

of SIDS, recommended that babies always be placed on their backs when put to sleep. As a result of this campaign, Sudden Infant Death Syndrome (SIDS) deaths between 1992 and 2004 in the United States decreased from 5,000 per year to 2,246 per year (based on vital statistics data of the United States). Although there has been a steady decrease in SIDS deaths, staff found there has not been a similar decrease in infant deaths associated with pillows and cushions. Even though the recommendation to place infants to sleep on their backs is being promoted, staff believes that the data indicates that there are still a significant number of people who continue to place infants to sleep in the prone position. For this reason, staff recommends increased information dissemination targeted at the population of caregivers whose infants are not placed to sleep in the supine position. Increased compliance with the recommendation for supine sleep, as well as continued vigilance in ensuring a safe sleeping environment, would have benefits in reducing the risk of infant suffocation deaths caused by adult pillows, sofa cushions, and other pillows as well as further reducing incidents involving SIDS.

In light of the ongoing risks posed by infant cushions/pillows when used in the sleep environment, the Commission found no justification for repealing the ban on infant cushions/pillows at this time. However, nursing pillows perform a related but different function than infant cushions/pillows. The purpose of nursing pillows is to provide a place for the mother to rest her arms while breastfeeding. The nursing pillow may also serve to give moldable but firm support to enhance comfort during extended periods when changing position during breastfeeding is difficult. The main risk of suffocation arises if the nursing pillow enters into the infant sleeping environment because suffocation can occur if children fall asleep on them in the prone position. However, an infant placed to sleep on any pillow or cushion, including a nursing pillow, in the prone position, is at risk for suffocation, regardless of size, type, shape of pillow or filling. Staff's review showed that when used for its intended purpose—nursing—the risk of infant suffocation on nursing pillows, including the Boston Billow Nursing Pillow, is very low. Staff estimates that 900,000 new nursing pillows are sold annually and that nursing pillows were used by approximately 1.8 million mothers in 2004. Exempting the Boston Billow Nursing Pillow would increase consumer choice by allowing consumers

an alternative to the nursing pillows already in the marketplace. Based on the staff's assessment, the Commission preliminarily concludes that an exemption from the ban on infant cushions/pillows should be granted for the Boston Billow Nursing Pillow and substantially similar nursing pillows.¹

D. Regulatory Flexibility Act Certification

Under the Regulatory Flexibility Act (RFA), when an agency issues a proposed rule, it generally must prepare an initial regulatory flexibility analysis describing the impact the proposed rule is expected to have on small entities. 5 U.S.C. 603. The RFA does not require a regulatory flexibility analysis if the head of the agency certifies that the rule will not have a significant effect on a substantial number of small entities.

The proposed exemption gives all companies more flexibility in the choice of material used in manufacturing nursing pillows. The exemption is deregulatory in nature and will not impose any additional costs on businesses of any size. Consequently, the Commission concludes that the proposed amendment exempting the Boston Billow Nursing Pillow and substantially similar nursing pillows would not have a significant impact on a substantial number of small entities.

E. Environmental Considerations

Generally, CPSC rules are considered to "have little or no potential for affecting the human environment," and environmental assessments are not usually prepared for these rules (see 16 CFR 1021.5(c)(1)). Nothing in this proposed rule alters that expectation. Therefore, the Commission does not expect the proposal to have any negative environmental impact.

F. Executive Orders

According to Executive Order 12988 (February 5, 1996), agencies must state in clear language the preemptive effect, if any, of new regulations. The preemptive effect of this proposed regulation is stated in section 18 of the FHSAA. 15 U.S.C. 1261n.

List of Subjects in 16 CFR Part 1500

Consumer protection, Hazardous materials, Hazardous substances,

Imports, Infants and children, Labeling, Law enforcement, and Toys.

G. Conclusion

For the reasons stated above, the Commission proposes to amend title 16 of the Code of Federal Regulations as follows:

PART 1500—HAZARDOUS SUBSTANCES AND ARTICLES: ADMINISTRATION AND ENFORCEMENT REGULATIONS

1. The authority for part 1500 continues to read as follows:

Authority: 15 U.S.C. 1261–1278.

2. Section 1500.86 is amended by adding a new paragraph (a)(9) to read as follows:

§ 1500.86 Exemptions from classification as banned toy or other banned article for use by children.

(a) * * *

(9) Boston Billow Nursing Pillow and substantially similar nursing pillows that may otherwise meet the criteria of the banned infant cushion/pillow at 16 CFR 1500.18(a)(16)(i).

Dated: August 27, 2008.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. E8-20280 Filed 9-2-08; 8:45 am]

BILLING CODE 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1500

Infant Cushions/Pillows; Termination of Rulemaking Other Than With Respect to Boston Billow Nursing Pillow and Substantially Similar Nursing Pillows

AGENCY: Consumer Product Safety Commission.

ACTION: Advance notice of proposed rulemaking; partial withdrawal.

SUMMARY: On September 27, 2006, the Commission issued an advance notice of proposed rulemaking (ANPR) to assess whether a rulemaking was necessary to address any unreasonable risk of injury or death which may be associated with the proliferation of infant cushions/pillows and pillow-like products intended for infants in the marketplace, including the Boston Billow Nursing Pillow. 71 FR 56418. After review of the comments, incident reports and other available information, the Commission has determined there is insufficient data or product information on infant cushions/pillows or pillow-like

¹ On February 1, 2008, Acting Chairman Nancy Nord and Commissioner Thomas Moore voted 2–0 to direct the Office of the General Counsel to prepare a notice of proposed rulemaking proposing an exemption for the Boston Billow Nursing Pillow and substantially similar nursing pillows. Acting Chairman Nord also voted to request ASTM to develop a product warning label for the product class.

products, other than the Boston Billow Nursing Pillow and substantially similar nursing pillows, to proceed with further rulemaking on those products at this time. Based on these findings, the Commission terminates the infant cushion/pillow rulemaking other than with respect to the Boston Billow Nursing Pillow and substantially similar nursing pillows.

DATES: The partial termination of the advance notice of proposed rulemaking that published in the **Federal Register** September 27, 2006 (71 FR 56418) is effective September 3, 2008.

FOR FURTHER INFORMATION CONTACT:
Suad Wanna-Nakamura, Directorate for Health Sciences, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, Maryland 20814; telephone (301) 504-7252; e-mail snakamura@cpsc.gov.

SUPPLEMENTARY INFORMATION:

A. Background

Between 1985 and 1992, there were 35 infant deaths associated with the use of infant cushions/pillows (also known, among other names, as "baby beanbag pillows" and "beanbag cushions"). In almost all of the cases where the infant's position could be determined, the infant was in a prone, face down, position. 55 FR 42202. The Commission initiated a rulemaking proceeding to assess whether a ban was necessary to address an unreasonable risk of injury and death associated with these types of infant cushions/pillows. Due to the number of infant deaths associated with these products, the Commission proposed a rule to ban infant cushions/pillows with certain characteristics. 56 FR 32352. On June 23, 1992, the Commission issued a rule codified at 16 CFR 1500.18(a)(16)(i), banning infant cushions/pillows that: (1) Have a flexible fabric covering; (2) are loosely filled with a granular material, including but not limited to, polystyrene beads or pellets; (3) are easily flattened; (4) are capable of conforming to the body or face of an infant; and (5) are intended or promoted for use by children under one year of age. 57 FR 27912.

On July 17, 2005, Boston Billows, Inc. (Boston Billows) submitted a petition requesting an amendment to 16 CFR 1500.18(a)(16)(i)(A)-(E) to allow an exception to the ban. The petitioner is the manufacturer of the Boston Billow Nursing Pillow, a granularly filled, C-shaped pillow intended for use by mothers when breastfeeding.

B. The ANPR

The Commission issued an ANPR on September 27, 2006, to assess whether a rulemaking was necessary to address any unreasonable risk of injury or death which may be associated with infant cushions/pillows. 71 FR 56418. In addition to the Boston Billow Nursing Pillow, which met the criteria of the ban, there appeared to be a proliferation of other infant cushions/pillows or pillow-like products in the marketplace, including nursing pillows which met some, but not all, of the criteria set forth in the ban. The potential regulatory alternatives noted included whether to: (1) Amend the regulation to allow an exemption to the ban; (2) delete, revise or add criteria to the ban; (3) leave the existing regulation unchanged; or (4) repeal the existing regulation. Nine written comments were received in response to the ANPR in support of Boston Billows' request for exemption from the ban.

C. Incident Data

Commission staff reviewed the incident data on infant cushions and nursing pillows for the period of January 1992 through June 2007. Staff also reviewed additional data from July 2007 through May 2008. Since 1992, there have been no reported deaths associated with infant cushions meeting the definition of a banned infant cushion/pillow. However, staff identified 531 infant deaths associated with pillows and cushions that did not meet the definition of a banned infant cushion/pillow. (From January 1992 through June 2007, there were 484 deaths reported and from July 2007 through May 2008, there were an additional 47 deaths reported.) The vast majority of these incidents involved adult pillows and sofa cushions which possess many of the same characteristics as the banned bean bag cushions. These products have soft covers and flexible filling material that can conform to an infant's face. A variety of pillow types and cushions with different types of filling including foam, feathers, and polyester were involved in the incidents. In this data set, two infant deaths have been associated with a polyester filled nursing pillow (which does not meet the definition of a banned infant cushion/pillow). One incident occurred in 2001 when a 4-month-old infant was placed to sleep on his stomach in a playpen with his head resting on the nursing pillow. The second incident occurred in 2007, when a 46-day-old infant was placed in a prone position inside a crib with his head propped on the nursing pillow.

CPSC staff was also made aware of three additional deaths in 2006 where a nursing pillow was in the infant's sleep environment. The pillows involved with these deaths were polyester filled crescent-shaped nursing pillows not subject to the CPSC's infant cushion ban. The cause of these deaths in all cases was initially determined by the medical examiner to be Sudden Infant Death Syndrome (SIDS)/undetermined. In 2008, the New York Westchester County Child Fatality Review Team examined the case files for these deaths. Further investigation of these incidents, including review of documents and photographs from the New York Westchester County Child Fatality Review Team and investigator interviews reveals that in two of the three deaths, while nursing pillows were in the sleep environment, the deaths were deemed to be caused by SIDS/undetermined and could not be causally connected to nursing pillows. With regard to the third death, the infant was propped to sleep in a prone position on a crescent-shaped nursing pillow. In summary, from 1992 to the present, staff is aware of a total of three cases where infants died from suffocation after being placed to sleep in a prone position with their heads propped on polyester filled crescent-shaped nursing pillows.

Staff's review revealed that in the vast majority of the 531 deaths associated with pillows and cushions, the infants were found in the prone position, lying on top of the pillow/cushion or with the head or neck propped on the pillow/cushion. A quarter of the deaths occurred in infant cribs, bassinets, cradles and playpens, while the rest occurred outside the normal infant sleep areas, such as on adult beds, on sofas, or on the floor. As with the banned infant bean bag cushion, these pillows and cushions can cause death by suffocation/asphyxiation when an infant is placed to sleep face down on them. According to staff, the analysis of the data does not reveal an increased risk due to any specific type of pillow or cushion filling, but rather it is the softness and malleability which are inherent properties of pillows that are the primary risk factors. The comparative risk of suffocation based upon filling is unknown; however, the greatest common risk factor is that infants were found in the prone position, face down, in the majority of the 531 deaths.

Prone sleeping is a high risk factor for infant suffocation on cushions/pillows. The limited physical and developmental capabilities of infants render them susceptible to danger from suffocation

in certain sleeping environments. Physiological abnormalities and delays in the development of vital systems can further hamper an infant's ability to react to a hazardous condition. Infants who are not placed on their backs are especially at risk for suffocation on any type of soft pillow, regardless of the type of filling.

In 1992, the American Academy of Pediatrics, in an effort to reduce the risk of SIDS, recommended that babies always be placed on their backs when put to sleep. As a result of this campaign, Sudden Infant Death Syndrome (SIDS) deaths between 1992 and 2004 in the United States decreased from 5,000 per year to 2,246 per year (based on vital statistics data of the United States). Although there has been a steady decrease in SIDS deaths, staff found there has not been a similar decrease in infant deaths associated with pillows and cushions. Even though the recommendation to place infants to sleep on their backs is being promoted, staff believes that the data indicates that there are still a significant number of people who continue to place infants to sleep in the prone position. For this reason, staff recommends increased information dissemination targeted at the population of caregivers whose infants are not placed to sleep in the supine position. Increased compliance with the recommendation for supine sleep, as well as continued vigilance in ensuring a safe sleeping environment would have benefits in reducing the risk of infant suffocation deaths caused by adult pillows, sofa cushions, and other pillows as well as further reducing incidents involving SIDS.

D. Conclusion

In light of the ongoing risks posed by infant cushions/pillows when used in the sleep environment, the Commission finds no justification for repealing the ban on infant cushions/pillows at this time. Moreover, after review of the comments, incident reports and other available information, the Commission determines there is insufficient data or product information on infant cushions/pillows or pillow-like products intended for infants, other than with respect to the Boston Billow Nursing Pillow and substantially similar nursing pillows, to proceed with further rulemaking on those products at this time. Thus, the Commission is terminating the rulemaking on infant cushions/pillows or pillow-like products, other than with respect to the Boston Billow Nursing Pillow and substantially similar nursing pillows effective upon publication in the **Federal Register** for good cause shown

in accordance with 5 U.S.C. 553(d)(3).¹ A proposed exemption from the ban for the Boston Billow Nursing Pillow and substantially similar nursing pillows appears elsewhere in this **Federal Register**.²

Dated: August 27, 2008.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

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BILLING CODE 6355-01-P

Independence Avenue, SW., Mail Stop 1103, Washington, DC 20250-1103. Comments may also be sent via e-mail to mrcta@fs.fed.us, or via facsimile to Lathrop Smith at (202) 205-1045.

All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at the office of the Director of Forest Management, Third Floor, Southwest Wing, Yates Building, 201 14th Street, SW., Washington, DC. Visitors are encouraged to call ahead to (202) 205-1496 to facilitate entry to the building.

FOR FURTHER INFORMATION CONTACT:

Lathrop Smith, Forest Management staff, at (202) 205-0858, or Richard Fitzgerald, Forest Management staff, at (202) 205-1753.

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339 between 8 a.m. and 8 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION:

Background

Prior to 1980, purchasers of National Forest timber defaulted very few timber sale contracts. Cyclic fluctuations in forest products markets occurred but were of comparatively short duration and limited impact. Forest Service timber sale contract terms were often as long as the cycles making it possible to overlap the market price cycles. Prior to 1980, it also was believed that the long-term projection for forest products prices indicated a continuing trend of price increases. Under those circumstances a purchaser could usually schedule a sale's harvest for a time when the markets were good or were at least good enough that the purchaser would not lose more money operating a sale than would be lost in a default.

Beginning in 1980, the forest products market began a serious and dramatic decline, leaving a large number of purchasers with timber sales bid at prices far higher than the market was bringing. Faced with the likelihood of massive defaults and attendant adverse economic impacts on industry and dependent communities, the government began taking steps to respond to the adverse economic impacts. In 1980, 1981, and 1982, the Chief of the Forest Service granted timber sale contract term extensions based on findings of substantial overriding public interest (48 FR 38862). The intent of these extensions was to provide purchasers additional contract

¹ On February 1, 2008, Acting Chairman Nancy Nord and Commissioner Thomas Moore voted 2-0 to direct the Office of the General Counsel to prepare a notice terminating the rulemaking other than with respect to the Boston Billow Nursing Pillow and substantially similar nursing pillows.

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