

and candles with such wicks are hazardous substances. 16 CFR 1500.12(a)(2). Second, pursuant to section 2(q)(1)(B) of the FHSA, the Commission is banning such wicks and candles with such wicks. 16 CFR 1500.17(a)(13).

A proceeding to declare a substance to be a "hazardous substance" under section 3(a) of the FHSA is governed by, *inter alia*, sections 701(e), (f), and (g) of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 371(e)–(g). *See* 15 U.S.C. 1262(a)(2).

The Commission is declaring that metal-cored candlewicks containing more than 0.06 percent lead by weight of the metal and candles with such wicks are "hazardous substances" within the meaning of section 2(f)(1)(A) of the FHSA because they are toxic, and "may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use. * * *" 15 U.S.C. 1261(f)(1)(A). The basis for this declaration is stated in section D. of this preamble, *The Risk of Illness*.

Under section 2(q)(1)(B) of the FHSA, the Commission may classify as a "banned hazardous substance" any hazardous substance intended for household use which, notwithstanding the precautionary labeling required by the FHSA, presents such a hazard that keeping the substance out of interstate commerce is the only adequate means to protect the public health and safety. 15 U.S.C. 1261(q)(1)(B). A proceeding to classify a substance as a banned hazardous substance under section 2(q)(1)(B) of the FHSA is governed by the requirements set forth in section 3(f) of the FHSA, and also by sections 701(e), (f), and (g) of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 371(e)). *See* 15 U.S.C. 1261(q)(2) and 1262(f).

The CPSC Human Factors staff analysis on the issue of precautionary labeling of individual candles concludes that labeling is not an acceptable strategy for protecting vulnerable populations from lead poisoning that may be caused by burning candles with lead-cored wicks.⁷

That analysis shows that since lead is emitted in unpredictable amounts from a candle with a metal-cored wick containing more than 0.06 percent lead in the metal when the candle is used as intended, the only preventative measures consumers could take to protect themselves against the hazard would be to not burn candles with such

wicks. No label or subsequent action by the consumer would prevent the release of lead into the air if the candle were used as intended. The Commission therefore finds that, notwithstanding the precautionary labeling required by the FHSA, metal-cored candlewicks containing more than 0.06 percent lead in the metal and candles with such wicks present a hazard such that keeping them out of interstate commerce is the only adequate means to protect the public health and safety.

In addition to today's final rule banning these wicks and candles, the FHSA requires that the Commission publish a final regulatory analysis that includes: (1) A description of the potential costs and benefits of the rule; (2) a description of alternatives considered by the Commission (including a description of their potential costs and benefits and an explanation of why they were not chosen); and (3) a summary of significant issues raised by comments on the preliminary regulatory analysis published with these proposed rules. 15 U.S.C. 1262(i)(1). The Commission must also find that: (1) Any relevant voluntary standard is unlikely to adequately reduce the risk of injury or substantial compliance with the voluntary standard is unlikely; (2) the expected benefits of the regulation bear a reasonable relationship to expected costs; and (3) the regulation imposes the least burdensome requirement that would adequately reduce the risk of injury. 15 U.S.C. 1262(i)(2).

Procedures established by section 701(e) of the FDCA govern this Commission action to finalize the hazardous substance declaration and the banning rule. 15 U.S.C. 1262(a)(2) and 1261(q)(2). These procedures provide that once the Commission issues a final rule, persons who would be adversely affected by the rule have a period of 30 days in which to file objections stating reasonable grounds therefor, and to request a public hearing on those objections. 21 U.S.C. 371(e). Should valid objections be filed, a hearing to receive evidence concerning the objections would be held and the presiding officer would issue an order after the hearing, based upon substantial evidence. 21 U.S.C. 371(e); 16 CFR part 1502.

G. Response to Comments on the NPR

Six comments were received in response to the NPR. All six comments were in favor of a ban on lead-cored wicks. One commenter expressed interest in allowing the use of lead-cored candlewicks in certain circumstances.

One wick manufacturer (Atkins and Pearce) and two industry groups (Consumer Specialty Products Association, National Candle Association) provided comments. One commenter represented a non-profit information and advocacy group in Australia (Global Lead Advice and Support Service). Two commenters were individual consumers or interested parties.

1. Federal Regulation

Comments: All six commenters support the concept of regulating the use of lead in metal-cored candlewicks, although there was disagreement about the scope of the proposed regulation, and the proposed requirements for testing, certifying, and tracking metal-cored wicks.

Response: The Commission acknowledges the interest among consumers, industry, and advocacy groups in the elimination of candlewicks as a source of lead exposure. Responses to specific questions and comments about the proposed rule are set forth below.

2. Proposed Record-Keeping Requirements

Comments: The rule as proposed included requirements that shipping cartons of metal-cored candlewicks and shipping cartons of candles with such wicks be labeled as complying with the ban and with a lot number or other designation, and that wick and candle manufacturers, importers, and distributors maintain records documenting compliance with the ban for each lot. Representatives from industry expressed concern about the costs and labor that would be involved in the tracking of metal-cored wicks used in specific candles, and the maintenance of records.

These commenters provided some information about the candle-making process to illustrate potential difficulties with the proposed requirements. For example, the commenters described machines that rapidly produce many candles at once, simultaneously drawing candlewick from several different spools. Consequently, a batch of finished candles could contain wicks from different lots or sources. Further, these candles with different wicks would be indistinguishable and would be packaged together at the end of production. Thus, a single shipping carton could contain identical candles with different lots of metal-cored candlewicks. The commenters believe it would be labor intensive and costly to change the current method of production so that individual lots of

⁷ See footnote 2 for sources for the CPSC staff analyses related to this rulemaking.