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[Proposed Rules]

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CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1500

Infant Cushions/Pillows; Advance Notice of Proposed Rulemaking;  
Request for Comments and Information

AGENCY: Consumer Product Safety Commission.

ACTION: Advance notice of proposed rulemaking.

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SUMMARY: Under the Commission's regulations, any infant cushion/pillow that meets the criteria set forth in the Commission's regulations at 16 CFR 1500.18(a)(16)(i), is currently a banned hazardous substance. In July 2005, the Commission received a petition from Boston Billows, Inc. asking the Commission to amend 16 CFR 1500.18(a)(16)(i)(A)-(E) to provide an exception to the ban when the product is specifically designed, intended and promoted for mothers to use when breastfeeding and requested by a Pediatrician or a Board Certified Lactation Consultant. On July 10, 2006, the Commission voted to grant the petition to the extent it requests the Commission to commence a rulemaking process to evaluate whether the Boston Billow nursing pillow and other infant cushions/pillows or pillow-like products \1\ could result in an amendment to the existing ban. Accordingly, this advance notice of proposed rulemaking (ANPR) initiates a rulemaking proceeding that could result in an amendment to the existing ban on infant cushions/pillows. This proceeding is commenced under the Federal Hazardous Substances Act (FHSA).

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\1\ The term ``infant cushions/pillows or pillow-like products'' used throughout this ANPR means infant cushions/pillows or pillow-like products intended for use by infants less than one year of age, including, but not limited to, nursing pillows, infant beanbag seats or carriers, infant sleep aid pillows or similar products.

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By this notice, the Commission solicits written comments from interested persons concerning, in general, the risk of injury associated with infant cushions/pillows or pillow-like products. The Commission requests written comments on the regulatory alternatives discussed in this notice and other possible ways to address these risks. The Commission also invites interested persons to submit an existing standard, or a statement of intent to modify or develop a voluntary standard, to address the risk of injury identified in the notice.

DATES: Written comments and submissions in response to this notice must be received by November 27, 2006.

ADDRESSES: Comments should be submitted to the Office of the Secretary by e-mail at [cpsc-os@cpsc.gov](mailto:cpsc-os@cpsc.gov), or mailed or delivered, preferably in five copies, to the Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, Maryland 20814. Comments may also be filed by facsimile to (301) 504-0127. Comments should be captioned ``Infant Cushions/Pillows ANPR.''

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](mailto: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''). The Commission initiated a rulemaking proceeding to determine whether a ban was necessary to address the unreasonable risks of injury and deaths associated with these types of infant cushions/pillows. 55 FR 42202. 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 under 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 submitted a petition requesting an

amendment to 16 CFR 1500.18(a)(16)(i)(A)-(E) to allow an exception to the ban when the product is specifically designed, intended and promoted for mothers to use when breastfeeding and requested by a Pediatrician or a Board Certified Lactation Consultant. The petitioner is the manufacturer of the Boston Billow nursing pillow, which is purportedly designed and promoted to aid mothers when breastfeeding.

The Commission published a notice in the Federal Register on October 13, 2005, requesting comments on the petition. 70 FR 59726. The Commission received a total of 5 comments on the petition. The Commission staff reviewed the petition, the comments, and available information and prepared a briefing package for the Commission (available at <http://www.cpsc.gov>). On July 10, 2006, the Commission voted 3-0 to grant the petition to commence an ANPR.

## B. The Product

There has been a proliferation of infant cushions/pillows or pillow-like products in the marketplace in all different shapes and sizes that meet some or all of the criteria set forth in the ban. For example, an infant cushion may have a flexible fabric covering, which conforms to the body or face of an infant, and is used by a child under one year of age, but contains a filling that is made of cotton or polyfill, instead of being filled with a granular material, such as polystyrene beads or pellets. The Commission believes that an examination of these different types of infant cushions/pillows or pillow-like products may now be warranted, given the proliferation of these products in the marketplace and their varying characteristics, including sizes, shapes and uses.

## C. The Risk of Injury

Between 1985 and 1992, there were 35 infant deaths associated with the use of infant cushions/pillows. The Commission is unaware of any deaths or injuries associated with infant cushions/pillows since the ban on infant cushions and pillows went into effect in 1992. At the time of the ban, the recommendation from pediatricians was to place infants to sleep in the prone position (on the

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stomach). In all infant cushion/pillow related deaths where the position could be ascertained, the infant was in the prone position. The prone position was likely a major contributing factor to the suffocation and death of the infant.

Since the ban and following considerable evidence that sleeping in the prone position is a significant risk factor in sudden infant death

syndrome (SIDS) incidents, a nationwide education campaign was launched in the United States recommending that infants be placed on their backs when put to sleep (Back to Sleep campaign). Since the launch of the Back to Sleep campaign there has been a dramatic drop in the number of SIDS incidents in the United States. The guidance provided by the campaign may make it less likely that infants will be placed on their stomachs to sleep, reducing the likelihood of suffocation. The Commission staff continues to believe that infant beanbag cushions, and similar infant cushions/pillows (including the Boston Billow nursing pillow) pose suffocation risks to infants if infants are placed in the prone position on them for sleeping. The same risk is not likely to be posed when infants are placed in the supine position. Accordingly, the Commission believes that the current regulation should be reexamined to evaluate the likely use patterns of these products, and any associated risk of injury.

#### D. Relevant Statutory Provisions

The petition was docketed under the FHSA, 15 U.S.C. 1261 et seq. Section 2(f)(1)(D) of the FHSA defines ``hazardous substance'' to include any toy or other article intended for use by children that the Commission determines, by regulation, presents an electrical, mechanical, or thermal hazard. 15 U.S.C. 1261(f)(1)(D). An article may present a mechanical hazard if ``in normal use or when subjected to reasonably foreseeable damage or abuse, its design or manufacture presents an unreasonable risk of personal injury or illness.'' 15 U.S.C. 1261(s).

Under section 2(q)(1)(A) of the FHSA, a toy, or other article intended for use by children, which is or contains a hazardous substance accessible by a child is a ``banned hazardous substance.'' 15 U.S.C. 1261(q)(1)(A). Currently, the Commission bans any article known as an infant cushion or infant pillow which contains a flexible fabric covering, is loosely filled with granular material (including but not limited to, polystyrene beads or pellets), is easily flattened, is capable of conforming to the body or face of an infant and is intended or promoted for use by children under one year of age. 16 CFR 1500.18(a)(16)(i).

Section 3(f) through 3(i) of the FHSA, 15 U.S.C. 1262(f)-(i), governs a proceeding to promulgate a regulation determining that a toy or other children's article presents an electrical, mechanical, or thermal hazard. As provided in section 3(f), this proceeding is commenced by issuance of this ANPR. After considering any comments submitted in response to this ANPR, the Commission will decide whether to issue a proposed rule and a preliminary regulatory analysis in accordance with section 3(h) of the FHSA. If a proposed rule is issued, the Commission would then consider the comments received in response to

the proposed rule in deciding whether to issue a final rule and a final regulatory analysis. 15 U.S.C. 1262(i).

#### E. Regulatory Alternatives

One or more of the following alternatives could be used to address the issues identified with infant cushions/ pillows and pillow-like products.

1. Amend regulation to allow exemption for certain infant cushions/ pillows and pillow-like products. The Commission could issue a rule amending the existing ban to exempt certain infant cushions/pillows and pillow-like products, such as the Boston Billows product, which currently fall within the scope of the ban, if the Commission finds that such products do not present an unreasonable risk of injury. If an exemption is granted, the Commission could still consider a labeling requirement if it found that such warnings were necessary to adequately protect children from hazards associated with infant cushions/pillows and pillow-like products.

2. Amend regulation to delete, revise or add criteria to the ban. The Commission could issue a rule amending the existing ban by deleting, revising or adding criteria, as the Commission found necessary to adequately address any risk of injury associated with infant cushions/pillows and pillow-like products used for sleeping. Thus, the Commission could either expand or narrow the ban to treat products of similar risk consistently.

3. Leave existing regulation unchanged. The Commission could leave the existing ban on infant cushions/pillows unchanged if the Commission finds that the existing banning criteria adequately address the risk of injury associated with infant cushions/pillows and pillow-like products.

4. Repeal existing regulation. The Commission could repeal the existing ban on infant cushions/pillows if the Commission finds that the currently banned infant cushions/pillows and pillow-like products no longer present an unreasonable risk of injury. If the existing regulation is repealed, the Commission has authority under section 15 of the FHSA, 15 U.S.C. 1274, to pursue corrective actions on a case-by-case basis. In addition, if the ban is repealed, the Commission could still consider a labeling requirement if it found that such warnings were necessary to adequately protect children from hazards associated with infant cushions/pillows and pillow-like products.

#### F. Solicitation of Information and Comments

This ANPR is the first step in a proceeding which could result in an amendment of the current ban on infant cushions/pillows. All interested persons are invited to submit to the Commission their comments on any aspect of the alternatives discussed above. In

particular, the Commission solicits the following additional information on infant cushions/pillows or pillow-like products intended for use by infants less than one year of age, including, but not limited to, nursing pillows, infant beanbag seats or carriers, infant wedges, infant sleep aid pillows, or similar products:

1. The models and model numbers of infant cushions/pillows and pillow-like products and the annual sales figures for each model from the time such product was made available in the marketplace;
2. The names and addresses of manufacturers and distributors who make and sell infant cushions/pillows and pillow-like products;
3. Information on any children believed to have been injured or killed as a result of infant cushions/pillows and pillow-like products;
4. The circumstances under which these injuries and deaths occur, including the ages of the victims;
5. The current regulation lists five criteria that define a banned infant cushion/pillow. Should any of these criteria be revised? Should any of these criteria be deleted? Are there criteria not in the current ban that should be added?
6. Whether the risk of injuries and deaths could be reasonably reduced by (a) Limiting sale of infant cushions/pillows to certain healthcare products firms or medical professionals, (b) restricting a consumer's purchase of an infant cushion/pillow to consumers with a medical professional's written recommendation or prescription, and (c)

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whether any such point-of-sale restriction would be practical or effective;

7. Other information on the potential costs and benefits of the regulatory options;
8. The likelihood and nature of any significant economic impact of a rule on small entities;
9. The basis for, and costs and benefits of, mandating a labeling or instructions requirement.

Also, in accordance with section 3(f) of the FHSA, the Commission requests:

- (1) Written comments with respect to the risk of injury identified by the Commission, the regulatory alternatives being considered, and other possible alternatives for addressing the risk;
- (2) Any existing standard or portion of a standard which could be issued as a proposed regulation;
- (3) A statement of intention to modify or develop a voluntary standard to address the risk of injury discussed in this notice, along with a description of a plan to do so.

Comments and other submissions should be captioned ``Infant Cushions/Pillows ANPR'' and e-mailed to [cpssc-os@cpssc.gov](mailto:cpssc-os@cpssc.gov) or mailed or

delivered, preferably in five copies, to the Office of the Secretary at Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, Maryland 20814. Comments and other submissions may also be filed by facsimile to (301) 504-0127. All comments and other submissions must be received by November 27, 2006.

Dated: September 21, 2006.

Todd A. Stevenson,  
Secretary, Consumer Product Safety Commission.  
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