§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9W, Airspace Designations and Reporting Points, dated August 8, 2012, and effective September 15, 2012, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface.

* * * * *

ASW TX E5 Presidio, TX [New]

Presidio Lely International Airport, TX
(Lat. 29°38′03″ N., long. 104°21′41″ W.)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Presidio Lely International Airport, and within 2 miles each side of the 070° bearing from the airport extending from the 6.5-mile radius to 13.4 miles east of the airport; and that airspace extending upward from 1,200 feet above the surface within a 62.5 mile radius of the airport, excluding that airspace within Mexico.

Issued in Fort Worth, Texas, on July 8, 2013.

David P. Medina,

Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2013–16437 Filed 7–11–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 175

[Docket No. FDA–2012–F–0728]

Indirect Food Additives: Adhesives and Components of Coatings

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the food additive regulations to no longer provide for the use of Bisphenol A (BPA)-based epoxy resins as coatings in packaging for infant formula because these uses have been abandoned. We are taking this action in response to a petition dated March 16, 2012.

DATES: This rule is effective July 12, 2013. See section VIII of this document for further information on the filing of objections. Submit either electronic or written objections and requests for a hearing by August 12, 2013.

ADDRESSES: You may submit either electronic or written objections and requests for a hearing, identified by Docket No. FDA–2012–F–0728, by any of the following methods:

Electronic Submissions

Submit electronic objections in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting objections.

Written Submissions

Submit written objections in the following ways:

- *Mail/Hand delivery/Courier* (for paper or CD–ROM submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2012–F–0728 for this rulemaking. All objections received will be posted without change to *http://www.regulations.gov,* including any personal information provided. For detailed instructions on submitting objections, see the ''Objections'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or objections received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Vanee Komolprasert, Center for Food Safety and Applied Nutrition (HFS–275), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 240–402–1217.

SUPPLEMENTARY INFORMATION:

I. Background

In a document published in the **Federal Register** of July 17, 2012 (77 FR 41953), we announced that food additive petition (FAP 2B4791) had been filed by then U.S. Representative Edward J. Markey, House of Representatives, 2108 Rayburn House Office Building, Washington, DC 20515–2107. The petition proposed to amend the food additive regulations in § 175.300 (21 CFR 175.300) to no longer provide for the use of BPA-based epoxy resins as coatings in packaging for infant formula because these uses have been abandoned. BPA-based epoxy resins are formed by the reaction of 4,4′-isopropylidenediphenol (i.e., BPA), and epichlorohydrin. BPA-based epoxy resins may be safely used as the food-contact surfaces of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, in accordance with the prescribed conditions of § 175.300.

II. Evaluation of Abandonment

Under section 409(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 348(i)), FDA ''shall by regulation prescribe the procedure by which regulations under the foregoing provisions of this section may be amended or repealed, and such procedure shall conform to the procedure provided in this section for the promulgation of such regulations.'' Our regulations specific to administrative actions for food additives provide as follows: ''The Commissioner, on his own initiative or on the petition of any interested person, pursuant to part 10 of this chapter, may propose the issuance of a regulation amending or repealing a regulation pertaining to a food additive or granting or repealing an exception for such additive.'' (§ 171.130(a) (21 CFR 171.130(a))). These regulations further provide: ''Any such petition shall include an assertion of facts, supported by data, showing that new information exists with respect to the food additive or that new uses have been developed or old uses abandoned, that new data are available as to toxicity of the chemical, or that experience with the existing regulation or exemption may justify its amendment or repeal. New data shall be furnished in the form specified in §§ 171.1 and 171.100 for submitting petitions.'' (§ 171.130(b)). Under these regulations, a petitioner may propose that FDA amend a food additive regulation if the petitioner can demonstrate that there are ''old uses abandoned'' for the relevant food additive. Such abandonment must be complete for any intended uses in the U.S. market. While section 409 of the FD&C Act and § 171.130 also provide for amending or revoking a food additive regulation based on safety, an amendment or revocation based on abandonment is not based on safety, but is based on the fact that the regulatory authorization is no longer necessary for the specific use of the food additive because that use has been permanently and completely abandoned.

Abandonment may be based on the abandonment of certain authorized food additive uses for a substance (e.g., if a substance is no longer used in certain product categories), or on the abandonment of all authorized food additive uses of a substance (e.g., if a substance is no longer being manufactured). If a petition seeks an

amendment to food additive regulations based on the abandonment of certain uses of the food additive, such uses must be adequately defined so that both the scope of the abandonment and any amendment to the food additive regulation are clear.

The petition contained public information and information collected from a survey of all of the U.S. registered manufacturers of infant formula to support the petitioner's claim that all U.S. infant formula manufacturers have abandoned the use of BPA-based epoxy resins as coatings in all food contact packaging for infant formula and that infant formula products with packaging containing BPA-based epoxy resins are not being introduced into the U.S. market. According to the petition, the manufacturers identified in the survey accounted for 100 percent of the current infant formula market in the United States.

III. Comments on the Filing Notice

We provided 60 days for comments on the filing notice. We received 21 comments from individuals, consumer groups, and trade associations. Eighteen comments supported the rulemaking based on concerns regarding the safety of BPA in food, six comments addressed both safety and abandonment, while one comment addressed only abandonment. Three comments opposed the rulemaking, asserting that the use of BPA-based epoxy resins as coatings in packaging for infant formula has not been permanently and completely abandoned. These supporting and opposing comments have raised seven main issues, which are discussed in the paragraphs that follow. For ease of reading, we preface each comment discussion with a numbered ''Comment,'' and each response by a corresponding numbered ''Response.'' We have numbered each comment discussion to help distinguish among different topics. The number assigned is for organizational purposes only and does not signify any individual comment's value, importance, or the order in which it was received.

A. The Safety of BPA

(Comment 1) Eighteen distinct comments (representing more than 7,200 individuals who submitted form letters) supported the rulemaking because they asserted that BPA exposure has been reported to be associated with a wide range of adverse health issues. One comment supported our commitment to study the significant emerging science around BPA, and encouraged us to expand the scope of its review beyond just infants, small children, and other vulnerable populations. Nine comments urged us to immediately release our safety assessment of BPA.

(Response) As indicated in the filing notice (77 FR 41953), because the petition was based on an assertion of abandonment, we did not request comments on the safety of the use of BPA-based epoxy resins as coatings in packaging for infant formula. Such safety information is not relevant to abandonment and, therefore, any comments addressing the safety of BPA-based epoxy resins were not considered in our evaluation of this petition. Separate from our consideration of this petition, we are actively assessing the safety of BPA (see 75 FR 17145; April 5, 2010; see also *http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm064437.htm*) Any comments regarding the safety of BPA should be sent in writing to the Division of Dockets Management (see **ADDRESSES**) and include Docket No. FDA–2010–N–0100.

B. Whether the Subject Uses Have Been Abandoned

(Comment 2) Three distinct comments, submitted by trade associations, opposed the rulemaking. These comments asserted that the use of BPA-based epoxy resins as coatings in packaging for infant formula has not been intentionally, permanently, and completely abandoned.

Specifically, two comments asserted that the petition does not adequately establish that the use of BPA-based epoxy resins as coatings in infant formula packaging has been intentionally, permanently, and completely abandoned because, the comments asserted, there remains a desire on the part of can manufacturers to maintain BPA-based epoxy resins as an option for future use as coatings in infant formula packaging.

The third comment asserted that the petition's proposed amendment is premature and unnecessary at this time, and mere non-use does not establish abandonment. This comment asserted that not all infant formula manufacturers believe they have permanently ''abandoned'' the use of packaging made using BPA.

(Response) We concluded that the three opposing comments raised significant questions regarding whether this use has been completely abandoned because these trade associations likely represent the opinions of their respective members that include the packaging suppliers and the infant formula manufacturers. We therefore asked the petitioner to provide additional data in support of the assertion that the use of BPA-based epoxy resins as coatings in infant formula packaging has been completely abandoned. We needed this new information to evaluate the comments asserting that, while infant formula manufacturers currently do not use BPA as a component of infant formula packaging, they have not abandoned this use. In response to our request, the petitioner subsequently amended the petition to include a new survey issued to the four infant formula manufacturers in the United States. These four infant formula manufacturers account for 100 percent of the current infant formula market. The survey specifically addressed whether these manufacturers have stopped the use of BPA-based epoxy coatings in infant formula packaging, and whether they have specific plans to reintroduce the use of BPA-based epoxy resins in their infant formula packaging in the future.

The amendment to the petition included a letter from one infant formula manufacturer that indicated that while it has no specific plans to use packaging materials with BPA in the future, it reserves the right to do so in the future should the circumstances warrant it. We considered whether this comment demonstrated that the use of BPA-based epoxy coatings in infant formula packaging has not been permanently and completely abandoned. We concluded that, because the comment did not indicate that the manufacturer had specific plans to use BPA-based epoxy coatings in the future, it did not demonstrate that this use has not been permanently and completely abandoned. We conclude that a mere assertion of a right to unspecified, hypothetical future use of an additive does not demonstrate that, at the present time, there is evidence that this use has not been permanently and completely abandoned. We emphasize that our determination that this use of BPA-based epoxy resins has been abandoned is made without prejudice to a future filing based on the safety of this use. A manufacturer could seek approval, establishing safe conditions of use for BPA-based epoxy coatings in infant formula packaging, via the food contact notification process.

C. Impact of the Rulemaking

(Comment 3) One comment opposed the rulemaking, expressing a concern that the rulemaking could impact consumer confidence negatively, restrict the wide range of canned food and beverages available to consumers, and

potentially put workers out of jobs in the United States.

(Response) We disagree with the comment for the following reasons. First, this rulemaking is premised on FDA's conclusion that the infant formula manufacturers have completely and permanently abandoned the use of BPA-based epoxy resins as coatings in packaging for infant formula. Because this use has been abandoned, the rulemaking will not impact the range of canned food and beverages currently available to consumers and will not affect jobs currently held in the United States. Further, the amendment to § 175.300 does not restrict the use of BPA-based epoxy resins as coatings in packaging for food other than infant formula.

D. Alternatives to BPA-Based Epoxy Resins

(Comment 4) Two comments supported the rule because alternatives to BPA-based epoxy resins as coatings in packaging for infant formula are available. However, another comment opposed the rule because the industry does not want to foreclose access to a safe material whose use may be necessary in the future, reasoning that if a current alternative to BPA-based packaging proves to have inadequate performance or becomes unavailable, the infant formula producers will need access to other safe and proven effective packaging options to ensure the continued supply of safe infant formula.

(Response) We are aware that alternatives to the use of BPA-based epoxy resins as coatings are listed in § 175.300, and some are being used to replace the BPA-based coatings in infant formula packaging. However, this information is not relevant to whether the use of BPA-based epoxy resins as coatings in infant formula packaging has been abandoned. As discussed in more detail previously, we have concluded that, because we did not receive any information from infant formula manufacturers that communicated specific plans to use BPA-based epoxy resins in their products in the future, we have no information to indicate that this use has not been completely and permanently abandoned.

(Comment 5) One comment stated that many consumers have opted to use glass baby bottles, given that glass is the only widely used packaging designated by FDA as generally recognized as safe.

(Response) This comment pertains to baby bottles and is not relevant to whether the use of BPA-based epoxy resins as coatings in infant formula packaging has been abandoned. Therefore, FDA did not consider this comment.

E. The Scope of the Use of BPA-Based Epoxy Resin Addressed by the Petition

(Comment 6) One comment stated that more BPA-containing products should be banned. Ten comments asserted that the rulemaking does not go far enough in protecting the health of infants. This comment stated that, because babies are also being exposed to BPA through baby food contained in glass jars with BPA-based liners for lids, as well as from cans and reusable food containers, FDA should remove BPA from all food packaging.

(Response) We have concluded that it is not appropriate, in this amendment to the food additive regulations, to address any uses of BPA-based food packaging materials beyond that specified in the petition, for the following reasons:

- A consideration of other BPA-based food packaging materials is beyond the scope of the petition and the evidence submitted with the petition, about which FDA requested and received comment.
- We did not receive comments providing specific information to demonstrate that any additional uses of other BPA-based food packaging materials have been completely and permanently abandoned.

F. Labeling of BPA-Containing Packaging Materials

(Comment 7) One comment asserted that consumers have a need to see what is in food, and proper, precise, and truthful labeling is a must. Therefore, the comment asserted that all products should be labeled so as to give the consumer a choice. Another comment recommended that labeling be required for food packaging materials that contain BPA.

(Response) The petition did not request that FDA establish requirements for the labeling of products manufactured with BPA. Therefore, these comments are outside the scope of the action requested by the petition, and FDA did not consider these comments.

G. Future Presence of BPA in Infant Formula Packaging

(Comment 8) One comment asserted that if the petition is granted and food additive regulations are amended to no longer provide for the use of BPA-based epoxy resins as coatings in infant formula packaging, it would raise concerns about the possible implications of current or future presence of BPA in infant formula packaging as a result of environmental contamination. Because no specific level was included in the petition, the comment asserted that the detection of any BPA level in infant formula packaging could result in an adulterated product. The comment asked that we explain how we will handle reports of detectable levels of BPA in infant formula packaging that may be due to environmental contamination.

(Response) This comment is not relevant to whether the use of BPA-based epoxy resins as coatings in infant formula packaging has been abandoned. The focus of this amendment is to no longer provide for the intentional use of BPA-based epoxy resins as coatings in infant formula packaging. However, we note that it is highly unlikely that BPA-based epoxy resins will be present in infant formula packaging as a result of environmental contamination when BPA-based epoxy resins are not being used as components in the manufacture of infant formula packaging. If FDA identifies the presence of BPA-based epoxy resins in infant formula packaging in the future, FDA will determine whether such presence causes an infant formula product to be adulterated under the FD&C Act.

IV. Conclusion

FDA reviewed the data and information in the petition and other available relevant material to determine whether the use of BPA-based epoxy resins as coatings in packaging for infant formula has been permanently and completely abandoned. Based on the available information, we conclude that this use has been permanently and completely abandoned. Therefore, we are amending § 175.300 to no longer provide for the use of BPA-based epoxy resins as coatings in packaging for infant formula.

V. Public Disclosure

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition will be made available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 171.1(h), the Agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

VI. Environmental Impact

We previously considered the environmental effects of this rule, as stated in the notice of petition for FAP 2B4791 (77 FR 41953 at 41954). We

stated that we had determined, under 21 CFR 25.32(m), that this action ''is of a type that does not individually or cumulatively have a significant effect on the human environment'' such that neither an environmental assessment nor an environmental impact statement is required. We have not received any new information or comments that would affect our previous determination.

VII. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VIII. Objections

If you will be adversely affected by one or more provisions of this regulation, you may file with the Division of Dockets Management (see **ADDRESSES**) either electronic or written objections. You must separately number each objection, and within each numbered objection you must specify with particularity the provision(s) to which you object, and the grounds for your objection. Within each numbered objection, you must specifically state whether you are requesting a hearing on the particular provision that you specify in that numbered objection. If you do not request a hearing for any particular objection, you waive the right to a hearing on that objection. If you request a hearing, your objection must include a detailed description and analysis of the specific factual information you intend to present in support of the objection in the event that a hearing is held. If you do not include such a description and analysis for any particular objection, you waive the right to a hearing on the objection.

It is only necessary to send one set of documents. Identify documents with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

List of Subjects in 21 CFR Part 175

Adhesives, Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 175 is amended as follows:

PART 175—INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS

■ 1. The authority citation for 21 CFR part 175 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

■ 2. Section 175.300 is amended by adding paragraph (i) to read as follows:

§ 175.300 Resinous and polymeric coatings.

* * * * *

(i) Epoxy resins derived by the reaction of 4,4′-isopropylidenediphenol and epichlorohydrin, as described in paragraph (b)(3)(viii)(*a*) of this section, may be used in accordance with this section except as coatings in packaging for powdered and liquid infant formula.

Dated: July 8, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–16684 Filed 7–11–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2013–0566]

Drawbridge Operation Regulation; Trent River, New Bern, NC

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Commander, Fifth Coast Guard District, has issued a temporary deviation from the operating schedule that governs the US 70/Alfred C. Cunningham Bridge across the Trent River, mile 0.0, at New Bern, NC. The deviation allows the bridge draw span to remain in the closed to navigation position to accommodate the free movement of pedestrians and vehicles during the annual Mumfest celebration.

DATES: This deviation is effective from 9 a.m. to 7 p.m. on October 12, 2013 and from 9 a.m. to 5 p.m. on October 13, 2013.

ADDRESSES: The docket for this deviation, [USCG–2013–0566] is available at *http://www.regulations.gov.* Type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this deviation. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Mrs. Jessica Shea, Bridge Management Specialist, Fifth Coast Guard District, telephone (757) 398–6422, email *jessica.c.shea2@uscg.mil.* If you have questions on viewing the docket, call Barbara Hairston, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION: The Event Director for the New Bern Mumfest, with approval from the North Carolina Department of Transportation, owner of the drawbridge, has requested a temporary deviation from the current operating regulations set out in 33 CFR 117.843(a) to accommodate safe passage for pedestrians and vehicles during Mumfest.

The US 70/Alfred C. Cunningham Bridge across the Trent River, mile 0.0, a double bascule lift Bridge, in New Bern, NC, has a vertical clearance in the closed position of 14 feet, above mean high water. Under the normal operating schedule, the US 70/Alfred C. Cunningham Bridge would open on signal during this timeframe. However, under this temporary deviation, the drawbridge will only be allowed to open every two hours, on the hour, starting at 9 a.m. and continuing until 7 p.m. on Saturday, October 12, and 9 a.m. to 5 p.m. on Sunday, October 13, 2013 to accommodate the New Bern Mumfest. From 8 p.m. on Saturday, October 12, until 9 a.m. Sunday, October 13, 2013, the drawbridge will open on signal.

Vessels able to pass under the closed span may do so. Mariners are advised to proceed with caution. The Coast Guard will inform users of the waterway through our Local and Broadcast Notices to Mariners of the limited operating schedule for the drawbridge so that vessels can arrange their transits to minimize any impacts caused by the temporary deviation. There are no alternate routes for vessels and the bridge will be able to open in the event of an emergency.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the designated time period. This deviation from the operating regulations is authorized under 33 CFR 117.35.