



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
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DATE: June 12, 2019

BALLOT VOTE SHEET

This document has been electronically approved and signed.

TO: The Commission
Alberta E. Mills, Secretary

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

FROM: Patricia M. Pollitzer, Assistant General Counsel
Mary A. House, Attorney, OGC

SUBJECT: Termination of Rulemaking for Infant Inclined Sleep Products

BALLOT VOTE DUE Tuesday, June 18, 2019

The U.S. Consumer Product Safety Commission (CPSC) issued a notice of proposed rulemaking (NPR) in April 2017 to establish a mandatory safety standard for infant inclined sleep products, pursuant to the Danny Keysar Child Product Safety Notification Act, section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA). The NPR proposed to adopt a voluntary standard for infant inclined sleep products developed by ASTM International, with a modification to the standard's definition of "accessory." Since then, CPSC has become aware of additional fatalities and information that warrant reconsideration of the requirements proposed in the NPR.

Accordingly, as requested by the Office of the Executive Director (OEX), the Office of the General Counsel (OGC) is forwarding for Commission consideration, the attached draft *Federal Register* notice, which would terminate the rulemaking to establish a mandatory safety standard for infant inclined sleep products and terminate associated amendments to the consumer registration rule and notice of requirements.

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

Please indicate your vote on the following options:

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

(Signature)

(Date)

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

(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: Safety Standard for Infant Inclined Sleep Products:
Termination of Rulemaking

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Billing Code 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1112, 1130, and 1235

[CPSC Docket No. 2017-0020]

Safety Standard for Infant Inclined Sleep Products: Termination of Rulemaking

AGENCY: Consumer Product Safety Commission.

ACTION: Termination of rulemaking.

SUMMARY: In the **Federal Register** of April 7, 2017, the Consumer Product Safety Commission (CPSC) published a notice of proposed rulemaking (NPR) pursuant to the Danny Keysar Child Product Safety Notification Act, section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), to promulgate a consumer product safety standard for infant inclined sleep products (inclined sleep products), a type of durable infant or toddler product. The NPR proposed to adopt a voluntary standard for inclined sleep products developed by ASTM International, with a modification to the standard's definition of "accessory." Based on subsequent information and events, the Commission is terminating the rulemaking and withdrawing the inclined sleep product NPR. Additionally, the Commission is terminating the related proposed amendment to include inclined sleep products in the list of notice of requirements (NORs), as well as the related proposed amendment to identify explicitly infant inclined sleep products as a durable infant or toddler product subject to CPSC's consumer registration requirements.

FOR FURTHER INFORMATION CONTACT: Celestine T. Kish, Project Manager, Directorate for Engineering, U.S. Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone: (301) 987-2547; email: ckish@cpsc.gov.

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SUPPLEMENTARY INFORMATION:

I. Background and Statutory Authority

One of the CPSC's missions is to protect the public against unreasonable risks of injury associated with consumer products. 15 U.S.C. 2051(b)(1). In furtherance of this mission, section 104(b) of the CPSIA, part of the Danny Keysar Child Product Safety Notification Act, requires the Commission to: (1) examine and assess the effectiveness of voluntary consumer product safety standards for durable infant or toddler products, in consultation with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts; and (2) promulgate consumer product safety standards for durable infant or toddler products. Standards issued under section 104 are to be "substantially the same as" the applicable voluntary standards, or more stringent than the voluntary standard if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product. 15 U.S.C. 2056a(b)(1).

A "durable infant or toddler product" is a "durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years." *Id.* 2056a(f)(1). The CPSIA also includes a non-exhaustive list of categories of products that are durable infant or toddler products, such as cribs, toddler beds, and bassinets and cradles. *Id.* 2056a(f)(2). Inclined sleep products are a "durable infant or toddler product" under section 104 of the CPSIA, as a subset of the bassinet and cradle category.

As stated in the NPR, CPSC staff initially considered inclined sleep products to fall within the scope of the bassinet/cradle standard, currently codified as 16 C.F.R. part 1218. 82 FR 16963, 16964 (April 7, 2017). As work progressed on the bassinet/cradle standard, staff advised the Commission that one rule could not effectively address all products, and the

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Commission directed staff to address inclined sleep products in a separate rulemaking. Thus, the NPR for inclined sleep products was an outgrowth of the bassinet/cradle safety standard to address products intended for infant sleep with an incline greater than 10 degrees and less than or equal to 30 degrees from horizontal. ASTM simultaneously began work on developing a voluntary standard for inclined sleep products. On April 7, 2017, the Commission issued an NPR, proposing to adopt as mandatory, the voluntary standard for inclined sleep products that ASTM International developed, ASTM F3118-17, *Standard Consumer Safety Specification for Infant Inclined Sleep Products* (ASTM F3118-17), with a modification to the standard's definition of "accessory." 82 FR 16963.

II. Termination of NPR to Create a Safety Standard for Inclined Sleep Products

The Commission is terminating this rulemaking for inclined sleep products. Based on the information described below, including the number of infant fatalities associated with inclined sleep products, the Commission's safety alerts based on some of these fatalities, and two recent recalls of inclined sleep products, the Commission concludes that the NPR proposing to incorporate by reference ASTM F3118-17, with a modification to the standard's definition of "accessory," is unlikely to adequately address the risk of injury associated with inclined sleep products. The Commission is terminating the rulemaking and withdrawing the NPR to reconsider requirements for inclined sleep products, including, but not limited to, the level of incline, appropriate age designations, use of restraints, side height, and accessories. CPSC staff will continue to assess all product requirements independently, as well as work with stakeholders, as appropriate, through the ASTM process.

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A. *Description of the Product*

The scope of products covered by the NPR tracked the scope of ASTM F3118-17, covering “a free standing product with an inclined sleep surface primarily intended and marketed to provide sleeping accommodations for an infant up to 5 months old or when the infant begins to roll over or pull up on sides, whichever comes first.” The NPR described the following categories of infant inclined sleep products.

- **Hammocks** (typically constructed of fabric and suspended from one or two points, either above or on either side; constructed of various materials; generally conform to the shape of the child when placed in the product; can either be supported by a frame or other structure, such as a ceiling);

- **Newborn or infant frame type** (intended to be placed on the floor; self-supporting; typically use a metal frame with a rigid or semi-rigid sleeping surface; base may be stationary or allow side to side rocking; may be intended for use by either newborns or infants, or both, depending on the size);

- **Compact** (freestanding with the bottom of the seat a maximum of 6 inches above the floor; generally constructed of foam with a fixed seat back angle between 10° and 30°; intended to be used on the floor); and

- **Newborn or infant inclined sleep product accessories** (intended to provide sleeping accommodations and are attached to or supported in some way by another product; a rigid frame product that has either a stationary or fixed base and in some cases may be removed and used independently; products intended for newborn use have a seat back less than 17 inches).

Products intended for use with newborns are generally similar in design to products intended for

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infants, except that products intended for use with newborns have a seat back length of 17 inches or less.

Additionally, the NPR described three key components of an “infant inclined sleep product” contained in ASTM F3118-17:

- **Age of intended product occupant:** the product must be intended for infants up to five months old (3 months for certain smaller products). The product may additionally be intended for older children, possibly in a different configuration, provided that its intended use also includes children up to five months.
- **Sleep:** the product must be primarily intended and marketed to provide sleeping accommodations.
- **Surface incline:** the product must have at least one inclined sleep surface position that is greater than 10 degrees, but less than or equal to 30 degrees.

B. Fatal Incidents and Recalls Associated With Inclined Sleep Products

1. Fatalities

At the time of the NPR, the Commission was aware of 14 fatal incidents related to infant inclined sleep products, which were reported to have occurred between January 1, 2005 and September 30, 2016. Eight of the 14 deaths involved rocker-like inclined sleep products; in three cases, the unstrapped decedent was found to have rolled over into a facedown position. Two additional cases also reported a rollover into a facedown position, but they did not include any information about use of a restraint. CPSC had little information about the cause or manner of the three remaining deaths. The NPR recognized that reporting was ongoing and the number of reported fatalities could change.

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Since the NPR published, CPSC staff has received reports of 42 additional fatalities that involved rocker-like inclined sleep products. The dates of death among the new reports span from 2011 to 2019. Among them, 10 decedents rolled over from supine to prone or side position in the product; 18 decedents did not roll over at all; and no roll-over information was available on 14 of the remaining deaths. CPSC staff is not usually able to obtain information on the use of restraints.

2. Safety Alerts and Recalls

The NPR described recalls involving inclined sleep products that occurred from May 10, 2000 to March 1, 2016. During that time, CPSC conducted nine consumer-level recalls involving infant inclined sleep products. CPSC conducted the recalls to resolve issues involving mold, structural stability, entrapment, suffocation, falls, and strangulation. Three recalls involved inclined sleep products, and six recalls involved infant hammocks. One recall for mold affected 800,000 units of infant inclined sleep products. Two recalls for entrapment and suffocation affected 195,000 units of inclined sleep products. The six additional recalls were the result of potential suffocation, strangulation, structural stability, entrapment, and fall hazards, collectively affecting 25,368 hammock units.

Since March 1, 2016, CPSC issued two safety alerts and conducted two recalls involving inclined sleep products. On May 31, 2018, the Commission issued a safety alert, “CPSC Consumer Alert: Caregivers Urged To Use Restraints With Inclined Sleep Products.”¹ The safety alert advised of infant rollover deaths in inclined sleep products, and reminded caregivers to always use restraints, and to stop using the product as soon as an infant can roll over. Additionally, on April 5, 2019, based on 10 fatalities involving unrestrained infants older than 3

¹ <https://www.cpsc.gov/content/cpsc-consumer-alert-caregivers-urged-to-use-restraints-with-inclined-sleep-products>

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months who rolled over in a Fisher-Price Rock ‘N Play, the Commission issued a safety alert, “CPSC ALERT: CPSC and Fisher-Price Warn Consumers About Fisher-Price Rock ‘N Play Due to Reports of Death When Infants Roll Over in the Product.”² The safety alert described the hazard and advised consumers to stop use of the product when an infant reaches three months of age, or as soon as an infant exhibits rollover capabilities. On April 12, 2019, CPSC announced a recall of this product, involving 4.7 million products.³ Shortly thereafter, on April 26, 2019, CPSC announced a recall of another, rocking style, inclined sleep product, the Kids II Rocking Sleeper, related to 5 rollover fatalities.⁴ Both recalled products met the requirements of ASTM F3118-17,⁵ the voluntary standard on which the NPR was based.

III. Termination of NPR to Amend the Consumer Registration Rule

The NPR also proposed to amend the definition of “durable infant or toddler product” in the consumer registration rule to explicitly include “infant inclined sleep products” to avoid possible confusion about whether an inclined sleep product is considered a durable infant or toddler product. 82 FR at 16969-70. Because the Commission is terminating the NPR for inclined sleep products, the Commission is also terminating the rulemaking to amend 16 C.F.R. part 1130 to include inclined sleep products in the definition of a “durable infant or toddler product.” However, as stated in the NPR, inclined sleep products meet the definition of a “durable infant or toddler product” and continue to be subject to part 1130. 82 FR at 16969.

² <https://www.cpsc.gov/Newsroom/News-Releases/2019/CPSC-ALERT-CPSC-and-Fisher-Price-Warn-Consumers-About-Fisher-Price-Rock-N-Play-Due-to-Reports-of-Death-When-Infants-Roll-Over-in-the-Product>

³ <https://www.cpsc.gov/Recalls/2019/Fisher-Price-Recalls-Rock-n-Play-Sleepers-Due-to-Reports-of-Deaths>

⁴ <https://www.cpsc.gov/Recalls/2019/Kids-II-Recalls-All-Rocking-Sleepers-Due-to-Reports-of-Deaths>

⁵ At the May 2019 ASTM meeting regarding inclined sleep products, ASTM subcommittee members decided to reconsider performance requirements in ASTM F3118-17, and is forming task groups to undertake such review.

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IV. Termination of NPR to Amend Notice of Requirements

The Commission is also terminating the NPR to issue an NOR for the inclined sleep products standard, which proposed to amend 16 CFR part 1112 to include 16 CFR part 1235, the CFR section where the inclined sleep products standard would have been codified, if the standard had become final. 82 FR at 16969.

V. Future Action

Although the Commission is terminating this rulemaking, CPSC staff will continue assessing requirements for inclined sleep products to address hazards presented by this product, independently, as well as working with stakeholders, as appropriate, through the ASTM process. CPSC plans to propose appropriate requirements for inclined sleep products in the future.

Dated: _____

Alberta E. Mills, Secretary
Consumer Product Safety Commission