cotton mattress sheet to verify the crib
	hot water (50° C [122° F] or higher) and dried	mattress is not adversely affected by the use of a
	a minimum of two times on the highest	used sheet. The wash cycles simulate the
	setting using household textile laundering	shrinkage of the sheet over time with use.
	units. This shall be the test mattress sheet.	
6.2.2 Test Method:	6.2.2 6.2.3 Test Method:	1.) Section numbers are revised based on the
6.2.2.1 Place the mattress into the	$6.2.2.1 \pm 6.2.3.1$ Place the mattress into the	addition of section 6.2.2 Test Equipment-
mattress measuring box so it is	mattress measuring box so it is touching	Mattress Sheet.
touching Walls C and D.	Walls C and D.	
6.2.2.2 To Position the mattress in the	$6.2.2.2  ext{ } 6.2.3.2  ext{ } To Position the mattress in the }$	2.) Add Sections 6.2.3.5 and 6.2.3.6 to define
measuring box, gradually apply a 7lbf	measuring box, gradually apply a 7lbf (31.1	how to measure corner gaps. This change will
(31.1 N) force to Panel A. Release	N) force to Panel A. Release this force. Then	address staff's recommendation that the corner
this force. Then gradually apply a 14	gradually apply a 14 lbf (62.3 N) force to	gap between a full-size crib and mattress should
lbf (62.3 N) force to Panel B. Release	Panel B. Release this force.	be no larger than 1.75 in. (44.5 mm).
this force.	$\frac{6.2.2.3}{6.2.3.3}$ Apply a 7 ± 1 lbf (31 ± 4.4 N)	
6.2.2.3 Apply a 7 $\pm$ 1 lbf (31 $\pm$ 4.4 N)	force to panel A within a period of 5 s. Within	3.) Add sections 6.2.3.6 through 6.2.3.8. This is
force to panel A within a period of 5	30 s of application of the force to Panel A,	the test method recommended by staff which
s. Within 30 s of application of the	and while maintaining this force, apply a 14 $\pm$	verifies that full-size crib mattresses are not
force to Panel A, and while	1 lbf (62.3 $\pm$ 4.4 N) force to Panel B within a	adversely affected by the use of a used sheet.
maintaining this force, apply a $14 \pm 1$	period of 5 s.	The dimensions and corner gaps of the mattress
lbf ( $62.3 \pm 4.4$ N) force to Panel B	6.2.2.4 6.2.3.4 Apply the forces from 6.2.2.3	should remain within the acceptable range.
within a period of 5 s.	for 60 s. With forces still applied, measure the	
6.2.2.4 Apply the forces from 6.2.2.3	length and width of the interior dimension	
for 60 s. With forces still applied,	measured from the horizontal midpoints of	
measure the length and width of the	Panel A to Wall C (length) and Panel B to	
interior dimension measured from the	Wall D (width). These measurements are to	
horizontal midpoints of Panel A to	be considered the mattress dimensions.	
Wall C (length) and Panel B to Wall	6.2.3.5 Measure the shortest gap between the	
D (width). These measurements are	mattress and the mattress measuring box at	
	the corner adjoining Walls C and D after the	

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ASTM F2933 – 19	Staff's Recommended Revisions	Rationale Summary
to be considered the mattress	dimensions of the mattress have been	
dimensions.	recorded. The mattress shall not be moved	
	before or during measurement. This shall be	
	the corner gap measurement.	
	6.2.3.6 Rotate the mattress 180° such that the	
	opposing corner is adjacent to Walls C and D,	
	then repeat 6.2.3.2 and 6.2.3.5.	
	6.2.3.7 The test mattress sheet shall be placed	
	on the mattress such that each sheet edge is	
	wrapped fully around and under the mattress.	
	6.2.3.8 The mattress with test mattress sheet	
	shall be measured following steps 6.2.3.1	
	through 6.2.3.6. The mattress dimensions	
	shall meet the requirements in 5.7.	
	6.3 Mattress Firmness	
	<u>6.3.1 Test Fixture</u>	This is the mattress firmness test based on
	6.3.1.1 The fixture, as shown in Fig. 2, shall	AS/NZS 8811.1:2013
	be a rigid, robust object with a round footprint	
	of diameter 203 ±1 mm, and an overall mass	
	of 5200 $\pm$ 20 g. The lower edge of the fixture	
	shall have a radius not larger than 1 mm.	
	Overhanging the footprint by $40 \pm 2 \text{ mm shall}$	
	be a flexible, flat bar of width 12 ±0.2 mm	
	with square-cut ends. This bar may be	
	fashioned from a shortened hacksaw blade.	
	The bar shall rest parallel to the bottom	
	surface of the fixture and shall be positioned	
	at a height of 15 ±0.2 mm above the bottom	
	surface of the fixture. The bar shall lay	
	directly over a radial axis of the footprint (i.e.	
	such that a longitudinal centerline of the bar	
	would pass over the center of the footprint).	

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	6.3.1.2 Included on the fixture, but not	
	overhanging the footprint, shall be a linear	
	level that is positioned on a plane parallel to	
	the bar, and in a direction parallel to the bar.	
	6.3.1.3 Other parts of the fixture, including	
	any handle arrangement and any clamping	
	arrangement for the bar, shall not comprise	
	more that 30% of the total mass of the fixture,	
	and shall be mounted as concentric and as low	
	as possible.	
	<u>6.3.2 Test Method:</u>	
	6.3.2.1 Mattresses that are supplied with a	
	product shall be tested when positioned on	
	that product. Mattresses, sold independent of	
	a product, shall be tested on a flat, rigid,	
	horizontal support. After-market mattresses	
	for play yards and non-full-size cribs shall be	
	tested with each brand and model of product	
	it is intended to replace.	
	6.3.2.2 Where a user of a mattress could	
	possibly position either side face up, even if	
	this is not an intended use, then both sides of	
	the mattress shall be tested.	
	6.3.2.3 Before testing each mattress, the	
	following steps shall be followed:	
	(1) <u>Verify there is no excess moisture in the</u>	
	mattress, beyond reasonable laboratory	
	humidity levels.	
	(2) <u>Allow sufficient time per the</u>	
	manufacturer's instructions to fully	
	inflate, if shipped in a vacuum sealed	
	package.	

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	(3) Shake and or agitate the mattress in order	
	to fully aerate and distribute all internal	
	components evenly.	
	(4) <u>Place the mattress in the manufacturer's</u>	
	recommended use position if there is one,	
	in the supplied product, or on a flat, rigid,	
	horizontal support.	
	(5) Let the mattress rest for at least 5 minutes.	
	(6) Mark a longitudinal centerline on the	
	mattress sleep surface, and divide this line	
	in half. This point will be the first test	
	location. Then further divide the two lines	
	on either side of the first test location into	
	halves. These will be the second and third	
	test locations.	
	<u>6.3.2.4 Position the test fixture on each of the</u>	
	test locations, with the footprint of the fixture	
	centered on the location, with the bar	
	extending over the centerline and always	
	pointing at the same end of the mattress sleep	
	surface.	
	(1) <u>At each test location in turn, rotate the</u>	
	bar to point in the required direction, and	
	gently set the fixture down on the	
	mattress sleep surface, ensuring that the	
	footprint of the fixture does not extend	
	beyond the edge of the mattress. The	
	fixture shall be placed as horizontal as	
	possible, using the level to verify. If the	
	bar makes contact with the top of the	
	mattress sleep surface, even slightly, the	

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	mattress is considered to have failed the	
	test.	
	(2) <u>Repeat Step (1) at the remaining</u>	
	locations identified in 6.3.2.1(6).	
	(3) <u>Repeat Step (1) at a location away from</u>	
	the centerline most likely to fail (e.g. a	
	very soft spot on the sleep surface or at a	
	raised portion of the sleep surface). In	
	the case of testing a raised portion of a	
	sleep surface, position center of the	
	fixture such that the bar is over the raised	
	portion, to simulate the position of an	
	infant's nose.	
	(4) In the event that the fixture is not resting	
	in a nearly horizontal orientation, repeat	
	the test procedure at that location by	
	beginning again from Step (1) above.	
	However, if the test produces a fail even	
	with the device tilted back away from the	
	bar so as to raise it, then a fail can be	
	recorded.	
	<u>6.4 Coil Spring Test</u>	
	6.4.1 General—This test consists of dropping	As discussed in the text of the memo, this is the
	a specified weight repeatedly onto the	impact loading test.
	mattress. The test assists in evaluating the	
	structural integrity of a mattress with coil	
	springs.	
	<u>6.4.2 Test Fixture:</u>	
	6.4.2.1 A guided free-fall impacting system	
	machine (which keeps the upper surface of	
	the impact mass parallel to the horizontal	

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	surface on which the crib is secured)(See Fig.	
	<u>3)</u>	
	6.4.2.2 A 30-lb (13.6-kg) impact mass (see	
	<u>Fig. 4 and Fig.5).</u>	
	6.4.2.3 A 6-in. (150-mm) long gauge.	
	6.4.2.4 An enclosed frame measuring 29	
	inches by 53 inches (737 mm by 1346 mm)	
	for the purpose of restricting mattress	
	movement. When testing full-size mattresses,	
	a full-size crib meeting the requirements of	
	ASTM F1169-19 would suffice.	
	6.4.2.5 a <sup>3</sup> / <sub>4</sub> " piece of plywood or OSB that is	
	rigidly supported along the perimeter.	
	7.4.3 Test Method:	
	6.4.3.1 Place the mattress on the wooden	
	support and inside the enclosed frame.	
	6.4.3.2 Position geometric center of the	
	impact mass above the geometric center of the	
	test mattress.	
	6.4.3.3 Adjust the distance between the top	
	surface of the mattress and bottom surface of	
	the impact mass to 6 in. (150 mm) (using the	
	6-in. (150-mm) long gauge, per 6.4.2.3) when	
	the impact mass is in its highest position.	
	Lock the impactor mechanism at this height	
	and do not adjust the height during impacting	
	to compensate for any change in distance as a	
	result of the mattress compressing or the	
	mattress support deforming or moving during	
	impacting.	
	6.4.3.4 Allow the 30-lb (13.6-kg) impact mass	
	to fall freely 250 times at the rate of one	

ASTM F2933 – 19	Staff's Recommended Revisions	Rationale Summary
	impact every 4 s. Load retraction shall not	
	begin until at least 2 s after the start of the	
	drop.	
	6.4.3.5 Repeat the step described in 6.4.3.4 at	
	the other test locations shown in Fig. 6	

Figures referenced in Staff's Recommended Revisions to Test Methods:



Figure 2. Firmness Test Fixture Adapted from Australian/New Zealand Standard 8811.1:2013 test apparatus



Figure 3. Typical free fall impacting system<sup>51</sup>

<sup>&</sup>lt;sup>51</sup> Reprinted, with permission, from ASTM F1169-19 Standard Consumer Safety Specification for Full-Size Baby Cribs, copyright ASTM International, 100 Barr Harbor Drive, West Conshohocken, PA 19428. A copy of the complete standard may be obtained from ASTM International, <u>www.astm.org</u>.





Figure 6. Impact test locations
# TAB C: Human Factors Assessment of Identified Hazards Associated with Crib Mattresses, Non-Full-Size Crib Mattresses, and After-Market Mattresses for Play Yards and Non-Full-Size Cribs





Memorandum

Date: September 30, 2020

TO:	Hope Nesteruk, Project Manager, Crib Mattress Team Division of Mechanical and Combustion Engineering, Directorate for Engineering Sciences
THROUGH:	Mark Kumagai, Associate Executive Director, Directorate for Engineering Sciences
	Rana Balci-Sinha, Director Division of Human Factors, Directorate for Engineering Sciences
FROM:	Stephen Harsanyi, Engineering Psychologist Division of Human Factors, Directorate for Engineering Sciences
SUBJECT:	Human Factors Assessment of Identified Hazards Associated with Crib Mattresses, Non-Full-Size Crib Mattresses, and After-Market Mattresses for Play Yards and Non-Full-Size Cribs

# I. Introduction

Staff of the U.S. Consumer Product Safety Commission (CPSC, or the Commission) has evaluated hazards associated with full-size crib mattresses, non-full-size crib mattresses, and after-market mattresses for cribs, play yards, and non-full-size cribs (collectively, "crib mattresses"), including, but not limited to, sudden unexpected infant death (SUID), material liberation, chemical concerns, and exposed springs or other sharp objects. In support of the staff briefing package for a notice of proposed rulemaking (NPR) for crib mattresses under section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), staff of CPSC's Directorate for Engineering Sciences, Division of Human Factors (ESHF), assessed the effectiveness of the voluntary standard, ASTM F2933 – 19, *Standard Consumer Safety Specification for Crib Mattresses*, to address factors associated with SUID, including positional asphyxia/suffocation related to prone positioning, soft bedding, and gap entrapment in sleep areas. To further reduce the risks of death and serious injury associated with crib mattresses, ESHF staff recommends that the Commission promulgate a mandatory standard for crib mattresses, which incorporates by reference ASTM F2933 – 19, with the addition of modifications discussed in this memorandum to make crib mattresses safer. This memorandum

discusses mattress-use factors related to SUID, and staff recommends additional requirements for safety information.

# II. Discussion

CPSC promulgated a mandatory standard for full-size cribs, 16 CFR part 1219, incorporating by reference, ASTM F1169 – 19, *Standard Consumer Safety Specification for Full-Size Baby Cribs*. Currently, however, there is only a voluntary standard for crib mattresses, ASTM F2933 – 19, which defines "mattress" in section 3.1.5 as "ticking filled with a resilient material used alone or in combination with other products intended or promoted for sleeping on it." ASTM F2933 – 19 establishes design requirements, testing requirements and methods, and requirements for labeling for full-size crib mattresses, non-full-size crib mattresses, and after-market mattresses for play yards and non-full-size cribs. Staff identified various mattress-use factors associated with deaths and serious injuries related to SUID, including, but not limited to, prone positioning of sleeping infants, soft bedding added to sleep areas, and gaps/pockets between mattresses and infant product sides. In this memorandum, CPSC staff explains the identified hazards, summarizes findings from incident data, supplies feedback from consumers regarding the contributing factors, describes ASTM voluntary standards activity for addressing the hazards, and provides ESHF staff's recommendations for addressing the hazards.

## **Explanation of the Identified Hazards**

The Centers for Disease Control and Prevention (CDC) defines "SUID" as a term used to describe the sudden and unexpected death of a baby less than 1-year-old, in which the cause was not obvious before investigation.<sup>52</sup> The American Academy of Pediatrics (AAP, 2016) explains that SUID, also known as "sudden unexpected death in infancy" (SUDI), includes explained and unexplained deaths, and it can be attributed to suffocation, asphyxia, entrapment, infection, ingestions, metabolic diseases, arrhythmia-associated cardiac channelopathies, and trauma.<sup>53</sup> Sudden infant death syndrome (SIDS) is a subcategory of SUID that refers to infant deaths that cannot be explained after a thorough case investigation. For the remainder of this memorandum, the terms SUID and SIDS are used interchangeably, as SIDS commonly is used to refer to SUID in warning labels and articles and given that consumers are more familiar with the term SIDS as opposed to SUID.

In Tab E, Health Sciences staff (Wanna-Nakamura, 2020) identifies several risk factors for SUID, including infant prone sleep, bedding items used to soften sleep surfaces, and excessive gaps caused by an ill-fitting mattress. Wanna-Nakamura explains that infants experiencing a compromised airflow are likely to undergo a cycle of decreased heart and respiration rate, resulting eventually in fatal cessation of breathing. Numerous public awareness campaigns have

<sup>&</sup>lt;sup>52</sup> See

https://www.cdc.gov/sids/about/index.htm?CDC\_AA\_refVal=https%3A%2F%2Fwww.cdc.gov%2Fsids%2FAboutS <u>UIDandSIDS.htm;</u> accessed July 20, 2020.

<sup>&</sup>lt;sup>53</sup> See <u>https://pediatrics.aappublications.org/content/pediatrics/138/5/e20162938.full.pdf;</u> accessed May 5, 2020.

aimed to educate caregivers regarding the identified hazards; these campaigns include: "Back to Sleep" (Moon et al., 2016, as cited in Fors Marsh Group, 2019), the "ABC's of safe sleep" (alone (no bed sharing), back-sleeping, and crib uncluttered),<sup>54</sup> and "Safe Sleep/Bare is Best."<sup>55,56</sup> Health and safety advocates, including the AAP, CDC,<sup>57</sup> CPSC, and Kids in Danger (KID)<sup>58</sup> support these efforts.

In the ESHF memorandum in response to Petition CP 15-2, Newens and Balci-Sinha (2017) explain that to make infant sleep environments more comfortable, caregivers commonly use soft bedding and after-market mattresses, instead of, or in addition to, the original equipment manufacturer (OEM) mattress. Newens and Balci-Sinha explain that infants can maneuver themselves into vulnerable positions, from which they cannot free themselves:

Infants between 2 and 6 months old are developing new skills in stages, such as rolling over and crawling. According to Bayley (1969), several developmental milestones occur within the first 6 months of life; some notable motor skills typically achieved are turning from side to back (average age: 1.8 months old), turning from back to side (average age: 4.4 months old), and turning from back to stomach (average age: 6.4 months old). Children as young as 8 to 12 weeks are likely to move around a play yard, including moving to the edge and possibly moving into vulnerable situations. However, children may not be able to remove themselves by reversing their actions because they may not have developed the skill.

Infants can become trapped in a gap between a crib mattress and the side wall(s) of their sleep environment, with their nose and mouth pressed against the mattress or side wall, experiencing compromised airflow. Discussed in section B below, gap entrapment is a hazard associated with ill-fitting mattresses in full-size cribs, play yards, and non-full-size cribs. To minimize the risk for entrapment in a gap, a full-size crib and full-size crib mattress that meet the applicable standards allow a maximum side gap of 1<sup>3</sup>/<sub>8</sub> inches.<sup>59</sup> Given non-flexible sides and infant head dimensions,<sup>60</sup> requirements in these standards work in tandem to help prevent head entrapment

<sup>58</sup> See <u>https://kidsindanger.org/protect-your-child/sleep/;</u> accessed May 6, 2020.

<sup>&</sup>lt;sup>54</sup> See <u>https://www.aappublications.org/news/2016/10/24/SIDS102416</u>; accessed May 7, 2020.

<sup>&</sup>lt;sup>55</sup> See <u>https://www.cpsc.gov/Safety-Education/Neighborhood-Safety-Network/Posters/Safe-Sleep-for-Babies;</u> accessed May 6, 2020.

<sup>&</sup>lt;sup>56</sup> See <u>https://www.cpsc.gov/safety-education/safety-guides/kids-and-babies-cribs/safe-sleepbare-best</u> and <u>https://www.nationwidechildrens.org/family-resources-education/health-wellness-and-safety-resources/helping-hands/safe-sleep-practices-for-babies;</u> accessed May 11, 2020.

<sup>&</sup>lt;sup>57</sup> See <u>https://www.cdc.gov/vitalsigns/safesleep/index.html</u>; accessed May 2, 2020.

<sup>&</sup>lt;sup>59</sup> Per 16 CFR part 1219, and by reference ASTM F1169 – 19, a full-size crib must have interior dimensions of 28  $\pm^{5}/_{8}$  inches wide by  $52^{3}/_{8} \pm^{5}/_{8}$  inches long. Per the existing voluntary standard for crib mattresses, ASTM F2933 – 19, a full-size crib mattress shall measure at least  $27^{1}/_{4}$  inches wide by  $51^{5}/_{8}$  inches long by 6 inches thick.

<sup>&</sup>lt;sup>60</sup> According to Snyder (1975), the 5<sup>th</sup> percentile head breadth, *i.e.*, the maximum breadth of the head above and behind the ears, of children 0 to 3 months old is approximately  $3^{3}/_{10}$  inches, which is more than twice as wide as the maximum allowable side gap between full-size cribs and full-size crib mattresses. ESHF staff selected head "breadth," as opposed to length or height, to err on the side of caution, as head breadth is the smallest of these three head dimensions that could cause a fatal entrapment. Similarly, staff selected the 5<sup>th</sup> percentile measurement for 0-to-3-month-old infants to reduce the likelihood of death or serious injury to those most vulnerable to the identified hazards.

and suffocation between the mattress and crib sides, even though a full-size crib manufacturer is not required to provide the mattress.<sup>61</sup> Still, incidents of gap entrapment involving these products continue to occur, including when the full-size crib and *non-compressed* full-size crib mattress measure the appropriate dimensions. As detailed in CPSC staff's letter to the ASTM subcommittee on Crib Mattresses (ASTM F15.66) in December 2019, gaps involving full-size crib mattresses can develop if the mattresses are too soft, such as when the mattress is compressed by mattress sheets. In the letter, staff describes testing and incidents demonstrating gaps widening over time from laundered crib mattress sheets, particularly in the corners of mattresses with rounded edges.

Gaps between the infant's mattress and sleep product sides are especially hazardous when aftermarket mattresses with thicker depth dimensions than the OEM mattress are used in products with flexible (e.g., mesh or fabric) sides, such as play yards and non-rigid-sided portable cribs. The side walls of these products typically expand more towards the center of the side wall, and, consequently, as the thickness of mattresses used in these products increases, the risk of gap entrapment often increases as well. In 2018, pursuant to CPSC staff's work with ASTM, section 5.9 of the crib mattress standard (ASTM F2933 - 18) was updated to specify that after-market mattresses for play yards and non-full-size cribs must have the same thickness (within  $\frac{1}{4}$  inch), floor support structure, and attachment method as the mattress it is intended to replace. In addition, after-market mattresses for play yards and non-full-size cribs must meet the mattress, mattresses for rigid-sided products, and mattress vertical displacement requirements specified in ASTM F406, Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards, when tested with each brand and model of product it is intended to replace.<sup>62</sup> Play yards and non-full-size cribs are not required to be standard sizes. Instead, ASTM F406 – 19 addresses the gap-entrapment hazard by requiring: (1) mattresses to be provided with play yards and non-fullsize cribs; (2) a maximum gap of 1 inch for rigid-sided products; and (3) a maximum thickness of  $1^{1}/_{2}$  inches (maximum of 1 inch of filling material) for mesh/fabric-sided products.<sup>63</sup> The thickness requirement for mesh/fabric-sided products often results in mattresses with less than 1 inch of filling material to account for manufacturing variance, which caregivers may find uncomfortable for their infants, resulting in the use of soft bedding, mattresses thicker than  $1^{1}/_{2}$ inches, use of supplemental mattresses, or a combination of these items. CPSC staff has been participating in the ASTM subcommittee for play yards and non-full-size cribs, ASTM F15.18, to address comfort concerns for mesh/fabric-sided products. ASTM F15.18 is considering increasing the thickness requirement beyond  $1^{1/2}$  inches, along with creating a test for gap entrapment.

<sup>&</sup>lt;sup>61</sup> See <u>https://www.cpsc.gov/Business-Manufacturing/Business-Education/Business-Guidance/Full-Size-Baby-Cribs/</u>, accessed May 1, 2020.

<sup>&</sup>lt;sup>62</sup> The definition of "After-market mattress for play yard or non-full-size crib" was added in 2018 (ASTM F2933 – 18) as section 3.1.1: "a mattress sold or distributed for a play yard or non-full-size crib." Section 3.1.1.1 elaborates on this definition, explaining the following: "This does not include a replacement mattress provided or sold by an original equipment manufacturer (OEM) if, and only if, it is equivalent with respect to dimensions, and specifications to the mattress that was provided with the original product."

<sup>&</sup>lt;sup>63</sup> March 1996 ASTM meeting minutes, which include the following rationale: "Limit the thickness of pads to prevent entrapment of an infant in a recess that could be created between the mattress and the play yard. Mesh/fabric side could deform to create a pocket between the sides and mattress."

## **Incident Data**

CPSC staff examined incident data from the Consumer Product Safety Risk Management System (CPSRMS)<sup>64</sup> and the National Electronic Injury Surveillance System (NEISS) for fatalities, incidents, and concerns associated with crib mattresses, reported to have occurred from January 1, 2010 through March 31, 2020 (Suchy, 2020). Incident data examined by CPSC staff included reports of issues such as follows:

- infants found with their faces in contact with a crib mattress or the crib sheet covering the crib mattress;
- infants found in a prone position on a crib mattress, with no mention of their faces being obstructed by the mattress or other crib bedding;
- infants found with soft bedding in the sleep area;
- crib mattress fit issues (such as being too small or shrinkage, causing an entrapment hazard); and
- crib mattress material, structural integrity, or quality issues (*e.g.*, chemical odor, causing rashes, protruding coils, falling apart, or too soft or flimsy).

CPSC staff reviewed reports pertaining to 439 incidents and complaints. Incidents resulted in fatalities in 116 cases. Victims in fatal incidents ranged in age from 1 month to 39 months. The causes of death were typically described as a form of SUID, such as asphyxia/suffocation, SIDS, or both. In Tab A, Epidemiology Division of Hazard Analysis (EPHA) staff details the findings of the data, including potential causes of deaths and injuries involving crib mattresses. To determine the prevalence of hazardous use cases, ESHF staff further examined the incident data for information regarding prone positioning, soft bedding, and gap entrapment. The counts below include staff's observation of factors related to the identified hazards, regardless of the factors' involvement in the specific deaths, injuries, and complaints. Therefore, one incident could be counted in multiple categories. ESHF staff cautions that the counts and percentages below are limited by the lack of sufficient detail in many reports to discern the specific circumstances involved in the incidents.

# a. Infant Positioning

Of the 116 incidents resulting in death, at least 102 incidents (about 88%) reported that infants were placed or found face down, chest down, or both, and many of these cases did not identify other contributing factors. Counting deaths, injuries, and complaints, at least 116 infants were placed or found face down, chest down, or both, on crib mattresses. Twenty-six of these cases reported that infants were *placed* on their mattresses face down, chest down, or both. In some cases, caregivers indicated that the infants initially were placed supine, or on their side, but later were seen sleeping prone, and were left in that position, to avoid disturbing them.

<sup>&</sup>lt;sup>64</sup> CPSRMS is the epidemiological database that houses all anecdotal reports of incidents received by CPSC, "external cause-" based death certificates purchased by CPSC, all in-depth investigations of these anecdotal reports, as well as investigations of select NEISS injuries. Examples of documents in CPSRMS are: hotline reports, internet reports, news reports, medical examiner's reports, death certificates, retailer/manufacturer reports, and documents sent by state/local authorities, among others.

## b. Soft Bedding

At least 41 of the deaths (about 35%) included reports of soft bedding added to the sleep area. "Soft bedding" generally included items such as blankets and pillows.<sup>65</sup> Counting deaths, injuries, and complaints, at least 49 cases involved soft bedding added to the sleep area. Where reasons were provided, caregivers typically explained that they used soft bedding to add comfort and warmth. Regarding items added for comfort, staff found that caregivers used an after-market mattress (typically 3" or greater) in 16 of the 26 cases involving play yards or non-full-size cribs. In at least 6 of these 16 cases, caregivers used the after-market mattress on top of the OEM mattress, including at least three cases involving full-size crib mattresses used to supplement another mattress in a play yard. These counts may be higher, given that the reports often lack enough information to discern whether an OEM mattress or multiple mattresses were used.

## c. Gaps

At least 25 deaths (about 22%) involved reported gaps between one or more sides of a crib mattress and the side wall(s) of a crib, play yard, or portable crib. Counting deaths, injuries, and complaints, at least 138 cases involved gaps between the side of the mattress and side wall of the crib, play yard, or portable crib. In most cases, caregivers indicated they were aware that these gaps are hazardous, and responded by either refusing to use the involved products, or by attempting to fill the gaps with items like soft bedding materials. Still, at least 54 incidents involved entrapment of infants' arms, legs, head, torso, or a combination. Some reports indicate that the gaps developed over time, as a result of deformations in springs and foam, or from compression of the mattress by mattress sheets.

At least seven cases involved gaps in the corners between crib mattresses and the side walls of the sleep products. For example, one report from 2010 (IDI 100302HCC3396) describes a mother finding her 8-month-old infant upside down with his head trapped in a gap in the corner of his standard crib and full-size crib mattress; his face was up against the corner of the mattress, and his arms, legs, and torso were above the mattress. Figure 1 below shows a re-creation of the entrapment in the IDI. The investigator measured the maximum corner gap and found it to be approximately 2½ inches wide with bedding, and 2¼ inches wide without bedding (see Tab B for more information).

<sup>&</sup>lt;sup>65</sup> This count does not include fitted sheets, mattress pads, or supplemental mattresses.



Figure 1. Re-creation of infant head entrapment in IDI 100302HCC3396.

In another example, which involved the death of a 6-month-old infant in 2019 (IDI 200127CBB1242),<sup>66</sup> the infant was found with her head wedged between an after-market mattress and the side wall of a play yard, potentially under the mattress. The after-market mattress and a blanket were used for comfort; the victim's grandparents explained that the mattress supplied with the play yard was "too hard for the baby to sleep on." Using surveys and focus groups, staff investigated these use patterns to inform staff's recommendations for addressing the identified hazards.

# Feedback from Consumers Regarding Use of Crib Mattresses in Sleep Products

CPSC issued contracts to conduct consumer feedback research on the use of various sleep products, including cribs, play yards, and non-full-size cribs. Researchers collected feedback from caregivers via a nationally representative survey in 2013, and six focus groups in 2019. Below, ESHF staff summarizes relevant findings from the reports provided by these contractors.

# a. 2014 Survey Regarding Durable Infant and Toddler Products

The 2014 "Durable Nursery Products Exposure Survey (DNPES): Final Summary Report," by Westat, details the findings of a survey conducted in 2013, which collected information about durable infant and toddler products. The survey included items regarding ownership characteristics, the life cycle of the products, and consumer behaviors and perceptions regarding the products. The survey used a national probability sample of households with children 5 years old and under. Product categories included cribs (full-size and non-full-size cribs combined) and play yards, among others. Relevant to this memorandum, the survey asked participants about items added to sleep products under the child. Westat found the following:

• Approximately 94 percent of crib users reported placing an item (other than the intended mattress) under the child in a crib; items added to cribs included pillows (~23%), blankets or quilts (~36%), fitted sheets (~84%), and mattress pads (~50%).

<sup>&</sup>lt;sup>66</sup> This incident is not included in the above counts, as the investigation review date was April, 20, 2020. The investigation is ongoing at this time.

• Approximately 75 percent of play yard users reported placing an item (other than the intended mattress) under the child in a play yard; items added to play yards included pillows (~26%), blankets or quilts (~62%), and mattress pads (~12%).

These findings suggest that consumers commonly add items to cribs, play yards, and non-fullsize cribs for comfort, including soft bedding materials. Discussed below, focus group research conducted more recently had similar results and expanded on potential underlying reasons for these findings.

# b. 2019 Focus Groups Regarding Safe Sleep Safety Messaging

The 2019 "Consumer Product Safety Commission (CPSC): Caregiver Perceptions and Reactions to Safety Messaging Final Report" (Safety Messaging Report) by Fors Marsh Group, summarizes focus group research and a literature review pertaining to safe sleep practices in various products, including cribs and play yards. The focus group participants were parents, grandparents, or both. The participants reported inconsistencies between their beliefs and behaviors regarding safe sleep practices. While some participants did report actively making changes to their behaviors as a result of the risks conveyed by safety messages, many participants stated that convenience is an underlying motivator, and they do whatever it takes to ensure their infant is "comfortable" and sleeps. The participants defined comfort by whether the infant sleeps all night or not. Many participants, particularly grandparents, reported adding comfort items to sleep environments, and explained that generally they avoided disturbing sleeping infants. Participants provided examples of comfort items, such as blankets, pillows, and mattresses (including memory foam and plush mattresses).

The Safety Messaging Report literature review identified concerns regarding marketing and warning information for infant products. According to Kreth *et al.* (2016) (as cited in Fors Marsh Group, 2019), warning messaging and product marketing regarding safe sleep best practices are not always consistent, and are not always prominent in product advertisements. Research by Joyner *et al.* (2009) (as cited in Fors Marsh Group, 2019), found that magazines targeting women of childbearing age often depict children in sleep environments with items added for comfort, such as loose bedding. Joyner *et al.*, also raised a concern that caregivers are likely to trust implicitly the safety of products under the misconception that if a product is sold to the public, then it is likely safe to use. Staff believes this misconception is likely more common for infant products, given the greater vulnerability of infants to hazards. Regarding ways to improve warning messaging, the Safety Messaging Report cited research by Trachtenberg *et al.* (2012), stating that highlighting specific risks to avoid reduces negative outcomes, such as SIDS.

Based on the focus group feedback and literature review, the Safety Messaging Report recommended improving safety messaging by making messages clear, concise, and consistent; explaining that research results emphasize that safety messages that are ambiguous or too long will deter individuals from paying attention to the messages. ESHF staff considered the results of these reports in assessing the adequacy of the requirements for safety information in ASTM F2933 – 19 to address the identified hazards.

## Adequacy of the Safety Information in ASTM F2933 - 19

As discussed in the ESHF staff memorandum assessing requirements for crib bumpers (Smith, 2019), warning about hazards is viewed universally as less effective at addressing hazards than either designing the hazard out of a product or guarding the consumer from the hazard. Use of warnings is lower in the hazard-control hierarchy than design-based approaches, because the effectiveness of a warning depends on persuading consumers to alter their behavior in some way to avoid hazards, rather than eliminating hazards, or inhibiting exposure to hazards. Therefore, when standards rely on warnings to address a hazard, warning statements must be as strong as possible; *i.e.*, the warnings must be noticeable, understandable, and motivating. 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; as cited in Smith, 2019), consistently recommend that on-product warnings include content that addresses the following three elements:

- a description of the hazard;
- information about the consequences of exposure to the hazard; and
- instructions regarding appropriate hazard-avoidance behaviors.<sup>67</sup>

Section 7 of ASTM F2933 – 19 specifies requirements for marking and labeling for full-size crib mattresses, non-full-size crib mattresses, and after-market mattresses for play yards and non-full-size cribs (see Appendix). Based on ESHF staff's examination of literature, incident data, and consumer feedback, staff concludes that the crib mattress warnings specified in ASTM F2933 – 19 do not adequately address these warning elements regarding the identified hazards. While there are warnings pertaining to infant positioning, soft bedding, and gap entrapment, the wording and formatting of the warning message needs to be improved to communicate the hazards effectively. Below, staff summarizes the relevant warnings in ASTM F2933 – 19 and staff's concerns with the warnings. Section E and the Appendix discuss these issues in greater detail.

## a. Warnings Regarding Infant Positioning

Regarding positioning babies on their backs to sleep, ASTM F2933 – 19 requires the following warning:

Failure to follow these warnings could result in serious injury or death. To prevent deaths, the U.S. Consumer Product Safety Commission (CPSC), the American Academy of Pediatrics (AAP), and the National Institute of Child Health and Human Development (NICHD) recommend the following:

To reduce the risk of Sudden Infant Death Syndrome (SIDS) and suffocation, pediatricians recommend healthy infants be placed on their backs to sleep, unless otherwise advised by your physician.

<sup>&</sup>lt;sup>67</sup> All three elements may not be necessary in some cases, *i.e.*, if certain information is open and obvious or can be readily inferred by consumers. However, determining what is "open and obvious" can be challenging, as consumers may vary meaningfully in their knowledge and expectations, and overestimating obviousness can lead to fatal outcomes.

The warning to place babies on their backs to sleep includes, and is presented after, a significant amount of unnecessary text. Given that at least 102 of the 116 deaths involved prone positioning, many of which indicated no other known contributing factors, staff concludes it is imperative that this warning be as clear and direct as possible. Discussed in section E and the Appendix, ESHF staff recommends modifying this warning statement and its position on the warning label to increase the likelihood of consumers reading and understanding the hazard of prone sleeping.

# b. Warnings Regarding Soft Bedding

Regarding soft bedding, ASTM F2933 – 19 includes the following warnings:

- Infants can suffocate on soft bedding. Never place a pillow or comforter under sleeping infant for additional padding or as a mattress substitute.
- Do not cover the heads of babies with a blanket or over bundle them in clothing and blankets. Overheating can lead to SIDS.
- [For full-size crib mattresses] Only use sheets and mattress pads designed specifically for crib mattresses.
- [For non-full-size crib mattresses] Only use sheets and mattress pads designed specifically for this mattress size.

Unnecessary wording is included in the warnings pertaining to soft bedding, and the warnings are not clearly organized. Reports for at least 49 incidents indicate that caregivers added soft bedding to the sleep area, and survey and focus group feedback demonstrate that consumers commonly use soft bedding in infant sleep areas. As advocated in numerous public awareness campaigns by health and safety professionals, warnings regarding soft bedding must be communicated effectively to motivate consumers to comply with the warnings. Staff recommends modifying the warning content and formatting to increase the readability and directness of the warnings.

# c. Warnings Regarding Gaps

Regarding gaps, in addition to specifying consumers use only sheets and mattress pads designed for the crib mattress, ASTM F2933 – 19 includes the following warnings:

- [For full-size crib mattresses] Do not use this mattress in a crib having interior dimensions that exceed 28<sup>5</sup>/<sub>8</sub> by 53 in. (73 by 135 cm) as measured from the innermost surfaces of the crib.
- [For non-full-size rigid sided rectangular products] Check for proper fit of the mattress. This mattress measures \_\_\_\_\_ long, \_\_\_\_ wide, and \_\_\_\_\_ thick when measured from seam to seam. (The blank is to be filled in.)
- [For play yards and non-full-size cribs] **Suffocation hazard:**

#### **Babies have suffocated:**

- In gaps between wrong-size mattress and side walls of product.
- Between the side walls and extra padding, such as stacked mattresses.

**ALWAYS** check mattress fit by pushing mattress tight to one corner. Look for any gaps between the mattress and the side walls. If this gap is larger than 1 in., the mattress does not fit and should **NOT** be used.

NEVER stack with another mattress. Use only ONE mattress.

For full-size crib mattresses, these warnings do not provide consumers with enough information about the gap entrapment hazard. Reports for at least 14 of the cases resulting in death describe gaps involving a full-size crib mattress (at least 119 incident reports including complaints with and without injuries). Regarding this hazard, the warnings in ASTM F2933 – 19 inform consumers that only the full-size crib mattress is to be used in a crib with the specified dimensions (full-size crib dimensions in compliance with 16 CFR part 1219), and that consumers are to use only sheets and mattress pads designed specifically for crib mattresses. A single statement about specified dimensions is not sufficient, given the prevalence of this hazard and that factors such as rounded edges and compression can increase the size of side wall or corner gaps. Staff recommends modifying these warnings to present more clearly and accurately the hazard information, including for full-size crib mattresses.

## d. Additional Concerns Regarding the Warnings

Staff has additional concerns with the safety information requirements in ASTM F2933 - 19, which undercut the effectiveness of the communication of the identified hazards. These concerns include, but are not limited to, the following:

- the definition of "conspicuous" in section 3 is ambiguous;
- the warning labels do not have a clear and comprehensive hazard identifier;
- the packaging requirements for marking and labeling are limited and exclude full-size crib mattresses;
- there are no requirements for warnings in instructional literature;
- the warning message includes a significant amount of superfluous text, resulting consequently in warning labels that are more difficult to understand and less likely to be read in their entirety; and
- the requirements in section 7 are worded and organized poorly, which may lead to confusion among manufacturers, test labs, and others viewing the standard.

Staff recommends improving the requirements for safety information in ASTM F2933 – 19 to address the above concerns and further reduce the risk of injury and death from the identified hazards. In a side-by-side comparison in the Appendix, staff identifies the specific weaknesses of ASTM F2933 – 19 for addressing the hazards, and provides modifications and explanations for the modifications. In the following section, staff provides the general basis for the recommended changes.

# Basis for Recommended Changes to Requirements for Safety Information in ASTM F2933 – 19

As detailed in the Appendix, ESHF staff recommends a significant number of modifications to the requirements for marking and labeling specified in ASTM F2933 – 19, and staff added a new section on instructional literature. For example, Figure 2 below shows a comparison of full-size crib mattress warning labels compliant with ASTM F2933 – 19's requirements versus staff's recommended requirements.

Current warning in ASTM F2933 - 19

# **A**WARNING

Failure to follow these warnings could result in serious injury or death.

To prevent deaths, the U.S. Consumer Product Safety Commission (CPSC), the American Academy of Pediatrics (AAP), and the National Institute of Child Health and Human Development (NICHD) recommend the following:

To reduce the risk of Sudden Infant Death Syndrome (SIDS) and suffocation, pediatricians recommend healthy infants be placed on their backs to sleep, unless otherwise advised by your physician.

• Infants can suffocate on soft bedding. Never place a pillow or comforter under sleeping infant for additional padding or as a mattress substitute.

• Do not cover the heads of babies with a blanket or over bundle them in clothing and blankets. Overheating can lead to SIDS.

• Do not use this mattress in a crib having interior dimensions that exceed 285% by 53 in. (73 by 135 cm) as measured from the innermost surfaces of the crib.

• Only use sheets and mattress pads designed specifically for crib mattresses.

DO NOT remove these important safety instructions.

Staff's recommended warning

# 

#### SIDS AND SUFFOCATION HAZARDS

**ALWAYS** place baby on back to sleep to reduce the risks of SIDS and suffocation.

Babies have suffocated:

- on pillows, comforters, and extra padding
- in gaps between a wrong-size mattress, or extra padding, and side walls of product.

**NEVER** add soft bedding, padding, or an extra mattress.

**USE ONLY** one mattress at a time.

**DO NOT** cover the faces or heads of babies with a blanket or over-bundle them. Overheating can increase the risk of SIDS.

**ALWAYS** check mattress fit **every time you change the sheets**, by pushing mattress tight to one corner. Look for any gaps between the mattress and the side walls. If a gap is larger than  $1^{3}/_{8}$  in. (3.5 cm), the mattress does not fit – **do not** use it.

**DO NOT** use this mattress in a crib having interior dimensions that exceed 28% by 53 in. (73 by 135 cm) as measured from the innermost surfaces of the crib.

**USE ONLY** sheets and mattress pads designed specifically for crib mattresses.

DO NOT remove these important safety warnings.

*Figure 2.* Current (left) and recommended (right) example warning labels for full-size crib mattresses. These labels are not shown in actual size.

ESHF staff's recommended changes consider improvements to the safety information from ASTM F15.66 and additional members of the ASTM F15 committee on consumer products.<sup>68</sup> Recently, ASTM F15 balloted changes to ASTM F2933 – 19, which were developed by ASTM F15.66.<sup>69</sup> The recommendations by ASTM F15.66, as well as those provided in comments by ASTM F15 members on the ballot, include improvements to the warning content and format, and clarifications for manufacturers, regulators, and test labs regarding the requirements of the standard. Many of the changes incorporate efforts to align with recommendations from the Ad Hoc Language task group.<sup>70</sup>

As discussed by Smith (2019), 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. The warning format recommendations from Ad Hoc are based primarily on the requirements of ANSI Z535.4, while also accounting for the wide range and unique nature of durable nursery products, the concerns raised by industry representatives, and ESHF staff's recommendations associated with durable nursery product rulemaking projects over the past several years. These recommendations include requirements for the following:

- 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:
  - 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 recommendations also include text for general labeling issues, such as labeling permanency, and content related to manufacturer contact information and date of manufacture.

While the majority of staff's modifications incorporate recommendations from stakeholders participating in ASTM F15, the following changes are notable deviations from what has been balloted and recommended by ASTM F15. These changes are based on staff's further

<sup>&</sup>lt;sup>68</sup> Since May 2018, staff has been participating in ASTM F15.66 to address the identified hazards. Subcommittee members include manufacturers, safety and health advocacy groups, and other interested parties.

<sup>&</sup>lt;sup>69</sup> ASTM F15 balloted revisions to ASTM F2933 – 19, particularly section 7, on April 6, 2020, resulting in 97 affirmatives, 7 negatives, and 293 abstentions (ASTM ballot F15 (20-02), item #15, *Proposed Changes to ASTM F2933-19 Standard Consumer Safety Specification for Crib Mattresses (WK 72077)*). Currently, ASTM F15.66 has not resolved the negative comments, so ESHF staff has considered the negative comments in developing staff's recommended changes to the safety information in ASTM F2933 – 19.

<sup>&</sup>lt;sup>70</sup> The "Recommended Language Approved by Ad Hoc Task Group Revision E," dated May 28, 2019, documents recommendations from the ASTM Ad Hoc Language task group for ASTM juvenile products standards.

consideration of the available data, and have not yet been reviewed by ASTM:

- 1. Section 7.3 (recommended section 7.5) Begin the warning message with the following hazard identifier: "SIDS AND SUFFOCATION HAZARDS." The inclusion of "SUFFOCATION HAZARD" at the beginning of the warning message was presented by ASTM F15.66 and supported by ASTM F15.<sup>71</sup> After further consideration, staff recommends beginning the hazard identifier with "SIDS AND" to convey more accurately the hazards addressed by the label. The warnings in ASTM F2933 19, and recommended by staff, include content regarding both SIDS and suffocation. SIDS is a less understood hazard than suffocation, so including SIDS in the hazard identifier adds motivation for consumers to read about the hazard and how to reduce the likelihood of it occurring. Additionally, staff found that SIDS, in addition to suffocation, is cited frequently in reports of fatal incidents. Therefore, staff recommends that both hazards be communicated to consumers foremost in the warning message to increase the likelihood of consumers reading the warning label, learning about the hazards, and following the guidance.
- 2. Section 7.3 (recommended section 7.5) Follow the hazard identifier immediately with the following warning regarding infant prone positioning:

**ALWAYS** place baby on back to sleep to reduce the risks of SIDS and suffocation.

ASTM F15 balloted and supported placement of this warning below the warnings pertaining to soft bedding and gap entrapment. After further consideration, staff concludes that such placement is inappropriate; this statement must be prioritized in the warning message because, as discussed in the above sections, the majority of deaths involved prone positioning, often with no other known contributing factors. Placing at the top of the warning message, a warning advising against infant prone sleep, will improve the likelihood that consumers will see this critical warning statement.

3. Sections 7.5 to 7.7 (recommended section 7.8) – Apply the packaging requirements for marking and labeling to full-size crib mattresses, in addition to non-full-size crib mattresses and after-market mattresses for play yards and non-full-size cribs. ASTM F2933 – 19 and the proposed changes balloted by ASTM F15 exclude full-size crib mattresses from the packaging requirements for marking and labeling. After further consideration, staff concludes that it is critical to include full-size crib mattresses to ensure that consumers purchasing crib mattresses, including full-size crib mattresses, are shown the important hazard and safe use information at the point of purchase.<sup>72</sup> In addition to providing another source of safety information, the required marking and labeling can help guide consumers to purchase the appropriate crib mattress for their

<sup>&</sup>lt;sup>71</sup> "Supported by ASTM F15" refers to items/statements included in the ASTM F15 (20-02) ballot on which no member of ASTM F15 provided a negative comment beyond editorial revisions.

<sup>&</sup>lt;sup>72</sup> In alignment with Ad Hoc recommendations, the warning statements are not required on the retail package if they are on the mattress and are visible in their entirety through the retail package.

infant's sleep environment.

As discussed above, safety information inherently is limited in effectiveness because it relies on hazard avoidance rather than prevention. As shown in feedback from consumers, caregivers may disregard warnings in attempts to get their infants to sleep. The identified hazards can be addressed most effectively through using performance requirements supported by safety information. In the next section, staff discusses recommendations for improving the performance requirements for full-size crib mattresses. Performance requirements for play yards and non-full-size cribs are being handled separately by the ASTM F15.18 subcommittee, as discussed in Section A.

## Performance Requirements to Address the Identified Hazards

The performance requirements specified in ASTM F2933 – 19 and staff's recommended improvements to the performance requirements are detailed in Tab B. As discussed by mechanical engineering (LSM) staff, full-size cribs and full-size crib mattresses, in compliance with the dimensional requirements of 16 CFR Part 1219 and ASTM F2933 – 19, respectively, will have a maximum side gap of  $13/_8$  inches, which is less than the head breadth of fifth percentile 0-to-3-month-old infants (approx. 3.3 inches). Even though this requirement reduces the risk of head entrapment, full-size crib mattress firmness and compression-related issues also present concerns for prone positioning and gap entrapment. Full-size crib mattresses that are too soft can lead to depressions or indentations, which can obstruct the airway of an infant positioned face down in the mattress, as well as contribute to infants rolling into the depression from side or supine position to prone. Infants that roll to the prone position may be developmentally, or otherwise physically, incapable of turning themselves back, potentially resulting in SUID. Similarly, enlarged gaps between the mattress and side wall(s) may result from mattresses being too soft, such as from compression by mattress sheets; and infants as young as 8 to 12 weeks may roll into such gaps and be unable to circumvent the hazardous position.

Based on incident reports and mattress firmness and compression testing, LSM staff (Sanborn, 2020) recommends adding to ASTM F2933 – 19 the following testing requirements: (1) "Mattress Sheet Fitted Test" for mattress compression, and (2) Australian/New Zealand Standard 8811.1:2013, *Methods of Testing Infant Products Method 1: Sleep Surfaces – Test for Firmness* (AS/NZS 8811.1) (see Tab B).<sup>73</sup> LSM staff's recommended "mattress sheet fitted test" involves placing a shrunken fitted sheet fully onto the full-size crib mattress, then measuring the mattress' dimensions according to section 6.2 of ASTM F2933 – 19. Due to incident reports involving corner gaps and results of testing demonstrating increased corner gaps, LSM staff recommends additionally measuring the maximum corner gap with the shrunken fitted sheet. Factoring in a  $\frac{1}{2}$ -inch safety factor, the recommended requirement will allow a maximum corner gap of  $1^{3}/_{4}$  inches. ESHF staff assesses that, given the fifth percentile head breadth of 0-to-3-month-old infants, compliance with this mattress sheet fitted test reduces the risk of head entrapment in gaps in the sides and corners of full-size cribs, including when the full-size mattress foreseeably is compressed, such as from laundered mattress sheets.

<sup>&</sup>lt;sup>73</sup> This test method is supported in CPSC staff's NPR briefing package for Crib Bumpers (Eilbert, 2019).

AS/NZS 8811.1:2013 includes a method for testing the firmness (softness) of horizontal infant sleep surfaces. The test method was developed to address infant mortality associated with overly soft sleep surfaces, which may obstruct an infant's breathing, such as when infants roll to a face down position and are unable to free themselves from obstructions. This test method involves placing a test apparatus on a horizontal sleep surface (*e.g.*, sides of a full-size crib mattress that foreseeably will be used for sleep). The test apparatus is approximately 11.46 pounds (5,200  $\pm$  20g) with a feeler arm that extends past the bottom disk of the apparatus. The feeler arm represents the infant's nose and mouth. The apparatus is to be placed such that the feeler arm covers the section of the sleep surface that would pose the greatest potential to block the infant's airway. If the feeler arm contacts the sleep surface, then the product (*e.g.*, crib mattress) is not sufficiently firm. ESHF staff's review shows that compliance with this testing requirement reduces the risk of infant airway occlusion due to hazardous surface depressions in full-size crib mattresses.

Additionally, staff finds that ASTM F2933 – 19 contains no apparent size requirements for aftermarket, rectangular non-full-size crib mattresses. Instead, ASTM F2933 – 19 relies only on warnings pertaining to appropriate mattress length and width dimensions and the risk of gap entrapment, placing the onus on the consumer to select an adequate mattress for a rectangular, non-full-size crib (see Appendix). Staff recommends that the draft NPR requires that all nonfull-size crib mattresses, meaning those supplied with the product and those sold as after-market mattresses, meet the dimensional requirements for non-full-size cribs stated in ASTM F406, section 5.17, as shown in Appendix B of Tab B.

# **III.** Conclusion

ESHF staff concludes that the requirements for safety information specified in ASTM F2933 – 19 do not adequately address the identified hazards associated with the use of crib mattresses. Staff recommends that the Commission adopt ASTM F2933 – 19, with staff's recommended changes to the standard, to further reduce the risk of death and serious injury associated with crib mattresses. Staff's recommended improvements to section 7, Marking and Labeling, addition of section 8, Instructional Literature, and revision of the term "conspicuous," (specified in the Appendix) help address SUID related to prone positioning of sleeping infants, soft bedding added to sleep areas, and gaps/pockets between mattresses and sleep environment sides. These modifications are likely to (1) improve consumer awareness and comprehension regarding safe use and the hazards associated with misuse of crib mattresses, (2) motivate consumers to comply with the warnings, and (3) provide clarity to manufacturers, test labs, and others who view the standard regarding how to understand the marking, labeling, and instructional literature requirements of the standard. While, as discussed in the above sections, even improved safety information addressing SUID-related use factors are limited in effectiveness, staff's improvements to the safety information support staff's recommended performance requirements for crib mattresses, summarized above, and detailed in Tab B, to mitigate the identified hazards.

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# Appendix: ESHF Staff's Recommended Revisions to ASTM F2933 – 1974

#### ASTM F2933 – 19, Section 3. Terminology

ASTM F2933 – 19	Staff's Recommended Revisions	<b>Rationale Summary</b>
3.1.2 <i>conspicuous, adj</i> —visible, when the	3.1.2 conspicuous, adj—visible, when while	1.) Change the definition of "conspicuous" from
mattress is being handled by a consumer.	the mattress is being handled by a consumer	"conspicuous, adj-visible, when mattress is being handled
	placed in its intended use position.	by a consumer," to "conspicuous, adj—visible while the
		mattress is being placed in its intended use position." This
		change clarifies for manufacturers, test labs, and other
		viewers of the standard, that the warning label's placement
		must make it visible to the consumer as s/he positions the
		mattress for use, thereby increasing the likelihood that the
		consumer will see the warnings. This revision considers
		language proposed by ASTM F15.66 and recommendations
		from members of ASTM F15.

## ASTM F2933 – 19, Section 7. Marking and Labeling

ASTM F2933 – 19	Staff's Recommended Revisions	<b>Rationale Summary</b>
7.1 The warning statements in this	7.1 The warning statements in this consumer	2.) Revise to align with recommendations by the Ad Hoc
consumer safety specification cannot be	safety specification cannot be placed on any	task group (see below). These changes increase the
placed on any other labels required by law	other labels required by law (for example, 16	consistency of the standard with similar juvenile products,
(for example, 16 CFR 1633 label or state law	CFR 1633 label or state law labels).	and, ultimately, result in warning labels that are more likely
labels).		to be read and understood. These changes are supported by
		ASTM F15. <sup>75</sup>
7.2 Warning statements shall be easy to	7.2 Warning statements shall be easy to read	3.) Revise to align with recommendations by the Ad Hoc
read and understand. The warning statements	and understand. The warning statements shall	task group. These changes increase the consistency of the
shall be conspicuous, permanent (as defined	be conspicuous, permanent (as defined in 6.1),	standard with similar juvenile products, and, ultimately,
in 6.1), and in sans serif type.	and in sans serif type.	result in warning labels that are more likely to be read and
	7.1 Each mattress and its retail package shall	understood. These changes are supported by ASTM F15.
	be marked or labeled clearly and legibly to	
	indicate the following:	

<sup>&</sup>lt;sup>74</sup> Recommended additions are underlined, and recommended deletions are single struck-through.

<sup>&</sup>lt;sup>75</sup> "Supported by ASTM F15" refers to items/statements included in the ASTM F15 (20-02) ballot on which no member of ASTM F15 provided a negative comment beyond editorial revisions.

ASTM F2933 – 19	Staff's Recommended Revisions	Rationale Summary
	7.1.1 The name, place of business (city,	
	state, and mailing address, including zip	
	code), and telephone number of the	
	manufacturer, distributor, or seller.	
	7.1.2 A code mark or other means that	
	identifies the date (month and year at a	
	minimum) of manufacture.	
	7.2 The marking and labeling on the product	
	shall be permanent.	
	7.3 Any upholstery labeling required by law	
	shall not be used to meet the requirements of	
	this section.	
7.2.1 The warning label shall include a	-7.2.1 The warning label shall include a	4.) Revise to align with recommendations by the Ad Hoc
delineated signal word panel containing the	delineated signal word panel containing the	task group. These changes increase the consistency of the
safety alert symbol followed by the signal	safety alert symbol followed by the	standard with similar juvenile products, and, ultimately,
word "WARNING" on a contrasting	signal word "WARNING" on a contrasting	result in warning labels that are more likely to be read and
background. The letters and safety alert	background. The letters and safety alert	understood. These changes are supported by ASTM F15.
symbol shall not be less than 0.2 in. (5 mm)	symbol shall not be less than 0.2 in. (5	
high. The remaining text shall be in	mm) high. The remaining text shall be in	5.) Add the example warning labels shown below this table.
characters whose upper case is at least 0.1 in.	characters whose upper case is at least 0.1 in.	The example labels provide clarity to manufacturers and
(2.5 mm) high.	<del>(2.5 mm) high.</del>	increase the likelihood of consumers seeing appropriate
7.2.2 The warning label shall meet one of	-7.2.2 The warning label shall meet one of	warnings. ASTM F15 supports providing similar example
the following conditions:	the following	labels (exceptions discussed below).
7.2.2.1 The safety alert symbol shall be an	conditions:	
orange filled triangle on a contrasting	-7.2.2.1 The safety alert symbol shall be an	
background.	orange filled triangle on a contrasting	
7.2.2.2 The signal word panel containing	background.	
both the safety alert symbol and signal word	-7.2.2.2 The signal word panel containing	
shall be orange in color on a contrasting label	both the safety alert symbol and signal word	
(for example, orange background on white	shall be orange in color on a contrasting label	
label).	(for example, orange background on white	
7.2.2.3 The entire warning label shall be	label).	
orange with the warning text and symbols in	-7.2.2.3 The entire warning label shall be	
contrasting color (for example, orange label	orange with the warning text and symbols in	
with black text and symbols).	contrasting color (for example, orange label	
	with black text and symbols).	
	7.4 Warning Design for Mattresses	

ASTM F2933 – 19	Staff's Recommended Revisions	Rationale Summary
	7.4.1 The warnings shall be easy to read and	
	understand and be in the English language at a	
	<u>minimum.</u>	
	7.4.2 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.	
	7.4.3 The warnings shall be conspicuous and	
	permanent.	
	7.4.4 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.	
	7.4.4.1 In sections 6.2.2, 7.3, 7.5, and 8.1.2,	
	replace "should" with "shall."	
	7.4.4.2 In section 7.6.3, replace "should	
	(when feasible)" with "shall."	
	7.4.4.3 Strike the word "safety" when used	
	immediately before a color (e.g., replace	
	"safety white" with "white").	
	NOTE 3—For reference, ANSI Z535.1	
	provides a system for specifying safety colors.	
	7.4.5 The safety alert symbol "[Safety Alert	
	Symbol]" and the signal word "WARNING"	
	shall be at least 0.2 in. (5 mm) high. The	
	remainder of the text shall be in characters	
	whose upper case shall be at least 0.1 in. (2.5	
	mm), except where otherwise specified.	
	NOTE 4—For improved warning readability,	
	typefaces with large height-to-width ratios,	
	which are commonly identified as	
	"condensed," "compressed," "narrow," or	
	similar should be avoided.	
	7.4.6 Message Panel Text Layout	
	7.4.6.1 The text shall be left aligned, ragged	
	right for all but one-line text messages, which	
	can be left aligned or centered.	

ASTM F2933 – 19	Staff's Recommended Revisions	Rationale Summary
	NOTE 5—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. 7	
	for examples of left aligned text.	
	7.4.6.2 The text in each column needs to be	
	arranged in list or outline format, with	
	precautionary (hazard avoidance) statements	
	preceded by bullet points. Multiple	
	precautionary statements shall be separated by	
	bullet points if paragraph formatting is used.	
	7.4.7 Example warnings in the format	
	described in this section are shown in FIGS. 8,	
	<u>9, and 10.</u>	
7.3 The following warning statements shall	-7.3 The following warning statements shall	6.) Remove the safety alert symbol and signal word. These
be included exactly as stated below:	be included exactly as stated below:	are required by the above sections. Their inclusion in the
▲ WARNING	WARNING	recommended section 7.5 would add redundancy in the
Failure to follow these warnings could	Failure to follow these warnings could result	standard, potentially confusing manufacturers, test labs, and
result in serious injury or death.	in serious iniury or death.	other viewers of the standard.
To prevent deaths, the U.S. Consumer	- To prevent deaths, the U.S. Consumer	
Product Safety Commission (CPSC), the	Product Safety Commission (CPSC), the	7.) Indicate that the warnings must be "addressed" rather
American Academy of Pediatrics (AAP), and	American Academy of Pediatrics (AAP), and	than included verbatim, unless otherwise stated. The Ad Hoc
the National Institute of Child Health and	the National Institute of Child Health and	task group recommends use of "address," to account for
Human Development (NICHD) recommend	Human Development (NICHD) recommend	product-specific variations that may affect the accuracy and
the following:	the following:	comprehensiveness of the warning label. ASTM F15
To reduce the risk of Sudden Infant Death	To reduce the risk of Sudden Infant Death	supports use of "address" with the stated exceptions.
Syndrome (SIDS) and suffocation,	Syndrome (SIDS) and suffocation,	
pediatricians recommend healthy infants be	pediatricians recommend healthy infants be	8.) Begin the warning message with the hazard identifier:
placed on their backs to sleep, unless	placed on their backs to sleep, unless	SIDS AND SUFFOCATION HAZARDS. By including
otherwise advised by your physician.	otherwise advised by your physician.	this hazard identifier, and in bold, capital letters, the
• Infants can suffocate on soft bedding.	-• Infants can suffocate on soft bedding.	consumer is clearly and concisely notified of the identified
Never place a pillow or comforter under	Never place a pillow or comforter under	nazarus and content of the warning label. AS I M F2955 – 19
sleeping infant for additional padding or as a	sleeping infant for additional padding or as a	ofter market mattrasses for non full size oribs (section 7.7)
mattress substitute.	mattress substitute.	The Ad Hog task group recommends use of the begard
• Do not cover the heads of babies with a	-• Do not cover the heads of babies with a	identifier "SUEEOCATION IIAZADD" for all applicable
blanket or over bundle them in clothing and	blanket or over bundle them in clothing and	neducte which in this case includes full size or h
blankets. Overheating can lead to SIDS.	blankets. Overheating can lead to SIDS.	mattrassas as the identified bazards apply also to full size
	7.5 Warning Statements - Each mattress	arib mattrassas. The inclusion of "SUFFOCATION
	shall have warning statements to address the	CITO MALLESSES. THE INCLUSION OF SUFFUCATION

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	following, at a minimum, unless otherwise	HAZARD" at the beginning of the warning message is
	specified. The blank in the mattress fit	supported by ASTM F15; however, after further
	statement beginning with "If a gap is larger	consideration, staff recommends beginning the hazard
	than," needs to be filled with " $1^{3}/_{8}$ in. (3.5)	identifier with "SIDS AND" to more accurately convey the
	cm)" for full-size crib mattresses and "1 in.	hazards addressed by the label; the warnings in ASTM
	(2.5 cm)" for all other mattresses.	F2933 – 19 and recommended by staff, include content
	NOTE 6—Address means that verbiage other	regarding both SIDS and suffocation. SIDS is a less
	than what is shown can be used as long as the	understood hazard than suffocation, so including SIDS in the
	meaning is the same or information that is	hazard identifier adds motivation for consumers to read
	product-specific is presented.	about the hazard and how to avoid it. Additionally, SIDS, in
	SIDS AND SUFFOCATION HAZARDS	addition to suffocation, is cited frequently in reports of fatal
	ALWAYS place baby on back to sleep to	incidents. Therefore, it is imperative that both hazards are
	reduce the risks of SIDS and suffocation.	communicated to consumers foremost in the warning
	<b>Babies have suffocated:</b>	message to increase the likelihood of consumers reading the
	<ul> <li>on pillows, comforters, and extra</li> </ul>	warning label and being made aware of the hazards.
	padding	
	<ul> <li>in gaps between a wrong-size mattress,</li> </ul>	9.) Remove the statements: "Failure to follow these
	or extra padding, and side walls of product.	warnings could result in serious injury or death." While a
	<b>NEVER</b> add soft bedding, padding, or an	similar statement is recommended for juvenile products by
	extra mattress.	the Ad Hoc task group, staff does not find it appropriate for
	<b>USE ONLY</b> one mattress at a time.	crib mattresses, given the length of the warning labels, and
	<b>DO NOT</b> cover the faces or heads of babies	because the risk of serious injury or death is conveyed
	with a blanket or over-bundle them.	adequately by the hazard identifier and warning statements
	Overheating can increase the risk of SIDS.	( <i>i.e.</i> , "SIDS AND SUFFOCATION HAZARD," "risks of
	ALWAYS check mattress fit every time	SIDS and suffocation," "Babies have suffocated," and "can
	you change the sheets, by pushing mattress	increase the risk of SIDS"). Therefore, staff recommends
	tight to one corner. Look for any gaps	removing this text to increase the readability and
	between the mattress and the side walls. If a	prioritization of the hazard warnings. This deletion is
	gap is larger than , the mattress does not fit	supported by ASTM F15.
	<u>– do not use it.</u>	
		10.) Remove the statements: "To prevent deaths, the U.S.
		Consumer Product Safety Commission (CPSC), the
		American Academy of Pediatrics (AAP), and the National
		Institute of Child Health and Human Development (NICHD)
		recommend the following." While staff recognizes the
		benefit of establishing authority figures for the warning
		statements, it is of greater value to prioritize the hazard
		warnings and increase the likelihood of consumers reading
		the warnings. This deletion is supported by ASTM F15.

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	11.) Follow the hazard identifier immediately with the following warning regarding infant prone positioning: " <b>ALWAYS</b> place baby on back to sleep to reduce the risks of SIDS and suffocation." This language is based on recommendations from the Ad Hoc task group; however, staff recommends stating "always" in bolded, capitalized text for emphasis. This statement replaces the existing wording: "To reduce the risk of Sudden Infant Death Syndrome (SIDS) and suffocation, pediatricians recommend healthy infants be placed on their backs to sleep, unless otherwise advised by your physician." Staff agrees with the Ad Hoc task group's recommended language because it is clear and direct, and it reduces the amount of unnecessary text on the warning label, thereby increasing the likelihood of consumers reading, understanding, and heeding the warning. The recommended language includes both information about the consequences of exposure to the hazard, and instructions regarding appropriate hazard-avoidance behaviors. As SIDS is now a commonly recognized term, it is sufficient to write only the acronym. This language, including the bolded and capitalized text, is supported by ASTM F15. In agreement with the requirements in ASTM F2933 – 19, this statement must be prioritized in the warning message because, as discussed in the above sections, placing babies prone is a major risk factor for death and serious injury ( <i>i.e.</i> , 102 of the 116 incidents resulting in death reviewed by staff involved prone positioning, many of which identified no other contributing factors). Placing a warning against infant prone sleep at the top of the warning message will improve the likelihood that consumers see this warning statement.
	12.) Remove the statements: "Infants can suffocate on soft bedding. Never place a pillow or comforter under sleeping infant for additional padding or as a mattress substitute." Instead, state the following:
	<ul> <li>"Babies have suffocated:</li> <li>on pillows, comforters, and extra padding</li> <li>in gaps between a wrong size mattrace, or extra padding</li> </ul>

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		and side walls of product.
		NEVER add soft bedding, padding, or an extra mattress.
		<b>USE ONLY</b> one mattress at a time."
		These changes in wording and formatting clarify the hazard
		statements pertaining to soft bedding, and warn the user
		about supplemental mattress use and gap entrapment. The
		statements are strengthened by indicating that the hazards
		have occurred rather than can occur. The recommended
		language includes both information about the consequences
		of exposure to the hazard, and instructions regarding
		appropriate hazard-avoidance behaviors. Similar
		requirements are included in ASTM F2933 – 19 as
		additional marking and warnings for after-market mattresses
		for non-full-size cribs (section 7.7); however, the
		information is relevant to full-size crib mattresses as well.
		Reports for at least 14 of the cases resulting in death (at least
		119 cases including complaints with and without injuries)
		describe gaps involving a full-size crib mattress. Factors
		such as rounded edges and compression can increase the size
		of side wall gaps, so it is imperative that consumers see this
		important hazard information on full-size crib mattresses.
		Bold and capitalization are used for emphasis. These
		changes consider recommendations from the Ad Hoc task
		group and are supported by ASTM F15.
		13.) Remove the statements: "Do not cover the heads of
		babies with a blanket or over bundle them in clothing and
		blankets. Overheating can lead to SIDS." Replace with "DO
		<b>NOT</b> cover the faces or heads of babies with a blanket or
		over-bundle them. Overheating can increase the risk of
		SIDS." The recommended language more accurately
		conveys to the consumer the risk of SIDS from overheating.
		and the uses of bold and capitalization add emphasis. This
		recommended language is supported by ASTM F15.
		14.) Add the following statements: "ALWAYS check
		mattress fit every time you change the sheets. by pushing
		mattress tight to one corner. Look for any gaps between the
		mattress and the side walls. If a gap is larger than , the

ASTM F2933 – 19	Staff's Recommended Revisions	Rationale Summary
		mattress does not fit – <b>do not</b> use it." The blank is to be filled with "1 <sup>3</sup> / <sub>8</sub> in. (3.5 cm)" for full-size crib mattresses, or "1 in. (2.5 cm)" for after-market mattresses for play yards and non-full-size cribs. Similar language currently is included in ASTM F2933 – 19 for after-market mattresses for play yards and non-full-size cribs (section 7.7). ASTM F15 supports these changes with the exception of one member, who questioned the appropriateness of "1 <sup>3</sup> / <sub>8</sub> in.," and "every time you change the sheets," and another member, who questioned the "excessiveness" of the paragraph beginning with "Always check." While staff acknowledges that consumers may find it easier to estimate, for example, "1 <sup>1</sup> / <sub>2</sub> in." than "1 <sup>3</sup> / <sub>8</sub> in.," the specified gap measurement of "1 <sup>3</sup> / <sub>8</sub> in." is based on the maximum gap allowed by full-size cribs and full-size crib mattresses in compliance with 16 CFR Part 1219 and ASTM F2933 – 19, respectively. The phrase, "every time you change the sheets," is important because, as evidenced in incident reports, gaps can develop over time, such as from being compressed by laundered mattress sheets. Adding these warning statements encourages consumers to be mindful of gaps between mattresses and side walls of sleep products, including full-size crib mattresses and full-size cribs.
<ul> <li>7.3.1 For full-size crib mattresses, the following warning statement shall be included with the warnings from 7.3 exactly as stated below:</li> <li>Do not use this mattress in a crib having interior dimensions that exceed 28<sup>5</sup>/<sub>8</sub> by 53 in. (73 by 135 cm) as measured from the innermost surfaces of the crib.</li> <li>Only use sheets and mattress pads designed specifically for crib mattresses.</li> </ul>	<ul> <li>7.35.1 For full-size crib mattresses, the following warning statements shall be included with the warnings from 7.53 exactly as stated below:</li> <li>DO NOT use this mattress in a crib having interior dimensions that exceed 285/8 by 53 in. (73 by 135 cm) as measured from the innermost surfaces of the crib.</li> <li>Only useUSE ONLY sheets and mattress pads designed specifically for crib mattresses.</li> </ul>	<ul> <li>15.) Add bold and capitalization for emphasis. These changes are supported by ASTM F15.</li> <li>16.) Editorial revision of "Only use" to "USE ONLY" to align with recommendations from the Ad Hoc task group.</li> </ul>
7.3.2 For non-full-size crib mattresses, the following warning statement shall be	7. <u>5</u> 3.2 For non-full-size crib mattresses and after-market mattresses for play yards and	17.) Add "and after-market mattresses for play yards and non-full-size cribs." The example warning labels balloted by

included with the warnings from 7.3 exactly as stated below:non-full-size cribs, the following warning statement shall be included with the warnings from 7.53 exactly as stated below:ASTM F15 included this warning for after-market mattress for play yards and non-full-size cribs. Staff agrees it is important that this warning is communicated to consumers using after-market mattresses for play yards and non-full-		Starr 5 Recommended Revisions	i autonato Sannia j
as stated below:statement shall be included with the warnings from 7.53 exactly as stated below:for play yards and non-full-size cribs. Staff agrees it is important that this warning is communicated to consumers using after-market mattresses for play yards and non-full-	ed with the warnings from 7.3 exactly	non-full-size cribs, the following warning	ASTM F15 included this warning for after-market mattresses
• Only use sheets and mattress pads designed specifically for this mattress size. from 7. <u>5</u> <sup>3</sup> exactly as stated below: • Only use <u>USE ONLY</u> sheets and mattress using after-market mattresses for play yards and non-full-	ed below:	statement shall be included with the warnings	for play yards and non-full-size cribs. Staff agrees it is
designed specifically for this mattress size. • Only use <u>USE ONLY</u> sheets and mattress using after-market mattresses for play yards and non-full-	ly use sheets and mattress pads	from 7. <u>5</u> <sup>3</sup> exactly as stated below:	important that this warning is communicated to consumers
	ned specifically for this mattress size.	<ul> <li>Only use<u>USE ONLY</u> sheets and mattress</li> </ul>	using after-market mattresses for play yards and non-full-
pads designed specifically for this mattress size cribs to discourage use of sheets and mattress pads that		pads designed specifically for this mattress	size cribs to discourage use of sheets and mattress pads that
size. may harmfully impact the safety of the products.		size.	may harmfully impact the safety of the products.
18.) Add bold and capitalization for emphasis. These			18.) Add bold and capitalization for emphasis. These
changes are supported by ASTM F15.			changes are supported by ASTM F15.
19.) Editorial revision of "Only use" to "USE ONLY" to			19.) Editorial revision of "Only use" to "USE ONLY" to
align with recommendations from the Ad Hoc task group.			align with recommendations from the Ad Hoc task group.
7.3.3 Additional manufacturer warnings 7. <u>5</u> 3.3 Additional <u>m</u> Manufacturers are 20.) Editorial revisions to add clarification for	3 Additional manufacturer warnings	7. <u>5</u> 3.3 Additional mManufacturers are	20.) Editorial revisions to add clarification for
may be included between the warnings permitted to include additional warnings may manufacturers, test labs, and others reading the requirement	e included between the warnings	permitted to include additional warnings may	manufacturers, test labs, and others reading the requirements.
specified in 7.3 and 7.4 if desired. between the warnings specified in These changes are recommended by members of ASTM	ied in 7.3 and 7.4 if desired.	be included between the warnings specified in	These changes are recommended by members of ASTM
$7.\underline{53} \text{ and } 7.\underline{64} \text{ if desired.} F15.$		7. <u>5</u> 3 and 7. <u>6</u> 4 if desired.	F15.
7.4 The following warning statement shall $7.64$ The following warning statement shall $21$ .) There is only one subsection, so combine the section	The following warning statement shall	7. <u>6</u> 4 The following warning statement shall	21.) There is only one subsection, so combine the section
be included exactly as stated below: be included exactly as stated below and shall and subsection to make the requirements clearer to	luded exactly as stated below:	be included exactly as stated below and shall	and subsection to make the requirements clearer to
DO NOT remove these important safety <u>be located at the bottom of the warnings on</u> manufacturers, test labs, and other viewers of the standard.	NOT remove these important safety	be located at the bottom of the warnings on	manufacturers, test labs, and other viewers of the standard.
instructions. <u>each mattress</u> : This change is recommended by members of ASTM F15.	ctions.	each mattress:	This change is recommended by members of ASTM F15.
7.4.1 This warning shall be located at the <b>DO NOT</b> remove these important safety	This warning shall be located at the	<b><u>DO NOT</u></b> remove these important safety	
bottom of the label that contains the <u>warningsinstructions</u> . 22.) Change "Instructions" to "warnings" to more accurately	n of the label that contains the	warningsinstructions.	22.) Change "Instructions" to "warnings" to more accurately
warnings from 7.3. $-7.4.1$ This warning shall be located at the refer to the label's contents. This change is recommended by	ngs from 7.3.	-7.4.1 This warning shall be located at the	refer to the label's contents. This change is recommended by
bottom of the label that contains the warnings members of ASTM F15.		bottom of the label that contains the warnings	members of ASTM F15.
$\frac{10007.3}{1000000000000000000000000000000000000$		trom 7.3.	
23.) Add bold for emphasis. This change is supported by			23.) Add bold for emphasis. This change is supported by
1.5 Additional Marking and Warnings for 1.1.5 Additional Marking and Warnings for 24.) Change the section heading from "Additional Marking	Additional Marking and Warnings for	1.13 Additional Marking and Warnings for	24.) Change the section heading from <i>Additional Marking</i>
After-Market Mattress for Mesn/Fabric After-Market Mattress for <u>Play Yaras ana</u> ana warnings for After-Market Mattress for Mesn/Fabric Sided New Products and Picid Sided New Products	Market Mattress for Mesn/Fabric	After-Market Mattress <u>es</u> for <u>Play Yaras ana</u>	and warnings for After-Market Mattress for Mesn/Fabric Sided Due due to and Dieid Sided New Destangular Due due to?
Sided Products and Rigid Sided Non- Restangular Disid Sided Non-Full-Size Criosimesity Fabric Sided Non Destangular Sided Products and Rigid Sided Non-Reciangular Products	Products and Rigid Sided Ivon-	<u>Non-Full-Size Cribs</u> mesn/Fabric Stata	Stated Products and Rigid Stated Non-Rectangular Products
Reciangular Products—1 the mattress shall bever bever the mattress shall be the second secon	<i>igular Products</i> —The matress shall	Products and Rigid Stated Non Rectangular	10 Additional Marking and warnings for After-Market Mattrasses for Play Yands and Non Full Size Cribe" This
7.5.1 All warnings the original 7.75.1 All warnings added by the original answers that consumers using after market mattrasses for	1 All warnings the original	7 75 1 All warnings added by the original	mainesses for Flay Taras and Non-Flait-Size Cribs. This
manufacturer may have added which are manufacturer may have added which are in triad sided rectangular products are shown important	Facturer may have added which are	manufacturer may have added which are in	rigid sided rectangular products are shown important
handracturer may have added which are maintracturer may have added which are in fight study rectaingular products are shown important, beyond the F2933 standard addition to those required by this beyond the product-specific safety information provided by the original	d the F2933 standard	addition to those required by this beyond the	nglu succi rectangular products are shown important,
$7.5.2$ Assembly/attachment instructions $E^{2023}$ standard $E^{$	2 Assembly/attachment instructions	E2032 standard	manufacturer ( $i \rho$ warnings added by the original
that were provided on the original mattress 7.75.2 Assembly/attachment instructions manufacturer assembly/attachment instructions provided or	ere provided on the original mattress	7 75 2 Assembly/attachment instructions	manufacturer assembly/attachment instructions provided on
that were provided on the original mattress and the brand(s) model(s) number(s)	ere provided on the original mattess.	that were provided on the original mattress	the original mattress and the brand(s) model(s) number(s)
of the product(s) in which it is intended to be used).		and were provided on the original mattress.	of the product(s) in which it is intended to be used).

ASTM F2933 – 19	Staff's Recommended Revisions	Rationale Summary
7.5.3 The following labeling and warnings	7.5.3 The following labeling and warnings	
shall be on the mattress and visible on the	shall be on the mattress and visible on the	25.) Move the requirements for marking and warnings on
retail packaging.	retail packaging.	retail packaging to a new section specific to packaging
7.5.3.1 The mattress shall specifically	7. <u>7</u> 5.3.1 The specificmattress shall	requirements, recommended as section 7.8 (see rationale for
identify the brand(s) and Model(s) numbers	specifically identify the brand(s) and	recommended section 7.8).
of products in which it is intended to be used.	$\underline{m}$ $\underline{M}$ odel(s) number(s) of the product(s) in	
7.5.3.2 Warnings according to 7.7 of this	which it is intended to be used.	
standard.	-7.5.3.2 Warnings according to 7.7 of this	
	standard.	
7.6 Additional Marking and Warnings for	7. <u>7.4</u> 6 Additional Marking and Warnings	26.) Adjust the section heading as specified for clarity for
After-Market Mattress for Rigid Sided	for After Market Mattress <u>fF</u> or Rigid Sided	manufacturers, test labs, and other viewers of the standard.
Rectangular Product:	Rectangular Product <u>s</u> :	This change is supported by ASTM F15.
7.6.1 The following labeling and warnings	-7.6.1 The following labeling and warnings	
shall be on the mattress and visible on the	shall be on the mattress and visible on the	27.) Move the requirements for marking and warnings on
retail packaging.	retail packaging.	packaging to a new section specific to packaging
7.6.1.1 The following statement shall	<u>-7.6.1.1 Tthe following statement shall</u>	requirements, recommended as section 7.8 (see rationale for
appear exactly as stated below.	appear exactly as stated below (the blanks are	recommended section 7.8).
Check for proper fit of the mattress. This	to be filled in as appropriate).	
mattress measures long, wide,	Check for proper fit of the mattress. This	28.) Remove the statement: "Check for proper fit of the
and thick when measured from seam	mattress measures long, wide,	mattress." It is redundant given the language in
to seam. (The blank is to be filled in.)	and thick when measured from seam to	recommended section 7.5.
7.6.1.2 The warnings according to 7.7 of	seam.	
this standard.	7.6.1.2 The warnings according to 7.7 of this	29.) Remove reference to section 7.7, which also will be
	<del>standard.</del>	removed.
7.7 The following warnings shall appear	7.7 The following warnings shall appear	30.) Remove section 7.7, which provides warning statements
exactly as stated below.	exactly as stated below.	now addressed in the recommended section 7.5.
Suffocation Hazard:	-Suffocation Hazard:	
"WARNING		
Babies have suffocated:	Babies have suffocated:	
• In gaps between wrong-size mattress and	<ul> <li>In gaps between wrong size mattress and</li> </ul>	
side walls of product.	side walls of product.	
• Between the side walls and extra padding,	<ul> <li>Between the side walls and extra padding,</li> </ul>	
such as stacked mattresses.	such as stacked mattresses.	
ALWAYS check mattress fit by pushing	-ALWAYS check mattress fit by pushing	
mattress tight to one corner. Look for any	mattress tight to one corner. Look for any	
gaps between the mattress and the side walls.	gaps between the mattress and the side walls.	
If this gap is larger than 1 in., the mattress	If this gap is larger than 1 in., the mattress	
does not fit and should <b>NOT</b> be used.	does not fit and should <b>NOT</b> be used.	

ASTM F2933 – 19	Staff's Recommended Revisions	Rationale Summary
<b>NEVER</b> stack with another mattress. Use	- NEVER stack with another mattress. Use	
only <b>ONE</b> mattress.	only ONE mattress.	
	7.8 Package Warnings	31.) Move the requirements for marking and warnings on
	7.8.1 The warnings and statements are not	packaging to a new section specific to packaging
	required on the retail package if they are on	requirements, recommended as section 7.8, which applies to
	the mattress and are visible in their entirety	full-size crib mattresses and after-market mattresses for play
	through the retail package. Cartons and other	yards and non-full-size cribs. ASTM F2933 – 19 has
	materials used exclusively for shipping the	requirements for marking and warnings on packaging spread
	mattress are not considered retail packaging.	out and combined with on-product requirements in numerous
	7.8.2 Warning Statements—Each mattress'	sections (7.5 to 7.7), and the requirements wrongfully
	retail package shall have statements to address	exclude full-size crib mattresses. Creating a separate
	the following, at a minimum.	packaging requirements section provides clarity to
	7.8.2.1 All warnings included in section 7.5,	manufacturers, test labs, and other viewers of the standard
	as applicable.	regarding the requirements for marking and warnings on the
	7.8.2.2 All additional markings and	retail package, and ensures that consumers are shown the
	warnings included in section 7.7, as	necessary marking and warnings at the point of purchase,
	applicable.	including for full-size crib mattresses. In addition to
		providing another source of safety information, the required
		marking and labeling can help guide consumers to purchase
		the appropriate crib mattress for their infant's sleep
		environment. This section is based on recommendations
		from the Ad Hoc task group and one comment on the ASTM
		F15 (20-02) ballot.



FIG. 7 Examples of Left Aligned Text.

Rationale for FIG. 7: 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.

# **A**WARNING

#### SIDS AND SUFFOCATION HAZARDS

**ALWAYS** place baby on back to sleep to reduce the risks of SIDS and suffocation.

#### Babies have suffocated:

- on pillows, comforters, and extra padding
- in gaps between a wrong-size mattress, or extra padding, and side walls of product.

NEVER add soft bedding, padding, or an extra mattress.

**USE ONLY** one mattress at a time.

**DO NOT** cover the faces or heads of babies with a blanket or overbundle them. Overheating can increase the risk of SIDS.

**ALWAYS** check mattress fit **every time you change the sheets**, by pushing mattress tight to one corner. Look for any gaps between the mattress and the side walls. If a gap is larger than  $1^{3}/_{8}$  in. (3.5 cm), the mattress does not fit – **do not** use it.

**DO NOT** use this mattress in a crib having interior dimensions that exceed 28% by 53 in. (73 by 135 cm) as measured from the innermost surfaces of the crib.

**USE ONLY** sheets and mattress pads designed specifically for crib mattresses.

DO NOT remove these important safety warnings.

#### FIG. 8 Example of warning label for Full-Size Crib Mattress.

Rationale for FIG. 8: Added figure to provide example of formatting and to reduce confusion regarding the required warning statements for particular products (*i.e.*, full-size crib mattresses, after-market mattresses for mesh/fabric sided products and rigid sided non-rectangular products, and after-market mattresses for rigid sided rectangular products). Providing this example increases the likelihood of consumers seeing an appropriate warning label. This figure is not shown in actual size.

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#### SIDS AND SUFFOCATION HAZARDS

**ALWAYS** place baby on back to sleep to reduce the risks of SIDS and suffocation.

#### Babies have suffocated:

- on pillows, comforters, and extra padding
- in gaps between a wrong-size mattress, or extra padding, and side walls of product.

**NEVER** add soft bedding, padding, or an extra mattress.

**USE ONLY** one mattress at a time.

**DO NOT** cover the faces or heads of babies with a blanket or overbundle them. Overheating can increase the risk of SIDS.

**ALWAYS** check mattress fit **every time you change the sheets**, by pushing mattress tight to one corner. Look for any gaps between the mattress and the side walls. If a gap is larger than 1 in. (2.5 cm), the mattress does not fit – **do not** use it.

**USE ONLY** sheets and mattress pads designed specifically for this mattress size.

[All warnings added by the original manufacturer which are in addition to those required by this standard.] [Assembly/attachment instructions that were provided on the original mattress.]

[The specific brand(s) and model(s) number(s) of the product(s) in which the mattress is intended to be used.]

DO NOT remove these important safety warnings.

FIG. 9 Example of warning label for After-Market Mattress for Mesh/Fabric Sided Products and Rigid Sided Non-Rectangular Products. Items italicized in brackets are to be added as appropriate.

Rationale for FIG. 9: Added figure to provide example of formatting and to reduce confusion regarding the required warning statements for particular products (*i.e.*, full-size crib mattresses, after-market mattresses for mesh/fabric sided products and rigid sided non-rectangular products, and after-market mattresses for

rigid sided rectangular products). Providing this example increases the likelihood of consumers seeing an appropriate warning label. This figure is not shown in

actual size.

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#### SIDS AND SUFFOCATION HAZARDS

**ALWAYS** place baby on back to sleep to reduce the risks of SIDS and suffocation.

Babies have suffocated:

- on pillows, comforters, and extra padding
- in gaps between a wrong-size mattress, or extra padding, and side walls of product.

**NEVER** add soft bedding, padding, or an extra mattress.

**USE ONLY** one mattress at a time.

**DO NOT** cover the faces or heads of babies with a blanket or overbundle them. Overheating can increase the risk of SIDS.

**ALWAYS** check mattress fit **every time you change the sheets**, by pushing mattress tight to one corner. Look for any gaps between the mattress and the side walls. If a gap is larger than 1 in. (2.5 cm), the mattress does not fit – **do not** use it.

**USE ONLY** sheets and mattress pads designed specifically for this mattress size.

[All warnings added by the original manufacturer which are in addition to those required by this standard.]

[Assembly/attachment instructions that were provided on the original mattress.]

[The specific brand(s) and model(s) number(s) of the product(s) in which the mattress is intended to be used.]

This mattress measures <u>long</u>, <u>wide</u>, and <u>thick</u> when measured from seam to seam. [*Fill in blanks as appropriate*.]

DO NOT remove these important safety warnings.

FIG. 10 Example of warning label for After-Market Mattress for Rigid Sided Rectangular Products. Items italicized in brackets are to be added as appropriate. The blanks are to be filled in as appropriate.

Rationale for FIG. 10: Added figure to provide example of formatting and to reduce confusion regarding the required warning statements for particular products (*i.e.*, full-size crib mattresses, after-market mattresses for mesh/fabric sided products and rigid sided non-rectangular products, and after-market mattresses for rigid sided rectangular products). Providing this example increases the likelihood of consumers seeing an appropriate warning label. This figure is not shown in actual size.

## Section 8. Instructional Literature

ASTM F2933 – 19	Staff's Recommended Revisions	Rationale Summary
(No requirement)	8. Instructional Literature	32.) Add a section on instructional literature, section 8,
	8.1 Instructions shall be provided with the	which specifies that instructional literature must accompany
	mattress and shall be easy to read and	crib mattresses. In alignment with recommendations from
	understand, and shall be in the English	the Ad Hoc task group and members of ASTM F15, these
	language, at a minimum. These instructions	requirements generally specify that these instructions shall
	shall include information on assembly,	(a) be easy to read and understand; (b) include information
	maintenance, cleaning, and use, where	regarding assembly, maintenance, cleaning, and use, where
	applicable.	applicable; and (c) address the same warning and safety-
	8.2 The instructions shall have statements to	related statements that must appear on the product, with
	address the following, at a minimum.	similar formatting requirements, but without the need to be
	8.2.1 All warnings included in section 7.5,	in color. Requiring instructional literature pertaining to the
	as applicable.	identified hazards ensures that consumers are provided an
	8.2.2 All additional markings and warnings	additional medium by which to be informed about the
	included in section 7.7, as applicable.	hazards.
	8.3 The warnings in the instructions shall	
	meet the requirements specified in 7.4.4,	33.) ASTM F2933 – 19, section 8, <i>Keywords</i> , would be
	7.4.5, and 7.4.6, except that sections 6.4 and	renumbered as section 9.
	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	
	cautions and warnings shall contrast with the	
	background of the instructional literature.	
	NOTE 7—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	

ASTM F2933 – 19	Staff's Recommended Revisions	Rationale Summary
	off-white background, or some other high-	
	contrast combination.	
	8.4 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 8—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.	

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TAB D: Crib Mattresses: Summary of recalls – June 2010 through June 2020

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UNITED STATES CONSUMER PRODUCT SAFETY COMMISSION BETHESDA, MD 20814

#### Memorandum

Date: June 19, 2020

ТО	:	Hope Nesteruk, Crib Mattress Project Manager, Directorate for Engineering Sciences, Division of Mechanical and Combustion Engineering
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 Mattresses: Summary of recalls – June 2010 through June 2020

CPSC staff recommends incorporating by reference ASTM F2933-19, *Standard Consumer Safety Specification for Crib Mattresses*, with modifications, in the draft notice of proposed rulemaking. Staff's recommendation addresses hazards associated with use of full-size crib mattresses, non-full-size crib mattresses, and after-market mattresses for cribs, play yards, and non-full-size cribs (collectively "crib mattresses"), such as, but not limited to, sudden unexpected infant death (SUID), material liberation, chemical concerns, and exposed springs or other sharp objects. In this memorandum, staff of CPSC's Division of Regulatory Enforcement (CRE), provides information related to previous crib mattress recalls.

#### COMPLIANCE ACTIVITIES

Compliance staff reviewed recalls of crib mattresses which occurred from June 1, 2010 to June 1, 2020. During this time period, CPSC staff negotiated five consumer-level recalls involving crib mattresses. The recalls were conducted to mitigate against risks of flammability and suffocation. Four out of the five recalls involved non-compliance with mandatory federal flammability requirements. These four recalls included approximately 80,000 units in total. Staff cannot provide an exact number of units that involved cribs mattresses because the recalls included both crib and adult mattresses. The fifth recall of crib mattresses involved a dimensional issue where the crib mattress models were ill-fitting, presenting an entrapment hazard. This recall included approximately 300,000 units.

Table 1 presents information on the five recalls conducted between June 1, 2010 and June 1, 2020, including the firm involved, the hazard presented, and the number of units affected.

Table 1.		
<b>Crib Mattress Recalls</b>		
June 1, 2010 to June 1, 2020		

		,	
Date	Firm	Hazard	# Recalled
05/01/2015	Ikea	Entrapment	Approximately 300,000
07/30/2015	Stork Craft	Fire	Approximately 18,500
09/08/2015	Ikea	Fire	Approximately 38,400
07/25/2017	Quality Foam	Fire	*Approximately 12,200
07/25/2017	Dream On Me	Fire	Approximately 23 400

\*Note that only a portion of the 12,200 units included in this recall were crib-size mattresses.

# TAB E: Health Sciences Staff Review of the Mechanisms of Death Associated with Crib Mattresses and After-Market Mattresses for Play Yards and Non-full-size Crib Mattresses.

Т



#### Memorandum

Date: September 30, 2020

TO :	Hope Nesteruk, Children's Program Manager Division of Mechanical and Combustion Engineering, Directorate for Engineering Sciences
THROUGH:	Jacqueline Ferrante, Ph.D., Acting Associate Executive Director Directorate for Health Sciences
FROM :	Suad Wanna-Nakamura Ph.D., Physiologist Division of Pharmacology and Physiology Directorate for Health Sciences
SUBJECT:	Health Sciences Staff Review of the Mechanisms of Death Associated with Crib Mattresses and After-Market Mattresses for Play Yards and Non-Full- Size Crib Mattresses.

#### I. Introduction and Background

In support of the staff briefing package for a draft notice of proposed rulemaking (NPR) for crib mattresses under section 104 of the Consumer Product Safety Improvement Act of (2008) (CPSIA), CPSC Epidemiology Hazard Analysis (EPHA) staff conducted two database searches: (1) the Consumer Product Safety Risk Management System<sup>76</sup> (CPSRMS); and (2) and the National Electronic Injury Surveillance System (NEISS) for fatal and non-fatal incidents associated with crib mattresses and after-market mattresses for play yards and non-full-size crib mattresses, reported to CPSC between January 1, 2010 and March 31, 2020, for all ages.

Staff's search retrieved a total of 439 reports: 199 (45%) resulted in no injury, 16 (4%) were coded as no incident, no injury, 116 (26%) reported fatalities, and 4 (1%) required hospital admission (Table 1, EPHA memorandum, Tab A). Victim age ranged from 1 to 39 months. Staff observed that most deaths involved infants from 1 to 5 months old, a vulnerable age group.

<sup>&</sup>lt;sup>76</sup> CPSRMS is the epidemiological database which houses all anecdotal reports of incidents received by CPSC, "external cause"-based death certificates purchased by CPSC, all in-depth investigations of these anecdotal reports, as well as investigations of select NEISS injuries. Examples of documents in CPSRMS are: hotline reports, internet reports, news reports, medical examiner's reports, death certificates, retailer/manufacturer reports, and documents sent by state/local authorities, among others. Tab- A

Severity	Number of	%
	Reports	
Fatalities	116	26%
Emergency Department Treatment Received	15	3%
Hospital Admission	4	1%
Seen by Medical Professional	1	<1%
First Aid Received by Non-Medical Professional	1	<1%
Level of care not known	66	15%
Incident, No Injury	199	45%
No First Aid or Medical Attention Received	8	2%
No Incident, No Injury	16	4%
Unspecified	13	3%
Total	439	100%

Table 1: Reports Associated with Crib Mattresses by Severity

Source: EPHA memorandum, Table 1, Tab A

### II. Pathophysiology of Asphysia and Sudden Infant Death Syndrome (SIDS)

Despite extensive research, the etiology of SIDS remains unidentified. However, based on available research, CPSC staff concludes that a number of physiological abnormalities and developmental delays in the brain stem are likely to play a role in SIDS-related deaths, including: impaired respiratory patterns of ventilation and arousal responses, impaired cardiac control and output chemoreceptor sensitivity, temperature regulation, and inborn errors of metabolism.<sup>6-8</sup> These factors, collectively referred to as exogenous stressor(s), can ultimately lead to difficulty breathing, resulting in death.<sup>7</sup> Prone sleeping is also associated with reduced ability to lose heat.<sup>12</sup> Studies have found that increased risk is also associated with infants born prematurely and is more common in very low birthweight infants. Additionally, research indicates that infants between birth and 4 months of age are particularly vulnerable to SIDS.<sup>1-5</sup> Parental smoking,<sup>9-11</sup> socioeconomic disadvantages, and lack of prenatal care may also play a role in SIDS-related deaths may be a consequence of delayed development in arousal and cardiovascular control, such that when an infant becomes compromised during sleep he/she may not be able to arouse themselves to avoid a life-threatening event.

Because of the lack of diagnostic features/markers at autopsy, SIDS remains a diagnosis by exclusion. Over the years, definitions and investigative guidelines for SIDS-related death classification have changed. Recently, a new classification was added, sudden unexpected infant death, or SUID<sup>13</sup>. This term is now used to describe a sudden and unexpected death for which no cause of death was obvious when the infant died (CDC, 2012). SIDS is a subset of SUID, and is assigned to infant deaths (under 1 year of age) that cannot be explained following a thorough case investigation, including: a death scene investigation, autopsy, and review of the clinical history. The National Institute of Child Health and Human Development (NICHD) defines SIDS as "*The sudden, unexplained death of an infant younger than 1 year of age that remains unexplained after a complete investigation. This investigation can include an autopsy, a review of the death scene, and complete family and medical histories."* Most SIDS deaths occur between 2 and 4 months of age. Considering all the changes in definitions and guidelines, staff

is not surprised to find differences in the cause of death reporting by medical examiners (MEs) and coroners, which is a well-documented observance. Because there is no standardized method for the classification of asphyxia deaths among MEs/coroners, staff observes that the terms "asphyxia" and "positional" are used differently by MEs and Coroners.

Suffocation-type asphyxial deaths (*e.g.*, smothering) involve occlusion of airways and can occur when an infant is placed to sleep in, or rolls into, a prone position on a surface capable of conforming to the body or face of an infant, such that the mouth and nose are physically blocked, preventing air passage. Positional asphyxia is a form of asphyxia associated with an abnormal body position which prevents adequate gas exchange. Positional asphyxia can result from entrapment in excessive gaps, which can cause direct obstruction of the airways. Infants found in this compromised position, with their nose and mouth pressed against the mattress or play yard side, are likely to remain in this position and experience compromised airflow.

Unlike adults, the limited physical and developmental capabilities of infants render them susceptible to danger from suffocation in certain sleep settings. Studies indicate that in addition to the normal problems with infants extricating themselves from a compromised situation, some infants may have delayed development of arousal and cardiovascular control mechanisms. If these systems are compromised, a sleeping infant may be unable to arouse him/herself sufficiently to react to a life-threatening event. The infant's inability to extricate him/herself due to the characteristics of the material constricting airflow, such as a pillow, cushion, mattress, or soft bedding, and the infant's developmental stage results in infant deaths.

# III. Fatal Incidents

EPHA staff identified five categories associated with crib mattress deaths. HS staff further reviewed the incident data in each of the five categories. The causes of death as determined by the ME or coroner for the 116 reported fatalities were positional asphyxia, SUID, asphyxia/suffocation, SIDS, or a combination of these. In most of the fatal incidents (102 of 116), the caregiver reportedly placed the infant in a prone position, "chest down" or "face down," or both. In some instances, the caregiver reported placing the infant to sleep in a supine position and later found the infant prone.

1. *Crib Mattress Used in a Play Yard:* Two fatal incidents involved a standard crib size mattress being used in a play yard. In each of these cases, the cause of death is listed as positional asphyxia, face wedged in a space between the mattress and the side of the play yard. An excessive gap between a mattress and the side of the crib or play yard creates an entrapment hazard that can cause death by positional asphyxia/suffocation. Infants found entrapped in excessive gaps, with their nose and mouth pressed against the mattress or play yard side, are likely to remain in this position and experience compromised airflow.

2. *Face in Mattress:* In 13 out of 116 (11%) fatalities, the child's face was reported to be in contact with a crib mattress. Staff's review of the incident data found the following:

(i) One of 13 fatal incident reports involved a clear statement by a medical official that an infant's airway openings were fully occluded. This death involved a 4-month, 29-day old infant

who died of asphyxia. "This infant was placed to sleep in a crib in the prone position on top of a *foam mattress pad* and *soft bedding*. The soft surface molded itself around the child's airway, preventing ventilation. Postmortem toxicology and histology were non-contributory."

(ii) Another death involved a two months and two weeks old infant who was hospitalized immediately after birth for two months due to severe congenital heart defects (including double outlet right ventricle or DORV<sup>77</sup>). Hospitalization included surgical insertion of a BT shunt.<sup>78</sup> The infant died at home two weeks later. The infant was found on her knees with her face in the crib mattress.

(iii) Seven of the 13 incidents contained limited or confounding information:

- an 8-month-old, not typically considered at risk for suffocation<sup>6</sup> unless entrapment is involved, was listed as "probable suffocation."
- one incident involved the death of a 7-month-old reported to have been found "face down in mattress with numerous blankets, death coded as "suffocation and strangulation."
- one incident reported the death of a 1-month-old placed prone in the crib with a pillow.
- one incident reported the death of a 1-month-old placed to sleep in a prone position, cause of death was listed as "suspected sudden unexpected death."
- one incident involved a 2-month-old sharing a crib with a twin where conflicting reports on victim's face position initially reported in the death certificate as "against a bumper pad" was later changed by the coroner to "against mattress."
- a 4-month-old born "a couple of months premature" died of positional asphyxia; three large pillows were also in the crib.
- one incident reported the death of a 2-month-old born 5 weeks premature who was placed prone in a play yard with a pillow and other bedding.

(iv) In four of the 13 incidents three reported that the mattresses were examined, the dimensions and thickness were reported, and described the mattress as "right fit," "thick," and "firm." In the fourth incident, a 2-month-old placed to sleep in a prone position by his mother was found unresponsive after 6 hrs. The police report noted that "there was nothing in the crib that would appear to interfere with his ability to breath or move." Overall, staff concludes that there was no clear indication that the mattress was a contributing factor in these four deaths.

3. *Fit Issues:* Twenty of the 116 reported fatalities involved issues with the fit of a mattress that led to entrapment when the infant became wedged in gaps between the side of a sleep product and the mattress. Twelve fatalities were reported in cribs, (two incidents reported 3- and 4.5-inch gaps), and eight fatalities in a play yard or non-full-size crib. The majority of infant deaths in play yards were also attributed to positional asphyxia and suffocation in gaps between the side of the play yard and added mattresses, generated by ill-fitting mattresses that created gaps between the added bedding and the side of the play yard. In each of these cases, the cause of death was listed as positional asphyxia. Excessive gaps in sleep settings are recognized entrapment hazards. Infants found in this compromised position, with their nose and mouth pressed against the

<sup>&</sup>lt;sup>77</sup>Is a congenital heart disease where the aorta and the pulmonary artery both connect to the right ventricular chamber of the heart. If not corrected it leads to the circulation of blood low in oxygen to the body.

<sup>&</sup>lt;sup>78</sup>A Blalock-Taussig (BT) shunt, is a small tube used to treat congenital heart defects that affect blood flow to the lungs.

mattress or play yard side, are likely to remain in this position and experience compromised airflow. A similar hazard has also been reported in the data for full-size cribs with ill-fitting mattresses.

When an infant's airflow is compromised, decreased levels of oxygen in the infant's blood can further impair the ability of the infant to respond to a developing hypoxic situation, and a vicious cycle of decreased heart and respiration rate develops that eventually leads to cessation of breathing. Cessation of breathing will be fatal if uninterrupted. The prognosis for hypoxic victims due to smothering is dependent primarily on the extent of oxygen deprivation, the duration of unconsciousness, and the speed of resuscitation. Rapid reversal of the hypoxic state is essential to prevent or limit the development of pulmonary and cerebral edema. Thus, infants who are oxygen deprived for short durations or who quickly receive cardiopulmonary resuscitation to reestablish air flow have the most favorable prognosis and recovery. The severity of oxygen deprivation ultimately governs the infant's chance for survival or the degree of neurological damage. Inadequate supply of oxygen to the brain can lead to loss of consciousness and death. (Health Sciences memorandum in response to petition CP 15-2 on supplemental mattresses, Wanna-Nakamura (2017)).

4. *Found Prone:* In fifty-seven percent (66 out of 116) of the fatalities, the infant was found prone, and staff found no mention of whether the face of the child was in contact with the crib mattress or crib sheet. While blankets were present, staff found no indication that the bedding contributed to the deaths. One incident reported the presence of a pillow; however, the report stated that the infant was far from the pillow.

The prone sleep position is a known high-risk for SIDS and suffocation, and young infants between birth and 4 months of age are particularly vulnerable to SIDS<sup>1-5</sup> because of limited physical and developmental capabilities. Increased risk of SIDS is also associated with preterm infants. In the absence of other external factors, and considering the vulnerability of infants, HS staff concludes that prone sleeping was likely a key factor in these deaths.

In addition to immaturity of the lungs, the following are likely to play a role in SIDS deaths in preterm infants, including a number of physiological abnormalities and developmental delays in the brainstem, <sup>6-8</sup> which impair respiratory patterns of ventilation and arousal reflexes and responses, as well as impair cardiac control and dysfunctional and/or immature cardiorespiratory and temperature regulation. Additionally, inborn errors of metabolism are likely to play a role in SIDS cases.

5 Multiple Contributing Factors (MCF): Thirteen percent (15 out of 116) of the fatalities involved MCF, with the majority due to unsafe sleep settings, a well-documented hazard in infant sleep environments that lead to death by asphyxia.<sup>14-25</sup> Some of these cases involved the use of extra mattresses, adult size pillows, and/or quilts placed under the infant, and sharing the same sleep surface with another infant. In three incidents, the child was entrapped between a bumper pad and crib mattress. One incident reported that one side of the crib was removed and the crib was pushed against an adult bed to align the crib mattress with the adult bed mattress. Examples of other contributing factors are entrapments between bumper pad and crib mattress, entrapment between the mattress and a crib rail, use of swaddling, that can decrease startling,

arousal, and spontaneous awakenings,<sup>21-25</sup> sharing of the sleep surface with another infant leading to overlay,<sup>26-31</sup> and presence of congenital factors and respiratory infections and other diseases that are also associated with an increased vulnerability to SIDS and suffocation.<sup>1-4</sup>

The American Academy of Pediatrics (AAP) Back to Sleep campaign<sup>3</sup> has been proven effective in reducing the incidents of SIDS, and the CPSC has continued its efforts to educate the public, including joint recommendations with AAP and other educational campaigns promoting that "Bare is Best" for safe sleep. Nevertheless, caregivers continue to place infants to sleep in the prone position and place pillows in the infant's sleep environment.<sup>32</sup>

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TAB F: Initial Regulatory Flexibility Analysis of the Draft Proposed Rule for Crib Mattresses Intended for Full-Size Cribs, Non-Full-Size Cribs, and After-Market Mattresses for Play Yards and Non-Full-Size Cribs





#### Memorandum

		Date:	September 30, 2020
To:	Hope E J. Nesteruk, Project Manager, Crib Mattress Team Division of Mechanical and Combustion En Directorate for Engineering Sciences	ngineering,	-
Through:	Gregory B. Rodgers Associate Executive Director, Directorate for Economic Analysis		
	Robert Franklin Senior Staff Coordinator, Directorate for Economic Analysis		
From:	Cynthia Gillham Economist, Directorate for Economic Analysis		
Subject:	Initial Regulatory Flexibility Analysis for N Full-Size Crib Mattresses, Non-Full-Size Cr Mattresses for Play Yards and Non-Full-Size	lotice of Prop rib Mattresses e Cribs	osed Rulemaking on , and After-Market

#### I. Introduction

This memorandum describes the possible economic impact of the draft proposed rule (NPR) for crib mattresses on small entities, including small businesses, as required by the Regulatory Flexibility Act (RFA). Under section 603 of the RFA, agencies must prepare an initial regulatory flexibility analysis (IRFA) and make it available to the public for comment when the NPR 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.

# II. Objectives and Legal Basis of the Draft Proposed Rule

The draft NPR proposes requirements to reduce the risk of injury and death associated with fullsize crib mattresses, non-full-size crib mattresses, and after-market mattresses for play yards and non-full-size cribs (collectively referred to as "crib mattresses"). Section 104 of the Consumer Product Safety Improvement Act (CPSIA) requires the CPSC to promulgate mandatory standards for durable infant or toddler products that are substantially the same as the voluntary standard if the Commission determines that more stringent requirements would further reduce the risk of injury associated with the product. CPSC staff identified 116 fatalities and 323 nonfatal incidents associated with crib mattresses between January 1, 2010 and March 31, 2020.<sup>79</sup>

To address fatal and nonfatal incidents associated with crib mattresses, the draft proposed rule would (1) create a mandatory standard for crib mattresses that would address the hazards associated with crib mattresses, (2) amend 16 CFR part 1112, Requirements Pertaining to Third Party Conformity Assessment Bodies, to include crib mattresses in the list of children's product safety rules for which the CPSC has issued a notice of requirements, and (3) update 16 CFR 1130 to include crib mattresses as a durable infant or toddler product that requires a product registration card.

# III. The Product

As defined by ASTM F2933 - 19, "crib mattresses" include full-size crib mattresses, non-full-size crib mattresses, and after-market mattresses for play yards and non-full-size cribs. Crib mattresses that meet these specifications come in a variety of designs, are made with a broad array of materials, and are marketed for infant and toddler use. Full-size crib mattresses are sold to fit full-size cribs and are referred to by industry as "Standard" crib mattresses. Accordingly, full-size crib mattresses have set dimensions. Non-full-size crib mattresses, on the other hand, are essentially crib mattresses that differ in dimension or shape from Standard crib mattresses.

The most common rectangular non-full-size crib mattress available for sale in the U.S. crib mattress market is the "mini" crib mattress. The mini crib mattress is smaller than the so called "standard" or full-size crib mattress. The typical size of a mini crib mattress is 24 in. wide and 38 in. long. The depth of a mini crib mattress varies but typically ranges from 1 in. to 6 in.

• Section 5.7 of ASTM F2933 – 19 identifies the dimensions of a full-size crib mattress to measure at least 27 <sup>1</sup>/<sub>4</sub> in. wide and 51 <sup>5</sup>/<sub>8</sub> in. long. The interior dimensions of full-size cribs are  $28 \pm \frac{5}{8}$  in. (710 ± 16 mm) wide and 52 <sup>3</sup>/<sub>8</sub> ± <sup>5</sup>/<sub>8</sub> in. (1330 ± 16 mm) long.

<sup>&</sup>lt;sup>79</sup> Suchy, Adam. CPSC Memorandum to Hope Nesteruk, "Crib Mattress and After-Market Play Yard Mattress-Associated Deaths, and Non-fatal Incidents and Concerns Reported to CPSC from January 1, 2010 to March 31, 2020" U.S. Consumer Product Safety Commission, Bethesda, MD.

- Non-full-size crib mattresses do not have defined dimensions, except for the minimum effective crib-side height. As defined by ASTM F2933 19, the dimensions of a mattress supplied with a non-full-size baby crib shall be such that the mattress, when inserted in the center of the crib, in a noncompressed state, shall not leave a gap of more than ½ in. at any point between the perimeter of the mattress and the perimeter of the crib.
- Section 5.9 of ASTM F2933 19 indicates that after-market mattresses for play yards and non-full-size cribs shall have the same (within ¼ in.) thickness, floor support structure, and attachment method as the mattress it is intended to replace.

Crib mattresses range in price from \$20 to \$500, with the more expensive crib mattresses typically being full-size crib mattresses with a firm coil or high-end foam core. Crib mattresses are sometimes sold with waterproof covers, specifically designed to be used with the mattress. While some manufacturers produce a large variety of crib mattress models, others produce only a small selection. Many crib mattresses are GreenGuard Certified, which is a UL-sponsored standard intended to reduce the emissions of volatile organic compounds from products.<sup>80</sup> Additionally, many full-size crib mattresses are advertised online as meeting the CPSC mattress and mattress pad flammability requirements.<sup>81</sup> Crib mattresses are defined as children's products and are already subject to various other federal safety rules, such as lead and phthalate testing.

#### IV. Crib Mattresses in Use

Crib mattresses are designed to provide sleeping accommodations for infants and toddlers and are marketed for use from birth through toddler age. According to estimates published by Statista-Grand View Research, the size of the U.S. market for standard and portable cribs was \$86.8 million in 2018.<sup>82</sup> According to data collected by staff, approximately 75 percent of crib mattresses available for sale in the U.S. are standard (full-size) crib mattresses and 7 percent are mini crib mattresses.

Based on information from the 2013 CPSC Durable Nursery Products Exposure Survey (DNPES) 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.<sup>83</sup> 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). Cribs, for the purposes of the DNPES, included both full-size and non-full-size cribs, which are designed to be used with a crib mattress; therefore, staff estimates at least 9.2 million (full-size and non-full-size) crib mattresses were in use in 2013.

According to DNPES results, 84 percent of respondents indicated they used a fitted sheet on the crib mattresses, and 50 percent indicated use of a mattress pad. Six percent of respondents

<sup>&</sup>lt;sup>80</sup> <u>https://www.ul.com/resources/ul-greenguard-certification-program.</u>

<sup>&</sup>lt;sup>81</sup> Review of manufacturers' websites, product labels, and materials.

<sup>&</sup>lt;sup>82</sup> November 2019 Statista estimates, Grand View Research.

<sup>&</sup>lt;sup>83</sup> Respondents were asked to include cribs that had been converted into toddler beds in their count of cribs owned, but were instructed to only include time used in the product *as a crib* in response to use questions.

indicated that nothing was placed under the child in the crib, other than the intended mattress, indicating the crib mattress was used bare.

According to the same survey, an estimated 5.8 million play yards were in use in households with young children. This represented about 54 percent of the estimated 10.9 million total play yards owned by households (*i.e.*, about 5.1 million play yards were owned, but not in use). Play yards are designed to be used with a play yard mattress; therefore, staff estimates at least 5.8 million play yard mattresses were in use in 2013. Twenty-five percent of respondents indicated that nothing was placed under the child in the play yard, other than the intended mattress; 12 percent indicated they used a mattress pad, but no respondents indicated that they used a fitted sheet.

In addition to the products in use in households with young children, as estimated from the survey, cribs and crib mattresses are probably in use in some households without young children (*e.g.*, unsurveyed homes of older adults providing care for grandchildren). Furthermore, the DNPES did not cover child care facilities. One childcare industry group's 2018 directory<sup>84</sup> lists more than 115,000 licensed childcare centers and more than 137,000 home daycare providers, some of which may use crib or play yard mattresses. 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.<sup>85</sup> Based on the Commission's contacts with childcare and lodging facilities, crib, play yard, and crib mattress usage in such establishments is relatively common.<sup>86</sup>

### V. Small Entities to Which the Draft Proposed Rule Would Apply

Manufacturers of crib mattresses are typically categorized under the NAICS category 337910 (Mattress Manufacturing). The Small Business Administration (SBA) guidelines consider mattress manufacturing establishments to be small if they have fewer than 1,000 employees.<sup>87</sup> Importers of crib mattresses are typically categorized under NAICS code 423210 (Furniture Merchant Wholesalers) and SBA guidelines would consider them small if they have fewer than 100 employees.

Staff identified 26 manufacturers and importers of full-size, non-full-size, and after-market play yard mattress suppliers. A majority of the 26 firms have under 50 employees. Most of the firms are domestic manufacturers (14) or domestic importers (8). Four firms are foreign. Sixteen of these 26 firms meet the SBA criteria for small businesses, and 10 firms would be considered large according to the SBA criteria.<sup>88</sup> Among the 16 small domestic firms identified by staff, 9 were manufacturers and 7 were importers. Staff observes that annual revenue varies among small domestic firms, as median annual revenue is estimated at \$6,740,000, but average annual revenue is higher at \$46,037,100.

<sup>&</sup>lt;sup>84</sup> Child Care Centers estimate entire U.S. (2018, April 27). http://childcarecener.us/.

<sup>&</sup>lt;sup>85</sup> U.S. Bureau of Labor Statistics, "Quarterly Census of Employment and Wages," April 2018. http://www.bls.gov/iag/tgs/iag721.htm.

<sup>&</sup>lt;sup>86</sup> Staff contacts included phone inquiries with daycare and hotel establishments.

<sup>&</sup>lt;sup>87</sup> The size guidelines are established by the U.S. Small Business Administration (SBA).

<sup>&</sup>lt;sup>88</sup> Based on size and revenue data from Reference USA and firm financial reports, websites, and press releases.

Online registries are widely available for new crib mattresses. Producers supply crib mattresses to the U.S. market via electronic commerce websites, such as Amazon.com, Buy Buy Baby, Hayneedle, KOHL'S, Overstock, Walmart, and Wayfair. According to a 2017 Statista survey of baby products, the majority (59 percent) of respondents indicated they buy baby products mainly or exclusively online.<sup>89</sup> Staff expects that consumers of crib mattresses that do not buy online, purchase their mattresses in retail stores.

The majority of crib mattresses on the market are full-size crib mattresses. Staff estimates that 40 percent of crib mattresses on the market are coil/innerspring mattresses, and approximately 60 percent of crib mattresses are foam-core mattresses.<sup>90</sup> Among small domestic manufacturers, approximately 45 percent of available crib mattresses are coil mattresses. Among small importers, just 25 percent of available crib mattresses are composed of a coil core. Seventy-five percent of crib mattresses supplied by small domestic importers of crib mattresses consist of a foam core. Staff identified at least three small firms that only produce foam-core mattresses, while the majority of small entities produce a combination of both coil and foam-core crib mattresses.

#### VI. Requirements of the Draft Proposed Rule

The draft proposed rule would incorporate by reference ASTM F2933 – 19, in addition to staffrecommended modifications intended to further reduce the risk of injury associated with crib mattresses. ASTM F2933 – 19 includes requirements for (1) mattress dimensions, (2) mattress thickness, (3) mattress seam stitching, and (4) replacement mattresses for after-market mattresses for play yards and non-full-size cribs. Staff-recommended testing would address entrapment hazards, excessive surface softness, and laceration hazards due to exposure to coil springs. The following three tests are recommended<sup>91</sup>:

- **Compression Test:** to address hazardous gaps created between the edge of a crib and a mattress when mattresses that are too soft and compress when used with a fitted sheet;
- **Firmness Test:** to address excessively soft mattress surfaces that create an asphyxiation hazard when the surface indents;
- **Cyclic Load Test:** to address laceration injury incurred as a result of exposure to inner-coil springs.

CPSC staff collected a sample of crib mattresses for testing to develop test methods that address the identified hazards. Although not a probability sample, staff tried to collect a wide variety of crib mattresses that included most types of crib mattresses that are available in the marketplace, including innerspring mattresses, 2-stage mattresses, and mattresses of an atypical design. Staff found that of the 11 mattresses tested according to the proposed Compression Test, eight mattresses shrank in length when fitted with a washed sheet, but these mattresses would still

<sup>&</sup>lt;sup>89</sup> Statista Survey of Baby Products in the U.S., 2017.

<sup>&</sup>lt;sup>90</sup> Based on staff's compiled search results of data available on the internet found on March-May 2020.

<sup>&</sup>lt;sup>91</sup> Mechanical Engineering Assessment, 30 September 2020.

comply with the proposed rule, if they fit properly into the crib for which they were designed for use, as indicated in ASTM F2933 – 19, section  $5.7.^{92}$  Results from the initial Firmness Test indicate 10 out of 11 models would pass the proposed firmness test without any modification to the product. Only three crib mattresses models were tested to the proposed Cyclic Load Test; therefore, additional testing is required.

#### VII. Impact of Draft Proposed Rule on Small Manufacturers and Importers

Of the 16 small manufacturers and importers identified by staff, 12 (8 manufacturers and 4 importers) are members of the Juvenile Products Manufacturers Association (JPMA), but staff cannot determine how many crib mattresses are currently certified to ASTM F2933 – 19. Many of the firms that would be subject to the draft proposed rule are known to produce a variety of children's products that are already subject to CPSC children's product safety rules, and therefore, are familiar with such requirements.<sup>93</sup> Additionally, two firms that are not JPMA members supply products that meet ASTM standards. Staff seeks comments from small firms on the number of mattress models they would typically certify to the ASTM standard annually.

Manufacturers and importers of crib mattresses would be responsible for ensuring that their products comply with the requirements of the draft proposed rule. If a crib mattress does not comply with the requirements, the manufacturers or importers will need to modify the product or cease manufacture or importation. Importers might be able to work with their manufacturers to supply compliant mattresses and could potentially switch suppliers if their current supplier is unwilling to supply current mattresses. Alternatively, they might simply drop the non-compliant mattresses from their product lines.

Additionally, as required by section 14 of the CPSA and its implementing regulations, manufacturers and importers of crib mattresses would be required to certify that their crib mattresses comply with the requirements of the draft proposed rule, based on the results of third party testing by a CPSC-accepted third party conformity assessment body (*i.e.*, testing laboratory). As mentioned, crib mattresses are already subject to third party testing requirements and adoption of the proposed rule would only augment existing testing requirements.<sup>94,95</sup>

<sup>&</sup>lt;sup>92</sup> Each tested mattress shrank in length by less than .5 in., the maximum gap allowed between any point between the perimeter of the mattress and the perimeter of the crib. The compression test is only applied to full-size crib mattresses.

<sup>&</sup>lt;sup>93</sup> Crib mattresses listed for sale on a variety of online retail websites often include product descriptions indicating that the crib mattress product meets CPSC general safety standards, while not referencing any one specific CPSC safety standard.

<sup>&</sup>lt;sup>94</sup> Manufacturers and importers of children's products must certify compliance with applicable federal safety requirements in a Children's Product Certificate (CPC). In most instances, testing by a third party CPSC-Accepted Laboratory must serve as the basis for the production of the CPC.

<sup>&</sup>lt;sup>95</sup> Mattresses intended for children must be tested at a third party test laboratory or a fire-walled internal laboratory: <u>https://cpsc.gov/s3fs-public/pdfs/blk\_media\_mattress.pdf</u>. In either case, the lab would need to be CPSC-accepted to test to the standards since crib mattresses are considered to be primarily intended for children 12 and under.

#### A. Costs Associated with Modifying Products

The majority of crib mattresses currently available on the market will not require extensive modification to comply. As mentioned, the majority of crib mattresses tested by staff already meet the performance requirements of the proposed rule. We do not know the exact costs of modifying crib mattresses to comply with the draft proposed rule, which would vary by product model. Modifying crib mattresses to comply with the compression standard could be as simple as adding a perimeter border wire to the mattress edge or an anti-sag weight distribution bar to the mattress structure. However, it is possible that a required modification would be prohibitively expensive, and therefore, the draft proposed rule may result in the removal of certain crib mattresses from commerce.

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 is generally low, especially if some warning labels are already present, and the product does not need to be modified to accommodate new labels.

### B. Third Party Testing Costs

Promulgating the draft proposed rule would require all manufacturers and importers of crib mattresses to meet additional third party testing requirements under section 14 of the Consumer Product Safety Act (CPSA). Third party testing requirements will include any physical and mechanical test requirements specified in the final crib mattress rule. Based on information from a testing laboratory, the cost of testing to the current version of ASTM F2933 is \$200 to \$250 per sample. The additional testing that would be required by the draft proposed rule would increase this cost by \$50 to \$75 per sample tested. Thus, the total cost of the third party testing would be \$250 to \$325 per sample. Given that the average number of crib mattress models per firm is approximately 12, the cost of the third party testing could be about \$3,000 to \$3,900, if only one model per sample were required to provide a high degree of assurance that the model complied with the requirements.

Additionally, according to conformity assessment bodies that staff contacted, for each mattress model to be tested, the firm will need to provide the crib or play yard equipment intended to be used with the mattress being tested. However, to comply with ASTM F2933 – 19 and other CPSC requirements for children's products, the costs of supplying a crib, crib mattress, or play yard to the conformity assessment body are already borne by the producer for testing under previously adopted rules and standards. Regardless, third party testing facilities have indicated that they are unable to store equipment that will be needed or used during testing, such as cribs or play yards, for long periods of time. Therefore, ensuring that all crib equipment needed for testing arrives at the testing lab at the appropriate time may pose a logistical burden, even if there is no increase in monetary costs for freight or shipping.

Additional costs of the proposed testing would include the cost of the 100 percent cotton sheets used during testing.<sup>96,97</sup> These sheets would be used in the proposed "Compression Test" for full-size crib mattresses. While the number of times a sheet can be reused has not yet been determined, we assume one new sheet per test. The cost of one, 100 percent cotton, full-size crib mattresses sheet to be approximately \$10.<sup>98</sup> Staff estimates approximately 3 out of 4 crib mattresses on the market are full-size crib mattresses.<sup>99</sup> Therefore, for a typical manufacturer or importer with 12 crib mattress models, 9 might be full-size crib mattresses and the additional cost of one fitted sheet per full-size mattress would be \$90, in addition to the testing costs charged by the conformity assessment body.

For a subset of mattresses, *i.e.*, metal coil spring crib mattresses, the proposed rule would include cyclic impact testing called the "Cyclic Load Test." During the Cyclic Load Test, an impactor weighing 30 pounds shall be dropped repetitively from above the mattress surface, and across four different locations on the mattress. As a result of the Cyclic Load Test, the mattress product is rendered unusable for either of the proposed firmness or compression tests. Under cyclic load testing the mattress product could be misshapen, deformed, or otherwise destroyed and wire coils may protrude from the mattress surface. Approximately 40 percent of crib mattresses available for sale are metal spring coil mattresses. The average cost of a crib mattress available for sale in the United States is \$150,<sup>100</sup> and on average, the typical manufacturer or importer of crib mattresses tests 12 models annually. Therefore, the cost to the typical small firm of the destroyed mattresses would amount to 40 percent of \$1,800 (12 models x \$150), or approximately \$720, as a result of the proposed Cyclic Load Test.

Therefore, for a typical manufacturer or importer with 12 crib mattress models that requires only one test per model to provide a high degree of assurance the full cost of third party testing will be approximately \$3,000 to \$3,900, plus \$90 in costs for fitted-sheet testing materials, and \$720 for the cost of used test mattresses, for a total of \$3,810 to \$4,710 or an average of \$318 to \$393 per model.

#### C. Summary of Impacts

Generally, based on Small Business Administration guidelines, CPSC considers impacts that exceed one percent of a firm's revenue to be *potentially* significant. The lowest reported annual revenue for any small domestic firm producing fewer than four crib mattress models was \$1.36 million. One percent of annual revenue for the firm is \$13,600 (\$1,360,000 x 0.01). Consequently, if the costs of modifying their mattresses to comply with the standard exceeded \$13,600, the rule could have a significant impact on some small firms. This would include the costs of modifying non-compliant mattresses to comply with the requirements, the loss of revenue that results from removing non-compliant mattresses from their product line, and the

<sup>&</sup>lt;sup>96</sup> The proposed test includes measuring the mattress without a fitted sheet and with a twice-washed fitted sheet.

<sup>&</sup>lt;sup>97</sup> With input from the ASTM standards organization, CPSC staff will determine the number of times a sheet can be reused.

<sup>&</sup>lt;sup>98</sup> Based on compiled search results of data available on the internet.

<sup>&</sup>lt;sup>99</sup> Based on a review of over 300 mattress models available for sale on the internet.

<sup>&</sup>lt;sup>100</sup> Price estimated from data available on the internet, collected between January 2020 and June 2020.

cost of third party testing. For manufacturers or importers with greater revenue, the impact of the draft proposed would have to be higher than this for the impact to be considered significant.

Given that a substantial number of mattresses already comply with the requirements of the draft proposed rule and some of the testing costs are already being borne by firms that certify to the current voluntary standard, it seems unlikely that the rule would have a significant impact on a substantial number of small entities. However, we request comments on the costs of the proposed rule, or impediments to modifying existing crib mattress products to conform to the draft proposed rule, especially those that would result in the removal of the mattress product from the market and other impacts of the draft proposed rule on small manufacturers and importers.

### VIII. Other Federal Rules that 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.

# IX. Alternatives Considered to Reduce the Impact on Small Entities

The Commission could consider the following alternatives to the draft proposed rule 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.

### A. Adopt ASTM F2933 – 19 without modification

The Commission could propose to incorporate by reference ASTM F2933 – 19, without any modifications, and direct staff to work with ASTM to improve test methods and the firmness of crib mattresses 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, many crib mattresses probably already comply with the draft proposed standard. The additional testing costs associated with the modifications to ASTM F2933-19 in the draft proposed rule would only increase the testing costs by \$50 to \$75 per sample. Moreover, adopting ASTM F2933-19 without modification would not address some of the hazard patterns identified in the incident data.

### B. Small Batch Exemption

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 Consumer Product Safety Improvement Act of 2008. Consequently, staff cannot recommend a small batch exemption absent a statutory change.

# 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. Additionally, 6 months from the change in a voluntary standard is the time frame that JPMA uses for its certification program, so compliant manufacturers are used to this time frame to comply with a modified standard.

One alternative that could reduce the impact of a mandatory rule on small firms would be to set an effective date later than 6 months. Implementing a later effective date could mitigate the effects of the rule on small businesses. For businesses that would choose to exit the crib mattress market, or discontinue certain crib mattress models currently in production (rather than produce conforming products), such a delay might provide them with more time to adjust marketing towards other product offerings, sell inventory, or consider alternative business opportunities.

#### D. Not Issue a Mandatory Standard

Another option available to the Commission that would reduce the burden on small firms is not to adopt a mandatory standard for crib mattresses. This would eliminate the cost impacts of complying with the proposed rule. However, failure to issue a mandatory standard for crib mattresses would not adequately address the hazard patterns for crib mattresses, especially for hazard patterns that are not adequately addressed in the voluntary standard, such as hazard pattern - Coil or Spring (which uses cyclic testing to identify the potential for springs to break through the mattress surface), or hazard pattern - Fit issues (which uses compression testing with a fitted sheet to ensure the proper fit of a sheeted full-size crib mattresses in a full-size crib).

#### X. Conclusion

This memorandum evaluated the possible impacts of the draft proposed rule on small entities, as required by the RFA. Staff identified 26 manufacturers and importers of mattress products. Sixteen of which would be considered small businesses (9 manufacturers and 7 importers). The potential impacts include the costs of modifying mattresses to conform to the requirements, the lost revenue if some models are discontinued, and the costs associated with the third party testing. It is possible that the draft proposed rule could have a significant impact on some small firms, but we cannot estimate how many. However, as described above, it seems unlikely that the proposed rule would have a significant impact on a substantial number of small entities. Staff considered several alternatives to the draft proposed rule to reduce any adverse impact on small firms, but determined that each of these alternatives would provide limited relief or were not available due to statutory limitations. We invite comments, particularly from small businesses, on the cost of making necessary modifications to noncomplying crib mattress models to comply with the draft proposed rule and alternatives that could reduce the burden on small businesses.

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