

candlewick(s) is/are shipped to a retailer.

(iii) *Findings*—(A) *General*. To issue a rule under section 2(q)(1) of the FHSA, 15 U.S.C. 1261(q)(1), classifying a substance or article as a banned hazardous substance, the Commission must make certain findings and include them in the regulation. These findings are discussed in paragraphs (a)(13)(iii)(B) through (D) of this section.

(B) *Voluntary Standard*. One alternative to the ban that the Commission considered is to take no mandatory action, and to depend on a voluntary standard. One organization has a standard for candlewicks intended to address the potential for substantial illness posed by such wicks and candles with such wicks. The Commission has found that the standard is technically unsound and that substantial compliance with it is unlikely. Furthermore, there is no evidence that the standard has been adopted and implemented by candlewick or candle manufacturers.

(C) *Relationship of Benefits to Costs*. The Commission estimates that the ban will reduce the potential for exposure to lead and resulting lead poisoning because there is no “safe” level of lead in the blood. The annual cost to the candle/wick industry of the ban is estimated by the Commission to be in the range of \$100,000 to \$300,000. On a percentage basis these costs represent only 0.005 to 0.015 percent of the overall value of candle shipments in 2000, which was approximately \$2 billion. Accordingly, the Commission finds that the benefits from the regulation bear a reasonable relationship to its costs.

(D) *Least burdensome requirement*. The Commission considered the following alternatives: no action; labeling all metal-cored candles with wicks containing more than 0.06 percent lead by weight of the metal; recordkeeping for shipments of wicks containing 0.06 percent or less lead by weight of the metal and of candles with such wicks; and relying on the voluntary standard. Neither no action, nor labeling, nor reliance on the voluntary standard would adequately reduce the risk of illness. Recordkeeping for shipments of wicks and of candles was not the least burdensome requirement that would pre-

vent or adequately reduce the risk of illness. Therefore the Commission finds that a ban on candlewicks containing more than 0.06 percent lead by weight of the metal and candles with such wicks is the least burdensome requirement that would prevent or adequately reduce the risk of illness.

(b) [Reserved]

(Secs. 2(f)(1), (A), (B), (g), (q)(1)(B), 3(a), 74 Stat. 372, 374, as amended 80 Stat. 1304-05, 83 Stat. 187-189, 90 Stat. 503 (15 U.S.C. 1261, 1262); sec. 701 (e), (f), (g), 52 Stat. 1055-56, as amended 70 Stat. 919, 72 Stat. 948 (21 U.S.C. 371 (e), (f), (g)), sec. 30(a), 86 Stat. 1231 (15 U.S.C. 2079(a)))

[38 FR 27012, Sept. 27, 1973, as amended at 38 FR 27514, Oct. 4, 1973; 38 FR 31520, Nov. 15, 1973; 39 FR 30114, Aug. 21, 1974; 39 FR 42903, Dec. 9, 1974; 41 FR 22935, June 8, 1976; 42 FR 44202, Sept. 1, 1977; 43 FR 12310, Mar. 24, 1978; 48 FR 16, Jan. 3, 1983; 56 FR 37837, Aug. 9, 1991; 61 FR 13095, Mar. 26, 1996; 61 FR 18245, Apr. 25, 1996; 68 FR 19147, Apr. 18, 2003]

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

(a) *Toys and other articles presenting mechanical hazards*. Under the authority of sections 2(f)(1)(D) and 24 of the act and pursuant to the provisions of section 3(e) of the act, the Commission has determined that the following types of toys or other articles intended for use by children present a mechanical hazard within the meaning of section 2(s) of the act because in normal use, or when subjected to reasonably foreseeable damage or abuse, the design or manufacture presents an unreasonable risk of personal injury or illness:

(1) Any toy rattle containing, either internally or externally, rigid wires, sharp protrusions, or loose small objects that have the potential for causing lacerations, puncture wound injury, aspiration, ingestion, or other injury. (But see § 1500.86(a)(1)).

(2) Any toy having noisemaking components or attachments capable of being dislodged by the operating features of the toy or capable of being deliberately removed by a child, which toy has the potential for causing laceration, puncture wound injury, aspiration, ingestion, or other injury.

(3) Any doll, stuffed animal, or other similar toy having internal or external

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components that have the potential for causing laceration, puncture wound injury, or other similar injury. (But see §1500.86(a)(2)); (See also §§1500.48 and 1500.49).

(4) Lawn darts and other similar sharp-pointed toys usually intended for outdoor use and having the potential for causing puncture wound injury.

(5) Caps (paper or plastic) intended for use with toy guns and toy guns not intended for use with caps if such caps when so used or such toy guns produce impulse-type sound at a peak pressure level at or above 138 decibels, referred to 0.0002 dyne per square centimeter, when measured in an anechoic chamber at a distance of 25 centimeters (or the distance at which the sound source ordinarily would be from the ear of the child using it if such distance is less than 25 centimeters) in any direction from the source of the sound. This paragraph is an interim regulation pending further investigation to determine whether prevention of damage to the hearing of children requires revision hereof.

(6) Any article known as a “baby-bouncer,” “walker-jumper,” or “baby-walker” and any other similar article (referred to in this paragraph as “article(s)”) which is intended to support very young children while sitting walking, bouncing, jumping, and/or reclining, and which because of its design has any exposed parts capable of causing amputation, crushing, lacerations, fractures, hematomas, bruises, or other injuries to fingers, toes, or other parts of the anatomy of young children. Included among, but not limited to, the design features of such articles which classify the articles as banned hazardous substances are:

(i) The areas about the point on each side of the article where the frame components are joined together to form an “X” shape capable of producing a scissoring, shearing, or pinching effect.

(ii) Other areas where two or more parts are joined in such a manner as to permit a rotational movement capable of exerting a scissoring, shearing, or pinching effect.

(iii) Exposed coil springs which may expand sufficiently to allow an infant’s finger, toe, or any other part of the

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anatomy to be inserted, in whole or in part, and injured by being caught between the coils of the spring or between the spring and another part of the article.

(iv) Holes in plates or tubes which provide the possibility of insertion, in whole or in part, of a finger, toe, or any part of the anatomy that could then be injured by the movement of another part of the article.

(v) Design and construction that permits accidental collapse while in use. (But see §1500.86(a)(4)).

(7) Toys usually known as clacker balls and consisting of two balls of plastic or another material connected by a length of line or cord or similar connector (referred to as “cord” in §1500.86(a)(5)), intended to be operated in a rhythmic manner by an upward and downward motion of the hand so that the two balls will meet forcefully at the top and bottom of two semicircles thus causing a “clacking” sound, which toys present a mechanical hazard because their design or manufacture presents an unreasonable risk of personal injury from fracture, fragmentations, or disassembly of the toy and from propulsion of the toy or its part(s). (But see §1500.86(a)(5).) This does not include products that are constructed so that the connecting members consist of plastic rods integrally molded to the balls and are mounted on a pivot so that movement of the balls is essentially limited to a single plane.

(8) Any pacifier that does not meet the requirements of 16 CFR part 1511 and that is introduced into interstate commerce after February 26, 1978.

(9) Any toy or other article intended for use by children under 3 years of age which presents a choking, aspiration, or ingestion hazard because of small parts as determined by part 1501 of this chapter and which is introduced into interstate commerce after January 1, 1980. For purposes of this regulation, introduction into interstate commerce is defined as follows: A toy or children’s article manufactured outside the United States is introduced into interstate commerce when it is first brought within a U.S. port of entry. A toy or children’s article manufactured in the United States is introduced into interstate commerce (1) at the time of

its first interstate sale, or (2) at the time of its first intrastate sale if one or more of its components and/or raw materials were received interstate, whichever occurs earlier. Part 1501 defines the term “toy or other article intended for use by children under 3,” as used in this regulation, and exempts certain products from banning under this regulation.

(10)–(11) [Reserved]

(12) Any bicycle as defined in §1512.2(a) of this chapter (except a bicycle that is a “track bicycle” or a “one-of-a-kind bicycle” as defined in §1512.2(d) and (e) of this chapter) that is introduced into interstate commerce on or after May 11, 1976, and that does not comply with the requirements of part 1512 of this chapter, except for §§1512.5(c)(3), 1512.9(a), 1512.18(e) and 1512.18(f) which become effective November 13, 1976.

(13) Any full-size baby crib (as defined in §1508.1(a) of this chapter) that is introduced into interstate commerce on or after February 1, 1974, and that does not comply with the requirements of §§1508.2 through 1508.10 of this chapter; and any full size baby crib (as defined in §1508.1(a) of this chapter) that is manufactured on or after April 27, 1983, and that does not comply with §§1508.2 through 1508.11 of this chapter.

(14) Any non-full-size baby crib (as defined in §1509.2 of this chapter) that is introduced into interstate commerce after August 9, 1976, and that does not comply with the requirements of §§1509.3 through 1509.12 of this chapter; and any non-full size baby crib (as defined in §1509.2 of this chapter) that is manufactured on or after April 27, 1983, and that does not comply with §§1509.3 through 1509.13 of this chapter.

(15) Any rattle (as defined in §1510.2 of this chapter) that is introduced into interstate commerce on or after August 21, 1978, and that does not comply with the requirements of part 1510 of this chapter. For purposes of the regulation, introduction into interstate commerce is defined as follows: A rattle manufactured outside the United States is introduced into interstate commerce when it is first brought within a U.S. port of entry. A rattle manufactured in the United States is introduced into interstate commerce

(a) at the time of its first interstate sale, or (b) at the time of its first intrastate sale if one or more of its components and/or raw materials were received interstate.

(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)):

(A) Has a flexible fabric covering. The term *fabric* includes those materials covered by the definition of “fabric” in section 2(f) of the Flammable Fabrics Act, 15 U.S.C. 1191(f).

(B) Is loosely filled with a granular material, including but not limited to, polystyrene beads or pellets.

(C) Is easily flattened.

(D) Is capable of conforming to the body or face of an infant.

(E) Is intended or promoted for use by children under one year of age.

(ii) *Findings*—(A) *General*. In order to issue a rule under section 2(q)(1) of the Federal Hazardous Substance Act (FHSA), 15 U.S.C. 1261(q)(1), classifying a substance or article as a banned hazardous substance, the FHSA requires the Commission to make certain findings and to include these findings in the regulation. These findings are discussed in paragraphs (a)(16)(ii) (B) through (D) of this section.

(B) *Voluntary standard*. No findings concerning compliance with or adequacy of a voluntary standard are necessary since no voluntary standard addressing infant cushions has been adopted or implemented.

(C) *Relationship of benefits to costs*. The Commission estimates that the removal of infant cushions from the market will result in total annual benefits of approximately five million dollars. The potential costs to businesses are expected to be offset by production of other products, and the potential costs to consumers are likely to be offset by the availability of substitutes for a comparable price.

(D) *Least burdensome requirement*. The Commission considered labeling and a design or performance standard as alternatives to the ban. The Commission does not believe that any form of labeling would have a significant effect in preventing the hazard associated with infant cushions. The Commission also

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concluded that no feasible standard exists that would address the hazard. Thus, the Commission determined that a ban of infant cushions is the least burdensome alternative that would prevent or adequately reduce the risk of injury.

(17) Any ball intended for children under three years of age that, under the influence of its own weight, passes, in any orientation, entirely through a circular hole with a diameter of 1.75 inches (44.4 mm.) in a rigid template $\frac{1}{4}$ inches (6 mm.) thick. In testing to evaluate compliance with this paragraph, the diameter of opening in the Commission's test template shall be no greater than 1.75 inches (44.4 mm.).

(i) For the purposes of this paragraph, the term "ball" includes any spherical, ovoid, or ellipsoidal object that is designed or intended to be thrown, hit, kicked, rolled, dropped, or bounced. The term "ball" includes any spherical, ovoid, or ellipsoidal object that is attached to a toy or article by means of a string, elastic cord, or similar tether. The term "ball" also includes any multi-sided object formed by connecting planes into a generally spherical, ovoid, or ellipsoidal shape that is designated or intended to be used as a ball, and any novelty item of a generally spherical, ovoid, or ellipsoidal shape that is designated or intended to be used as a ball.

(ii) The term "ball" does not include dice, or balls permanently enclosed inside pinball machines, mazes, or similar outer containers. A ball is permanently enclosed if, when tested in accordance with 16 CFR 1500.52, the ball is not removed from the outer container.

(iii) In determining whether such a ball is intended for use by children under three years of age, the criteria specified in 16 CFR 1501.2(b) and the enforcement procedure established by 16 CFR 1501.5 shall apply.

(18)(i) Any bunk bed (as defined in §1513.2(c) of this chapter) that does not comply with the requirements of part 1513 of this chapter.

(ii) *Findings.* In order to issue a rule under Section 3(e) of the Federal Hazardous Substances Act (FHSA), 15 U.S.C. 1262(e), classifying a toy or other article intended for use by chil-

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dren as a hazardous substance on the basis that it presents a mechanical hazard (as defined in Section 2(s) of the FHSA), the FHSA requires the Commission to make the following findings and to include these findings in the regulation: Bunk beds present a mechanical hazard; Where a voluntary standard has been adopted and implemented by the affected industry, that compliance with such voluntary standard is not likely to result in the elimination or adequate reduction of the risk of injury, or it is unlikely that there will be substantial compliance with such voluntary standard; The benefits expected from the rule bear a reasonable relationship to its costs; and The rule imposes the least burdensome requirement that prevents or adequately reduces the risk of injury for which the rule is being promulgated. These findings are made in the appendix to Part 1513.

(19)(i) Dive sticks, and other similar articles, that are used in swimming pools or other water environments for such activities as underwater retrieval games or swimming instruction, and which, when placed in the water, submerge and rest at the bottom of the pool. This includes products that are pre-weighted to sink to the bottom and products that are designed to allow the user to adjust the weight. Dive sticks and similar articles that come to rest underwater at an angle greater than 45 degrees from vertical when measured under the test at §1500.86(a)(7) and dive sticks and similar articles that maintain a compressive force of less than 5-lbf under the test at §1500.86(a)(8) are exempt from this banning rule. Articles that have a continuous circular shape, such as dive rings and dive disks are also exempt.

(ii)(A) *Findings.* In order for the Commission to issue a rule under section 2(q)(1) of the FHSA classifying a substance or article as a banned hazardous substance, the Commission must make certain findings and include these findings in the regulation. 15 U.S.C. 1262(i)(2). These findings are discussed in paragraphs (a)(18)(ii)(B) through (D) of this section.

(B) *Voluntary standard.* No findings concerning compliance with and adequacy of a voluntary standard are necessary because no relevant voluntary standard addressing the risk of injury posed by dive sticks has been adopted and implemented.

(C) *Relationship of benefits to costs.* The Commission estimates the potential benefits of removing hazardous dive sticks from the market to be 2 to 4 cents per dive stick. With the availability of substitutes and the expected low cost of modifying dive sticks to conform to the rule, the Commission anticipates that necessary changes will be minimal. The Commission estimates that the costs of the rule will be no more than 2 to 4 cents per dive stick. Thus, the Commission finds that there is a reasonable relationship between the expected benefits of the rule and its costs.

(D) *Least burdensome requirement.* The Commission considered pursuing voluntary recalls, following a voluntary standard, requiring labeling or changing the scope of the rule. A banning rule would be more effective than case-by-case recalls because the impalement hazard affects all dive sticks, not a specific brand or model. Awaiting recalls would allow these hazardous items on the market until the Commission obtained recalls. No applicable voluntary standard exists, and compliance may be low if one did. Although labeling could help reduce the risk of injuries from dive sticks, it would be less effective than a banning rule. It may be difficult for a label to convey the necessary information at the time of use. Modifying the scope so that the rule would only apply to pre-weighted dive sticks would continue to permit hazardous items because the unweighted dive sticks can easily be weighted to stand vertically at the bottom of the water. Thus, the Commission finds that a ban of dive sticks with the hazardous characteristics it has identified is the least burdensome alternative that would adequately reduce the risk of injury.

(b) *Electrically operated toys and other electrical operated children's articles presenting electrical, thermal, and/or certain mechanical hazards.* Under the authority of section 2(f)(1)(D) of the act and

pursuant to provisions of section 3(e) of the act, the Commission has determined that the following types of electrically operated toys or other electrically operated articles intended for use by children present electrical, thermal, and/or certain mechanical hazards within the meaning of section 2 (r), (s), and/or (t) of the act because in normal use or when subjected to reasonably foreseeable damage or abuse, the design or manufacture may cause personal injury or illness by electric shock and/or presents an unreasonable risk of personal injury or illness because of heat as from heated parts, substances, or surfaces, or because of certain mechanical hazards.

(1) Any electrically operated toy or other electrically operated article intended for use by children (as defined in §1505.1(a)(1)) that is introduced into interstate commerce and which does not comply with the requirements of part 1505 of this chapter.

NOTE: Paragraph (b)(1) was originally promulgated as 21 CFR 191.9a(b)(1) with an effective date of September 3, 1973 (38 FR 6138).

(2) [Reserved]

(c) *Toys and other articles (not electrically operated) presenting electric hazards.* Under the authority of section 2(f)(1)(D) of the act and pursuant to provisions of section 3(e) of the act, the Commission has determined that the following types of toys or other articles intended for use by children (not electrically operated) present an electrical hazard within the meaning of section 2(r) of the act.

(1) Any kite 10 inches or greater in any dimension constructed of aluminized polyester film or any kite having a tail or other component consisting of a piece of aluminized polyester film 10 inches or greater in any dimension presents an electrical hazard and is a banned hazardous substance because its design (specifically its size and electrical conductivity) presents a risk of personal injury from electric shock due to its ability to conduct electricity and to become entangled in or otherwise contact high voltage electric power lines.

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(2) [Reserved]

(15 U.S.C. 1261 (f)(1)(D), (g)(1)(A), (r); 15 U.S.C. 1262(e)(1); 15 U.S.C. 2079(a))

[38 FR 27012, Sept. 27, 1973, as amended at 38 FR 30105, Nov. 1, 1973; 38 FR 32132, Nov. 21, 1973; 41 FR 4144, Jan. 28, 1976; 41 FR 6240, Feb. 12, 1976; 42 FR 36823, July 18, 1977; 42 FR 61594, Dec. 6, 1977; 43 FR 22005, May 23, 1978; 44 FR 34903, June 15, 1979; 44 FR 55819, Sept. 28, 1979; 48 FR 16, Jan. 3, 1983; 48 FR 57268, Dec. 29, 1983; 53 FR 46839, Nov. 18, 1988; 57 FR 27915, June 23, 1992; 59 FR 9076, Feb. 25, 1994; 60 FR 10752, Feb. 27, 1995; 64 FR 71907, Dec. 22, 1999; 66 FR 13650, Mar. 7, 2001; 73 FR 77495, Dec. 19, 2008]

§ 1500.19 Misbranded toys and other articles intended for use by children.

(a) *Definitions.* For the purposes of this section, the following definitions shall apply.

(1) *Ball* means a spherical, ovoid, or ellipsoidal object that is designed or intended to be thrown, hit, kicked, rolled, dropped, or bounced. The term “ball” includes any spherical, ovoid, or ellipsoidal object that is attached to a toy or article by means of a string, elastic cord, or similar tether. The term “ball” also includes any multi-sided object formed by connecting planes into a generally, spherical, ovoid, or ellipsoidal shape that is designated or intended to be used as a ball, and any novelty item of a generally spherical, ovoid, or ellipsoidal shape that is designated or intended to be used as a ball. The term “ball” does not include dice, or balls permanently enclosed inside pinball machines, mazes, or similar outer containers. A ball is permanently enclosed if, when tested in accordance with 16 CFR 1500.53, it is not removed from the outer container.

(2) *Small ball* means a ball that, under the influence of its own weight, passes, in any orientation, entirely through a circular hole with a diameter of 1.75 inches (44.4 mm.) in a rigid template ¼ inches (6 mm.) thick. In testing to evaluate compliance with this regulation, the diameter of opening in the Commission’s test template shall be no greater than 1.75 inches (44.4 mm.).

(3) *Latex balloon* means a toy or decorative item consisting of a latex bag that is designed to be inflated by air or gas. The term does not include inflat-

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able children’s toys that are used in aquatic activities such as rafts, water wings, swim rings, or other similar items.

(4) *Marble* means a ball made of a hard material, such as glass, agate, marble or plastic, that is used in various children’s games, generally as a playing piece or marker. The term “marble” does not include a marble permanently enclosed in a toy or game. A marble is permanently enclosed if, when tested in accordance with 16 CFR 1500.53, it is not removed from the toy or game.

(5) *Small part* means any object which, when tested in accordance with the procedures contained in 16 CFR 1501.4(a) and 1501.4(b)(1), fits entirely within the cylinder shown in Figure 1 appended to 16 CFR part 1501. The use and abuse testing provisions of 16 CFR 1500.51 through 1500.53 and 1501.4(b)(2) do not apply to this definition.

(6) *Package* or packaging refers to the immediate package in which a product subject to labeling under section 24 of the act is sold, as well as to any outer container or wrapping for that package.

(7) *Descriptive material* means any discrete piece of written material separate from the label of the package that contains an instruction (whether written or otherwise) for the use of a product subject to these labeling requirements, any depiction of the product, and any written material that specifically describes any function, use, warnings, user population, design or material specification, or other characteristic of the product. A catalog or other marketing material or advertisement that depicts other products in addition to the product it accompanies is not “descriptive material” unless it contains additional information, such as instructions for use of the product it accompanies or lists of accessories exclusively for use with that product, that are designed to focus the purchaser’s attention on the product. Descriptive material “accompanies” a product subject to the labeling requirements when it is packaged with the product or when it is intended to be distributed with the product at the time of sale or delivery to the purchaser. “Descriptive material” does