

**List of Subjects in 16 CFR Part 1303**

Consumer protection, Hazardous substances, Infants and children, Labeling, Lead poisoning.

■ Accordingly, 16 CFR part 1303 is amended as follows:

**PART 1303—BAN LEAD-CONTAINING PAINT AND CERTAIN CONSUMER PRODUCTS BEARING LEAD-CONTAINING PAINT**

■ 1. The authority citation for part 1303 is revised to read as follows:

**Authority:** Secs. 8, 9, 86 Stat. 1215–1217, as amended 90 Stat. 506, 122 Stat. 3016, (15 U.S.C. 2057, 2058), Sec. 101, 122 Stat. 3016.

■ 2. Amend § 1303.1 by revising paragraphs (a) introductory text and (c) and adding paragraph (d) to read as follows:

**§ 1303.1 Scope and application.**

(a) In this part 1303, the Consumer Product Safety Commission declares that paint and similar surface-coating materials for consumer use that contain lead or lead compounds and in which the lead content (calculated as lead metal) is in excess of 0.06 percent (0.06 percent is reduced to 0.009 percent effective August 14, 2009 as mandated by Congress in section 101(f) of the Consumer Product Safety Improvement Act of 2008, Pub. L. 110–314) of the weight of the total nonvolatile content of the paint or the weight of the dried paint film (which paint and similar surface-coating materials are referred to hereafter as “lead-containing paint”) are banned hazardous products under sections 8 and 9 of the Consumer Product Safety Act (CPSA), 15 U.S.C. 2057, 2058. The following consumer products are also declared to be banned hazardous products:

\* \* \* \* \*

(c) The Commission has issued the ban because it has found that there is an unreasonable risk of lead poisoning in children associated with lead content of over 0.06 percent in paints and coatings to which children have access and that no feasible consumer product safety standard under the CPSA would adequately protect the public from this risk. The 0.06 percent is reduced to 0.009 percent effective August 14, 2009 as mandated by Congress in section 101(f) of the Consumer Product Safety Improvement Act of 2008, Public Law 110–314.

(d) Any ban or rule promulgated under 16 CFR 1303.1 shall be considered a regulation of the Commission promulgated under or for the enforcement of section 2(q) of the

Federal Hazardous Substances Act (15 U.S.C. 1261(q)).

■ 3. Amend § 1303.2 by revising paragraph (b)(2) to read as follows:

**§ 1303.2 Definitions.**

\* \* \* \* \*

(b) \* \* \*

(2) *Lead-containing paint* means paint or other similar surface coating materials containing lead or lead compounds and in which the lead content (calculated as lead metal) is in excess of 0.06 percent (0.06 percent is reduced to 0.009 percent effective August 14, 2009) by weight of the total nonvolatile content of the paint or the weight of the dried paint film.

\* \* \* \* \*

Dated: December 15, 2008.

**Todd A. Stevenson,**

*Secretary, Consumer Product Safety Commission.*

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**BILLING CODE 6355–01–P**

**CONSUMER PRODUCT SAFETY COMMISSION****16 CFR Part 1500****Exemption From Classification as Banned Hazardous Substance; Exemption for Boston Billow Nursing Pillow and Substantially Similar Nursing Pillows**

**AGENCY:** Consumer Product Safety Commission.

**ACTION:** Final rule.

**SUMMARY:** The Commission is issuing a rule to exempt the Boston Billow Nursing Pillow and substantially similar nursing pillows from the Commission’s regulations banning infant cushions/pillows set forth in the Commission’s regulations at 16 CFR 1500.18(a)(16)(i).

**DATES:** The rule becomes effective on December 19, 2008.

**FOR FURTHER INFORMATION CONTACT:**

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**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 determine 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.

**B. Petition**

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.

**C. The ANPR**

The Commission issued an advance notice of proposed rulemaking (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. After review of the comments, incident reports and other available information, the Commission determined there was insufficient data or product information on infant cushions or pillow-like products, other than the Boston Billow Nursing Pillow, to proceed with further rulemaking on those products at this time. Accordingly, the Commission issued a notice in the **Federal Register** on September 3, 2008, terminating the rulemaking on infant cushions/pillows or pillow-like products intended for use by infants, other than with respect to the Boston Billow Nursing Pillow and substantially similar nursing pillows. 73 FR 51386.

#### D. The Proposed Exemption

The ban on infant cushions/pillows was promulgated pursuant to the Federal Hazardous Substances Act (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 which 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 its design or manufacture presents an unreasonable risk of personal injury or illness during normal use or when subjected to reasonably foreseeable damage or abuse. 15 U.S.C. 1261(s). To grant Boston Billows’ request for an exemption, the Commission must find that the Boston Billow Nursing Pillow does not present an unreasonable risk of injury from the mechanical hazard that the banning rule was intended to prevent.

The Commission preliminarily found that based on the incident data on infant cushions and nursing pillows for the period of January 1992 through May 2008, there have been no reported deaths associated with infant cushions meeting the definition of a banned infant cushion/pillow since 1992. However, there were 531 infant deaths associated with pillows and cushions that did not meet the definition of a banned infant cushion/pillow. The majority of these incidents involved adult pillows and sofa cushions which possessed 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.

The Commission also preliminarily found 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. The Commission preliminarily determined that the analysis of the data does not reveal an increased risk due to any specific type

of pillow or cushion filling, but rather it was the softness and malleability which are inherent properties of pillows that are the primary risk factors. Although the comparative risk of suffocation based upon filling was unknown, the greatest common risk factor was that infants were found in the prone position, face down, in the majority of the 531 deaths.

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. The Commission’s preliminary 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. Accordingly, based on the staff’s assessment, the Commission issued a notice of proposed rulemaking (NPR) proposing an exemption for the Boston Billow Nursing Pillow and substantially similar nursing pillows that would otherwise be banned under the Commission’s regulations banning infant cushions/pillows. 73 FR 51384.

#### E. Comments on the NPR

Seven comments were received on the NPR from board certified lactation consultants, all in support of an exemption of the Boston Billow Nursing Pillow. According to the commenters, the unique design and flexibility of the Boston Billow Nursing Pillow provides for better positioning and comfort of breastfeeding mothers, particularly mothers who have delivered by Caesarean section, had post-delivery surgery, or were nursing premature infants.

#### F. The Final Rule

Based on the staff’s assessment, the incident data, and the comments, the

Commission 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. A substantially similar nursing pillow is a pillow designed to be used only as a nursing aide for breastfeeding mothers. For example, one that is tubular in form, C- or crescent-shaped to fit around a nursing mother’s waist, round in circumference and filled with granular material. An estimated 900,000 new nursing pillows are sold annually and nursing pillows are used by approximately 1.8 million mothers. Exempting the Boston Billow Nursing Pillow would increase consumer choice by allowing consumers an alternative to the nursing pillows already in the marketplace.

However, the Commission continues to emphasize that 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 Sudden Infant Death Syndrome (SIDS), recommended that babies always be placed on their backs when put to sleep. As a result of this campaign, 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, the Commission has found that 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, the Commission 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, the Commission intends to increase its dissemination of information 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.

#### G. Effective Date

This rule exempts the Boston Billow Nursing Pillow and substantially similar nursing pillows that would otherwise be banned under the FHSA. Because the rule grants an exemption, it is not subject to the requirement under the Administrative Procedure Act (APA) that a rule must be published 30 days before it takes effect. 5 U.S.C. 553(d)(1). The rule lifts an existing restriction and allows a product not previously permitted. Thus, the Commission believes it is appropriate for the rule to become effective upon publication in the **Federal Register**.

#### H. Impact on Small Businesses

The NPR discussed the Commission assessment of the impact that a rule to exempt the Boston Billow Nursing Pillow and similar nursing pillows might have on small businesses. There are approximately 15 firms that either manufacture or import nursing pillows. Most, if not all, firms are considered to be small businesses. Because the exemption is deregulatory in nature and will not increase production costs on businesses, 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.

#### I. Environmental Considerations

The National Environmental Policy Act and the Council on Environmental Quality Act regulations, and CPSC procedures for environmental review require the Commission to assess the possible environmental effects associated with the proposed exemption. As discussed in the NPR, a proposed exemption for nursing pillows is expected to have little or no potential for affecting the human environment, and is considered to fall within the "categorical exclusions" under the CPSC regulations that cover its environmental review procedures (see 16 CFR 1021.5(c)(1)). The Commission concludes that the rule would have no adverse effect on the environment and thus, no environmental assessment or environmental impact statement is required in this proceeding.

#### J. 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 exemption is stated in section 18 of the FHSA. 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.

#### K. Conclusion

■ For the reasons stated above, the Commission amends 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. Amend section 1500.18 by revising paragraph (a)(16)(i) introductory text to read as follows:

#### § 1500.18 Banned toys and other banned articles intended for use by children.

\* \* \* \* \*

(a) \* \* \*

(16) \* \* \*

(i) Any article known as an "infant cushion" or "infant pillow," and any other similar article, which has all of the following characteristics (But see § 1500.86(a)(9)):

\* \* \* \* \*

■ 3. 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 are designed to be used only as a nursing aide for breastfeeding mothers. For example, are tubular in form, C- or crescent-shaped to fit around a nursing mother's waist, round in circumference and filled with granular material.

Dated: December 15, 2008.

**Todd A. Stevenson,**

*Secretary, Consumer Product Safety Commission.*

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## DEPARTMENT OF TRANSPORTATION

### Federal Highway Administration

#### 23 CFR Parts 620, 635, 636, and 710

[FHWA Docket No. FHWA–2008–0136]

RIN 2125–AF29

#### Fair Market Value and Design-Build Amendments

**AGENCY:** Federal Highway Administration (FHWA), DOT.

**ACTION:** Final rule.

**SUMMARY:** The FHWA is revising its regulations to require State departments of transportation (DOT) and other public authorities to obtain fair market value as part of any concession agreement involving a facility acquired or constructed with Federal-aid highway funds. Additionally, the FHWA is revising its regulations to permit public agencies to compete against private entities for the right to obtain a concession agreement involving such facilities. Also, the FHWA is revising its design-build regulations to permit contracting agencies to incorporate unsuccessful offerors' ideas into a design-build contract upon the acceptance of a stipend.

**DATES:** *Effective Dates:* This rule is effective January 18, 2009.

**FOR FURTHER INFORMATION CONTACT:** Mr. Marcus J. Lemon, Chief Counsel, Mr. Michael Harkins, Office of Chief Counsel, or Mr. Steve Rochlis, Office of Chief Counsel, (202) 366–0740, Federal Highway Administration, 1200 New Jersey Avenue, SE., Washington, DC 20590. Office hours are from 7:45 a.m. to 4:15 p.m., *e.t.*, Monday through Friday, except Federal holidays.

#### SUPPLEMENTARY INFORMATION:

##### Electronic Access and Filing

Internet users may access this document, the notice of proposed rulemaking (NPRM), and all comments received by the U.S. DOT by visiting <http://www.regulations.gov>. It is available 24 hours each day, 365 days each year. Electronic submission and retrieval help and guidelines are available under the help section of the Web site.

An electronic copy of this document may also be downloaded by accessing the Office of the Federal Register's home page at: <http://www.archives.gov> or the Government Printing Office's Web page at <http://www.gpoaccess.gov/nara>.

#### I. Background

In recent years, some State and local governments have entered into