

Opelousas, LA, KOPL, Takeoff Minimums and Obstacle DP, Amdt 1A  
 Leonardtown, MD, 2W6, RNAV (GPS) RWY 11, Amdt 3  
 Leonardtown, MD, 2W6, Takeoff Minimums and Obstacle DP, Amdt 1  
 Bellaire, MI, ACB, RNAV (GPS) RWY 2, Amdt 1  
 Boyne City, MI, N98, RNAV (GPS) RWY 9, Orig-C  
 Charlevoix, MI, CVX, RNAV (GPS) RWY 27, Orig-D  
 Gaylord, MI, GLR, RNAV (GPS) RWY 9, Amdt 1  
 Gaylord, MI, GLR, RNAV (GPS) RWY 27, Amdt 1  
 Gaylord, MI, KGLR, Takeoff Minimums and Obstacle DP, Orig-A  
 Ontonagon, MI, OGM, RNAV (GPS) RWY 35, Orig-A  
 Blue Earth, MN, SBU, RNAV (GPS) RWY 34, Orig-A  
 Hattiesburg-Laurel, MS, PIB, VOR-A, Orig-B, CANCELED  
 Laurel, MS, LUL, VOR-A, Amdt 6, CANCELED  
 Kinston, NC, ISO, RNAV (GPS) RWY 5, Amdt 3C  
 Falls City, NE, FNB, RNAV (GPS) RWY 33, Amdt 2A  
 Dansville, NY, DSV, RNAV (GPS)-A, Orig-B  
 Sand Springs, OK, OWP, RNAV (GPS) RWY 17, Amdt 1  
 Sand Springs, OK, OWP, RNAV (GPS) RWY 35, Amdt 1  
 Watonga, OK, KJWG, Takeoff Minimums and Obstacle DP, Amdt 1A  
 Bradford, PA, KBFD, Takeoff Minimums and Obstacle DP, Orig-A  
 Lancaster, PA, KLNS, Takeoff Minimums and Obstacle DP, Amdt 2  
 Savannah, TN, KSNH, Takeoff Minimums and Obstacle DP, Amdt 3A  
 Sevierville, TN, GKT, Takeoff Minimums and Obstacle DP, Amdt 4B  
 Dallas, TX, DAL, ILS OR LOC RWY 13L, ILS RWY 13L (SA CAT I), ILS RWY 13L (SA CAT II), Amdt 34A  
 Dallas, TX, DAL, ILS OR LOC RWY 13R, Amdt 6C  
 Madisonville, TX, 51R, RNAV (GPS) RWY 1, Amdt 1  
 Madisonville, TX, 51R, RNAV (GPS) RWY 19, Amdt 1  
 Madisonville, TX, 51R, Takeoff Minimums and Obstacle DP, Amdt 1  
 Madisonville, TX, 51R, VOR RWY 19, Amdt 3  
 Manti, UT, 41U, RNAV (GPS) RWY 3, Orig-C  
 Quinton, VA, W96, RNAV (GPS) RWY 11, Amdt 3  
 Quinton, VA, W96, RNAV (GPS) RWY 29, Amdt 3  
 Saluda, VA, W75, RNAV (GPS) RWY 1, Amdt 1  
 Saluda, VA, W75, Takeoff Minimums and Obstacle DP, Amdt 3  
 Port Angeles, WA, KCLM, WATTR NINE, Graphic DP  
 Boscobel, WI, OVS, RNAV (GPS) RWY 7, Orig-C  
 Boscobel, WI, OVS, RNAV (GPS) RWY 25, Amdt 2A  
 Eau Claire, WI, EAU, Takeoff Minimums and Obstacle DP, Amdt 2B

Racine, WI, RAC, Takeoff Minimums and Obstacle DP, Amdt 5B  
 Pineville, WV, I16, RNAV (GPS) RWY 26, Orig-E

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 175, 176, 177, and 178

[Docket No. FDA-2018-F-3757]

#### Indirect Food Additives: Adhesives and Components of Coatings; Paper and Paperboard Components; Polymers; Adjuvants, Production Aids, and Sanitizers

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; response to objection; confirmation of effective date.

**SUMMARY:** The Food and Drug Administration (FDA or we) is responding to the objection that we received from the Environmental Defense Fund, Breast Cancer Prevention Partners, Environmental Protection Network, Environmental Working Group, and Healthy Babies Bright Futures on the final rule that amended the food additive regulations to no longer provide for the use of 25 plasticizers that the petition identified as *ortho*-phthalates because these food additive uses have been permanently abandoned. After reviewing the objection, FDA has concluded that the objection does not provide a basis for modifying FDA's final rule amending the food additive regulations.

**DATES:** The effective date of May 20, 2022, for the final rule published on May 20, 2022 (87 FR 31080), is confirmed.

**ADDRESSES:** For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and insert the docket number found in brackets in the heading of this final rule into the "Search" box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

**FOR FURTHER INFORMATION CONTACT:** Stephen DiFranco, Office of Food Chemical Safety, Dietary Supplements, and Innovation (HFS-275), Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740-3835, 240-402-2710; or Lauren Kleinman, Human

Foods Program, Office of Policy, Regulations and Information (HFS-024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the **Federal Register** of November 14, 2018 (83 FR 56750), we announced that we filed a food additive petition (FAP 8B4820) (Petition) submitted by The Flexible Vinyl Alliance (FVA or Petitioner), c/o Keller and Heckman, LLP, 1001 G St. NW, Suite 500 West, Washington, DC 20001. The Petition requested that we amend our food additive regulations in parts 175, 176, 177, and 178 (21 CFR parts 175, 176, 177, and 178) to no longer provide for the use of 26 plasticizer substances that the Petition identified as *ortho*-phthalates. (FAP 8B4820 submitted by FVA claimed that the food additive uses of di(2-ethylhexyl) hexahydrophthalate and diphenylguanidine phthalate are abandoned. We note that these substances are not chemically classified as *ortho*-phthalates and that characterization as such is incorrect.) The Petition requested that we revoke the approvals on the basis that the food additive uses have been permanently abandoned.

One of the 26 plasticizers identified in the Petition was diallyl phthalate (Chemical Abstract Services number (CAS Reg No.) 131-17-9). The filing document indicated that this substance may be used as a food additive under §§ 175.105, 176.180, 176.300, and 177.1210 (21 CFR 175.105, 176.180, 176.300, and 177.1210) (see 83 FR 56750). However, upon further review, we determined that the use of diallyl phthalate is only authorized for use in these regulations as a monomer to produce polymers and not as a plasticizer. FVA made no claims in their Petition that the use of polymers produced with diallyl phthalate for food contact applications have been abandoned. Thus, after FDA followed up with the Petitioner, diallyl phthalate was no longer subject to this Petition (87 FR 31080). In the **Federal Register** of May 20, 2022 (87 FR 31080), FDA issued a final rule amending the food additive regulations in parts 175, 176, 177, and 178 to no longer provide for the use of 25 plasticizers in various food contact applications (final rule). We gave interested persons until June 21, 2022, to file objections and requests for a hearing on the final rule.

##### II. Objection and Comments

Section 409(f)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21

U.S.C. 348(f)(1)) provides that, within 30 days after publication of an order relating to a food additive regulation, any person adversely affected by such order may file objections, specifying with particularity, the provisions of the order deemed objectionable, stating reasonable grounds therefor and requesting a public hearing upon such objections.

Under 21 CFR 171.110, objections and requests for a hearing relating to food additive regulations are governed by 21 CFR part 12. Under § 12.22(a) (21 CFR 12.22(a)), each objection must: (1) be submitted on or before the 30th day after the date of publication of the final rule; (2) be separately numbered; (3) specify with particularity the provision of the regulation or proposed order objected to; (4) specifically state each objection on which a hearing is requested; failure to request a hearing on an objection constitutes a waiver of the right to a hearing on that objection; and (5) include a detailed description and analysis of the factual information to be presented in support of the objection if a hearing is requested; failure to include a description and analysis for an objection constitutes a waiver of the right to a hearing on that objection.

Following the publication of the final rule in which we granted the Petition asserting abandonment of the 25 plasticizers in various food contact uses, we received a submission from the Environmental Defense Fund, Breast Cancer Prevention Partners, Environmental Protection Network, Environmental Working Group, and Healthy Babies Bright Futures (Objectors) containing one objection and two comments (see submission from Tom Neltner, Senior Director for Safer Chemicals, Environmental Defense Fund, et al., submitted to the Dockets Management Staff, Food and Drug Administration, dated June 19, 2022 (Submission) (Ref. 1). The Submission does not contain a request for a hearing.

### III. Analysis of Objections and Comments

The Submission contains one numbered objection and two numbered comments. We address each objection and comment below.

#### A. Objection 1

The Submission states that “The agency [improperly] denied FVA’s request to remove approval of diallyl phthalate because it was used as a monomer to produce polymers and not as a plasticizer” (Ref. 1 at page 1). The Submission states that the FVA survey that FVA submitted to provide evidence

of abandonment asked survey recipients about food contact applications for the listed substances, not about use of the listed substances as plasticizers. According to this objection, FVA “clearly considered diallyl phthalate as abandoned,” and therefore FDA should have removed diallyl phthalate from its food additive regulations on the basis that its use has been abandoned. The Submission also states the Objectors are not requesting a hearing on this Objection. Therefore, the Objectors have waived any right to a hearing on their Objection (see § 12.22(a)(4)). The only remaining question under § 12.24(a) is whether the Objection establishes that the final rule should be modified or revoked with respect to diallyl phthalate. As described below, we conclude that the Objectors have not established a basis for modifying or revoking the final rule.

As FDA stated in the **Federal Register** document announcing the final rule, after following up with the Petitioner, diallyl phthalate was no longer subject to the Petition. In an email correspondence dated July 20, 2018, between FDA and FVA’s agent, FVA confirmed that diallyl phthalate is not within the scope of the abandonment request (see also 87 FR 31080 at 31080 through 31081; Ref. 2). Thus, diallyl phthalate was removed from the Petition. Because diallyl phthalate was removed from the scope of the Petition, when FDA issued the final rule granting the Petition, the final rule did not cover diallyl phthalate. Thus, the final rule did not impact the regulatory authorizations for diallyl phthalate. Accordingly, FDA’s actions regarding diallyl phthalate were reasonable, and there is no need for FDA to modify or revoke the final rule in response to Objection 1.

#### B. Comment 1

The Submission asserts that FDA should remove the existing prior sanctioned uses of diethyl phthalate (CAS Reg. No. 84–66–2), diisooctyl phthalate (CAS Reg. No. 27554–26–3), ethylphthalyl ethyl glycolate (CAS Reg. No. 84–72–0), and butylphthalyl butyl glycolate (CAS Reg. No. 85–70–1) as a plasticizer at § 181.27 (Ref. 1 at page 3). The Submission states that the survey that FVA used to support the request to remove food additive approvals for these substances did not differentiate between food additive and prior-sanctioned uses of these substances, and so therefore the prior-sanctioned uses should also be considered abandoned. The comment states that based on this evidence, FDA should have either removed the prior-sanction approvals as

part of the final rule “or initiated rulemaking to do so.”

Prior-sanctioned uses are beyond the scope of food additive petitions, which apply only to substances that meet the definition of “food additive” in section 201(s) of the FD&C Act (21 U.S.C. 321(s)). Consequently, prior-sanctioned uses are not the subject of the final rule (87 FR 31080 at 31081). Furthermore, section 409(f)(1) of the FD&C Act permits objections and requests for a hearing only to orders made under section 409(c) and (d) of the FD&C Act. Because FDA has not issued any orders under section 409(c) or (d) of the FD&C Act taking action on the specified prior-sanctioned-uses, the Submission’s request regarding prior-sanctioned uses is not an objection to an order under section 409(c)(1)(B) of the FD&C Act and is not subject to the objections and hearing procedure in section 409(f) of the FD&C Act. Therefore, we will not address requests related to prior-sanctioned uses as part of this objections procedure under section 409(f) of the FD&C Act. The appropriate procedure for requesting rulemaking with respect to prior-sanctioned uses is to submit a citizen petition in accordance with 21 CFR 10.30.

#### C. Comment 2

The Submission states that “we do not object” to the FVA abandonment claim, but states that some of the abandoned substances “may be present in food, food packaging and food handling equipment.” According to the Submission, there is a need for FDA to “clearly communicate to food manufacturers and food packaging and handling equipment manufacturers that they are not permitted to use [the abandoned substances] in food uses that may migrate into food without a specific food additive use approval or a specific authorization[.]”

With respect to the suggestion that FDA needs to further communicate about the final rule, we disagree. We have already adequately communicated the nature and the scope of this action, in accordance with our standard procedures when granting a food additive petition. Specifically, we published the final rule in the **Federal Register**, which is the standard way for Agencies to communicate with regulated parties about substantive matters. We also posted a constituent update on FDA’s website on the date the final rule went on display, informing industry and the public of the changes to the food additive regulations that resulted from the May 20, 2022, final rule and the circumstances around the action (Ref. 3). The constituent update

remains available on FDA's website. Furthermore, in the **Federal Register** of May 20, 2022 (87 FR 31090), we issued a notice requesting information on the use of some *ortho*-phthalates still authorized for food contact uses. The notice also discusses FAP 8B4820 and provides a citation to the final rule (see 87 FR 31090 at 31091).

#### IV. Summary and Conclusions

After evaluating the Submission, for the reasons above, we conclude that the objection does not provide any basis for us to modify our regulations.

#### V. References

The following references are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

1. Neltner, T., Environmental Defense Fund et. al., to the Dockets Management Staff, Food and Drug Administration, dated June 19, 2022.
2. Email from D.W. Hill, Keller and Heckman LLP to S. DiFranco, DPR, OFAS, CFSAN, FDA July 20, 2018.
3. "Phthalates in Food Packaging and Food Contact Applications." Available at: <https://www.fda.gov/food/food-ingredients-packaging/phthalates-food-packaging-and-food-contact-applications>.

Dated: October 22, 2024.

#### Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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**BILLING CODE** 4164-01-P

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 117

[Docket No. USCG-2024-0392]

RIN 1625-AA09

#### Drawbridge Operation Regulation; Dutch Kills, Queens County, NY

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary interim rule and request for comments.

**SUMMARY:** The Coast Guard is temporarily modifying the operating schedule that governs the Hunters Point Ave Bridge across Dutch Kills, mile 1.4,

at Queens County, NY. NYCDOT installed a temporary work platform at Hunters Point Ave Bridge on May 6, 2024 to perform blasting and painting operations. The work platform prevents the bridge from opening to marine traffic. Until the bridge operations are complete the bridge must remain in the closed position.

**DATES:** This temporary interim rule is effective October 30, 2024 through 12:01 a.m. on July 1, 2025. Comments and related material must reach the Coast Guard on or before November 29, 2024.

**ADDRESSES:** To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>. Type the docket number (USCG-2024-0392) in the "SEARCH" box and click "SEARCH". In the Document Type column, select "Supporting & Related Material."

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this temporary interim rule, call or email, Stephanie E. Lopez, Coast Guard; telephone 212-514-4335, email [Stephanie.E.Lopez@uscg.mil](mailto:Stephanie.E.Lopez@uscg.mil).

#### SUPPLEMENTARY INFORMATION:

##### I. Table of Abbreviations

CFR Code of Federal Regulations  
 DHS Department of Homeland Security  
 FR Federal Register  
 NPRM Notice of proposed rulemaking  
 Pub. L. Public Law  
 § Section  
 U.S.C. United States Code  
 NYCDOT New York City Department of Transportation  
 TIR Temporary Interim Rule

##### II. Background Information and Regulatory History

The Coast Guard is issuing this temporary interim rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. This bridge has a work platform installed which keeps the bridge in the closed to navigation position.

On May 6, 2024, the Coast Guard issued a general deviation which allowed the bridge owner, NYCDOT, to deviate from the current operating schedule in 33 CFR 117.801(d) to

conduct bridge blasting and painting operations. Due to additional work that has been discovered, the bridge owner has requested an extension of closure that will take the project past the allowable 180 days for a deviation. Since the bridge cannot be brought back to operating condition until the completion of the mechanical rehabilitation there is insufficient time to provide a reasonable comment period and then consider those comments before issuing the modification.

However, we will be soliciting comments on this rulemaking during the first 30 days while this rule is in effect. If the Coast Guard determines that changes to the temporary interim rule are necessary, we will publish a temporary final rule or other appropriate document.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making it effective in less than 30 days after publication in the **Federal Register**. For reasons presented above, delaying the effective date of this rule would be impracticable and contrary to the public interest because the bridge is currently incapable of normal operations and will not be back into full operation until the rehabilitation work can be completed.

##### III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 499. Hunters Point Ave Bridge across Dutch Kills is a bascule bridge with a vertical clearance of 5.3 feet mean high water in the closed position and unlimited vertical clearance in the open position.

The existing drawbridge regulation, 33 CFR 117.801(d), states that the draw of the Hunters Point Ave Bridge, mile 1.4, shall open on signal if at least two-hour advance notice is given. NYCDOT, the bridge owner, has requested to keep the bridge in the closed position during the remainder of the work.

##### IV. Discussion of the Rule

The Coast Guard is issuing this rule to allow the bridge owner of the Hunters Point Ave Bridge across Dutch Kills, mile 1.4, Queens, New York, to keep the bridge in the closed to navigation position until July 1, 2025. The rule is necessary to accommodate the completion of the blasting and painting operations.

##### V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive Orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive Orders.