

## REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (b), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

## CODIFICATION

Section was enacted as part of the Crime Control Act of 1990, and not as part of the Consumer Product Safety Act which comprises this chapter.

**§ 2057c. Prohibition on sale of certain products containing specified phthalates**

**(a) Prohibition on the sale of certain products containing phthalates**

Beginning on the date that is 180 days after August 14, 2008, it shall be unlawful for any person to manufacture for sale, offer for sale, distribute in commerce, or import into the United States any children's toy or child care article that contains concentrations of more than 0.1 percent of di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), or benzyl butyl phthalate (BBP).

**(b) Prohibition on the sale of additional products containing certain phthalates**

**(1) Interim prohibition**

Beginning on the date that is 180 days after August 14, 2008, and until a final rule is promulgated under paragraph (3), it shall be unlawful for any person to manufacture for sale, offer for sale, distribute in commerce, or import into the United States any children's toy that can be placed in a child's mouth or child care article that contains concentrations of more than 0.1 percent of diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), or di-n-octyl phthalate (DnOP).

**(2) Chronic Hazard Advisory Panel**

**(A) Appointment**

Not earlier than 180 days after August 14, 2008, the Commission shall begin the process of appointing a Chronic Hazard Advisory Panel pursuant to the procedures of section 28 of the Consumer Product Safety Act (15 U.S.C. 2077) to study the effects on children's health of all phthalates and phthalate alternatives as used in children's toys and child care articles.

**(B) Examination**

The panel shall, within 18 months after its appointment under subparagraph (A), complete an examination of the full range of phthalates that are used in products for children and shall—

(i) examine all of the potential health effects (including endocrine disrupting effects) of the full range of phthalates;

(ii) consider the potential health effects of each of these phthalates both in isolation and in combination with other phthalates;

(iii) examine the likely levels of children's, pregnant women's, and others' exposure to phthalates, based on a reasonable estimation of normal and foreseeable use and abuse of such products;

(iv) consider the cumulative effect of total exposure to phthalates, both from children's products and from other sources, such as personal care products;

(v) review all relevant data, including the most recent, best-available, peer-reviewed, scientific studies of these phthalates and phthalate alternatives that employ objective data collection practices or employ other objective methods;

(vi) consider the health effects of phthalates not only from ingestion but also as a result of dermal, hand-to-mouth, or other exposure;

(vii) consider the level at which there is a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals and their offspring, considering the best available science, and using sufficient safety factors to account for uncertainties regarding exposure and susceptibility of children, pregnant women, and other potentially susceptible individuals; and

(viii) consider possible similar health effects of phthalate alternatives used in children's toys and child care articles.

The panel's examinations pursuant to this paragraph shall be conducted *de novo*. The findings and conclusions of any previous Chronic Hazard Advisory Panel on this issue and other studies conducted by the Commission shall be reviewed by the panel but shall not be considered determinative.

**(C) Report**

Not later than 180 days after completing its examination, the panel appointed under subparagraph (A) shall report to the Commission the results of the examination conducted under this section and shall make recommendations to the Commission regarding any phthalates (or combinations of phthalates) in addition to those identified in subsection (a) or phthalate alternatives that the panel determines should be declared banned hazardous substances.

**(3) Permanent prohibition by rule**

Not later than 180 days after receiving the report of the panel under paragraph (2)(C), the Commission shall, pursuant to section 553 of title 5, promulgate a final rule to—

(A) determine, based on such report, whether to continue in effect the prohibition under paragraph (1), in order to ensure a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals with an adequate margin of safety; and

(B) evaluate the findings and recommendations of the Chronic Hazard Advisory Panel and declare any children's product containing any phthalates to be a banned hazardous product under section 8 of the Consumer Product Safety Act (15 U.S.C. 2057), as the Commission determines necessary to protect the health of children.

**(c) Application**

Effective on August 12, 2011,<sup>1</sup> subsections (a) and (b)(1) and any rule promulgated under subsection (b)(3) shall apply to any plasticized component part of a children's toy or child care article or any other component part of a children's toy or child care article that is made of other materials that may contain phthalates.

**(d) Exclusion for inaccessible component parts****(1) In general**

The prohibitions established under subsections (a) and (b) shall not apply to any component part of a children's toy or child care article that is not accessible to a child through normal and reasonably foreseeable use and abuse of such product, as determined by the Commission. A component part is not accessible under this paragraph if such component part is not physically exposed by reason of a sealed covering or casing and does not become physically exposed through reasonably foreseeable use and abuse of the product. Reasonably foreseeable use and abuse shall include swallowing, mouthing, breaking, or other children's activities, and the aging of the product.

**(2) Limitation**

The Commission may revoke an exclusion or all exclusions granted under paragraph (1) at any time and require that any or all component parts manufactured after such exclusion is revoked comply with the prohibitions established under subsections (a) and (b) if the Commission finds, based on scientific evidence, that such compliance is necessary to protect the public health or safety.

**(3) Inaccessibility proceeding**

Within 1 year after August 12, 2011, the Commission shall—

(A) promulgate a rule providing guidance with respect to what product components, or classes of components, will be considered to be inaccessible for purposes of paragraph (1); or

(B) adopt the same guidance with respect to inaccessibility that was adopted by the Commission with regards to accessibility of lead under section 1278a(b)(2)(B) of this title, with additional consideration, as appropriate, of whether such component can be placed in a child's mouth.

**(4) Application pending commission guidance**

Until the Commission promulgates a rule pursuant to paragraph (3), the determination of whether a product component is inaccessible to a child shall be made in accordance with the requirements laid out in paragraph (1) for considering a component to be inaccessible to a child.

**(e) Treatment of violation**

A violation of subsection (a) or (b)(1) or any rule promulgated by the Commission under subsection (b)(3) shall be treated as a violation of section 19(a)(1) of the Consumer Product Safety Act (15 U.S.C. 2068(a)(1)).

**(f) Treatment as consumer product safety standards; effect on State laws**

Subsections (a) and (b)(1) and any rule promulgated under subsection (b)(3) shall be considered consumer product safety standards under the Consumer Product Safety Act [15 U.S.C. 2051 et seq.]. Nothing in this section or the Consumer Product Safety Act (15 U.S.C. 2051 et seq.) shall be construed to preempt or otherwise affect any State requirement with respect to any phthalate alternative not specifically regulated in a consumer product safety standard under the Consumer Product Safety Act.

**(g) Definitions****(1) Defined terms**

As used in this section:

(A) The term "phthalate alternative" means any common substitute to a phthalate, alternative material to a phthalate, or alternative plasticizer.

(B) The term "children's toy" means a consumer product designed or intended by the manufacturer for a child 12 years of age or younger for use by the child when the child plays.

(C) The term "child care article" means a consumer product designed or intended by the manufacturer to facilitate sleep or the feeding of children age 3 and younger, or to help such children with sucking or teething.

(D) The term "consumer product" has the meaning given such term in section 3(a)(1) of the Consumer Product Safety Act (15 U.S.C. 2052(a)(1)).

**(2) Determination guidelines****(A) Age**

In determining whether products described in paragraph (1) are designed or intended for use by a child of the ages specified, the following factors shall be considered:

(i) A statement by a manufacturer about the intended use of such product, including a label on such product if such statement is reasonable.

(ii) Whether the product is represented in its packaging, display, promotion, or advertising as appropriate for use by children of the ages specified.

(iii) Whether the product is commonly recognized by consumers as being intended for use by a child of the ages specified.

(iv) The Age Determination guidelines issued by the Commission staff in September 2002 and any successor to such guidelines.

**(B) Toy that can be placed in a child's mouth**

For purposes of this section a toy can be placed in a child's mouth if any part of the toy can actually be brought to the mouth and kept in the mouth by a child so that it can be sucked and chewed. If the children's product can only be licked, it is not regarded as able to be placed in the mouth. If a toy or part of a toy in one dimension is smaller than 5 centimeters, it can be placed in the mouth.

(Pub. L. 110-314, title I, §108, Aug. 14, 2008, 122 Stat. 3036; Pub. L. 112-28, §5(a), Aug. 12, 2011, 125 Stat. 280.)

<sup>1</sup> See References in Text note below.

## REFERENCES IN TEXT

August 12, 2011, referred to in subsec. (c), was in the original “the date of enactment of this Act”, which was translated as meaning the date of enactment of Pub. L. 112–28, which enacted subsec. (c), to reflect the probable intent of Congress.

The Consumer Product Safety Act, referred to in subsec. (f), is Pub. L. 92–573, Oct. 27, 1972, 86 Stat. 1207, which is classified generally to this chapter. For complete classification of this Act to the Code, see Short Title note set out under section 2051 of this title and Tables.

## CODIFICATION

Section was enacted as part of the Consumer Product Safety Improvement Act of 2008, and not as part of the Consumer Product Safety Act which comprises this chapter.

## AMENDMENTS

2011—Subsecs. (c) to (g). Pub. L. 112–28 added subsecs. (c) and (d) and redesignated former subsecs. (c) to (e) as (e) to (g), respectively.

## DEFINITION

For definition of “Commission” used in this section, see section 2(a) of Pub. L. 110–314, set out as a note under section 2051 of this title.

### § 2058. Procedure for consumer product safety rules

#### (a) Commencement of proceeding; publication of prescribed notice of proposed rulemaking; transmittal of notice

A proceeding for the development of a consumer product safety rule may be commenced by the publication in the Federal Register of an advance notice of proposed rulemaking which shall—

- (1) identify the product and the nature of the risk of injury associated with the product;
- (2) include a summary of each of the regulatory alternatives under consideration by the Commission (including voluntary consumer product safety standards);
- (3) include information with respect to any existing standard known to the Commission which may be relevant to the proceedings, together with a summary of the reasons why the Commission believes preliminarily that such standard does not eliminate or adequately reduce the risk of injury identified in paragraph (1);
- (4) invite interested persons to submit to the Commission, within such period as the Commission shall specify in the notice (which period shall not be less than 30 days or more than 60 days after the date of publication of the notice), 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;
- (5) invite any person (other than the Commission) to submit to the Commission, within such period as the Commission shall specify in the notice (which period shall not be less than 30 days after the date of publication of the notice), an existing standard or a portion of a standard as a proposed consumer product safety standard; and
- (6) invite any person (other than the Commission) to submit to the Commission, within

such period as the Commission shall specify in the notice (which period shall not be less than 30 days after the date of publication of the notice), a statement of intention to modify or develop a voluntary consumer product safety standard to address the risk of injury identified in paragraph (1) together with a description of a plan to modify or develop the standard.

The Commission shall transmit such notice within 10 calendar days to the appropriate Congressional committees.

#### (b) Voluntary standard; publication as proposed rule; notice of reliance of Commission on standard

(1) If the Commission determines that any standard submitted to it in response to an invitation in a notice published under subsection (a)(5) of this section if promulgated (in whole, in part, or in combination with any other standard submitted to the Commission or any part of such a standard) as a consumer product safety standard, would eliminate or adequately reduce the risk of injury identified in a notice under subsection (a)(1) of this section, the Commission may publish such standard, in whole, in part, or in such combination and with nonmaterial modifications, as a proposed consumer product safety rule.

(2) If the Commission determines that—

(A) compliance with any standard submitted to it in response to an invitation in a notice published under subsection (a)(6) of this section is likely to result in the elimination or adequate reduction of the risk of injury identified in the notice, and

(B) it is likely that there will be substantial compliance with such standard,

the Commission shall terminate any proceeding to promulgate a consumer product safety rule respecting such risk of injury and shall publish in the Federal Register a notice which includes the determination of the Commission and which notifies the public that the Commission will rely on the voluntary standard to eliminate or reduce the risk of injury, except that the Commission shall terminate any such proceeding and rely on a voluntary standard only if such voluntary standard is in existence. For purposes of this section, a voluntary standard shall be considered to be in existence when it is finally approved by the organization or other person which developed such standard, irrespective of the effective date of the standard. Before relying upon any voluntary consumer product safety standard, the Commission shall afford interested persons (including manufacturers, consumers, and consumer organizations) a reasonable opportunity to submit written comments regarding such standard. The Commission shall consider such comments in making any determination regarding reliance on the involved voluntary standard under this subsection.

#### (c) Publication of proposed rule; preliminary regulatory analysis; contents; transmittal of notice

No consumer product safety rule may be proposed by the Commission unless the Commission publishes in the Federal Register the text of the