



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 175, 176, 177, and 178

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

Flexible Vinyl Alliance; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a petition, submitted by the Flexible Vinyl Alliance (FVA), requesting that we amend our food additive regulations to no longer provide for the use of 26 ortho-phthalates in various food-contact applications because these uses have been permanently abandoned.

DATES: The food additive petition was filed on July 3, 2018. Submit either electronic or written comments by (INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*).

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/ Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2018-F-3757 for "Flexible Vinyl Alliance; Filing of Food Additive Petition." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions:* To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: 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 document into the "Search" box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Stephen DiFranco, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2710.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 409(b)(5) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 348(b)(5)), we are giving notice that we have filed a food additive petition (FAP 8B4820), submitted by FVA, c/o Keller and Heckman, LLP., 1001 G St. NW, suite 500 West, Washington, DC 20001. The petition requests that we amend our food additive regulations in parts 175, 176, 177, and 178 (21 CFR parts 175, 176, 177, and 178) to revoke the approvals for 26 substances that the petition identifies as ortho-phthalates. The petition requests that we revoke the approvals because the food additive uses have been permanently abandoned. The substances affected by this petition and their corresponding Chemical Abstracts Service (CAS) numbers (when available) are listed in table 1. Some of the substances are the subject of approvals in multiple food additive regulations for different uses, and the petition identifies the regulations that authorize the food additive use of the substances. Therefore, we are also listing the regulations that would be affected by this FAP (see tables 2-19). For each regulation that would be affected, we list the specific ortho-phthalates that the regulation authorizes. The petition asserts that the uses of the ortho-phthalates identified in tables 2-19 have been

abandoned. If the FAP is granted in full, none of the ortho-phthalates listed in table 1 would be authorized for food additive use in FDA's food additive regulations. Some of the substances are the subject of prior sanction authorizations. The FAP does not pertain to those prior sanction uses.

Table 1.--Ortho-phthalates That Would be Affected by this FAP

Food Additive	CAS No.
Dimethyl phthalate (dimethyl orthophthalate)	131-11-3
Diphenyl phthalate	84-62-8
Methyl phthalyl ethyl glycolate (1,2-Benzenedicarboxylic acid, 1-(2-ethoxy-2-oxoethyl) 2-methyl ester)	85-71-2
Diethyl phthalate	84-66-2
Diphenylguanidine phthalate ¹	17573-13-6
Ethyl phthalyl ethyl glycolate (Ethyl carbethoxymethyl phthalate)	84-72-0
Diallyl phthalate	131-17-9
Diisobutyl phthalate	84-69-5
Butyl benzyl phthalate	85-68-7
Di-n-butyl phthalate	84-74-2
Butyl phthalyl butyl glycolate ² (Butyl carbobutoxymethyl phthalate)	85-70-1
Dihexyl phthalate (Di-n-hexyl phthalate)	84-75-3
Di(butoxyethyl) phthalate (Bis(2-n-butoxyethyl) phthalate)	117-83-9
Dimethylcyclohexyl phthalate	1322-94-7
Diisooctyl phthalate	27554-26-3
Dioctyl phthalate (Di-n-octyl phthalate)	117-84-0
Butyloctyl phthalate (n-butyl n-octyl phthalate)	84-78-6
Di(2-ethylhexyl) hexahydrophthalate ¹	84-71-9
Amyl decyl phthalate (n-amyl n-decyl phthalate)	7493-81-4
Butyl decyl phthalate (n-butyl n-decyl phthalate)	89-19-0
Decyl octyl phthalate (Octyldecyl phthalate/n-octyl n-decyl phthalate)	119-07-3
Didecyl phthalate (Di-n-decyl phthalate)	84-77-5
Dodecyl phthalate	21577-80-0
Dihydroabietyl phthalate	26760-71-4
Castor oil phthalate, hydrogenated	N/A
Castor oil phthalate with adipic acid and fumaric acid-diethylene glycol	68650-73-7

¹ We note that while these substances are not chemically classified as ortho-phthalates, they are included in FAP 8B4820. The FAP describes all of the substances as ortho-phthalates, although for these substances that characterization is incorrect.

² Substance is named Butyl phthalate butyl glycolate in 21 CFR 175.105. We believe this is a typographical error, and it should be named butyl phthalyl butyl glycolate or butyl carbobutoxymethyl phthalate.

The petition identifies § 175.105, "Adhesives" (21 CFR 175.105) as being impacted by the FAP. Specifically, the petition identifies the use of the substances listed in table 2 as being impacted.

Table 2.--Ortho-phthalates Authorized by § 175.105 That Would be Affected by this FAP ("Adhesives")

Food Additive	CAS No.
Dimethyl phthalate (dimethyl orthophthalate)	131-11-3
Diphenyl phthalate	84-62-8
Methyl phthalyl ethyl glycolate (1,2Benzenedicarboxylicacid, 1-(2-ethoxy-2-oxoethyl) 2-methyl ester)	85-71-2
Diethyl phthalate	84-66-2
Ethyl phthalyl ethyl glycolate (Ethyl carbethoxymethyl phthalate)	84-72-0
Diallyl phthalate	131-17-9
Diisobutyl phthalate	84-69-5
Butyl benzyl phthalate	85-68-7
Di-n-butyl phthalate ¹	84-74-2
Butyl phthalyl butyl glycolate (Butyl carbobutoxymethyl phthalate) ²	85-70-1
Dihexyl phthalate (Di-n-hexyl phthalate)	84-75-3
Di(butoxyethyl) phthalate (Bis(2-n-butoxyethyl) phthalate)	117-83-9
Diisooctyl phthalate	27554-26-3
Dioctyl phthalate (Di-n-octyl phthalate)	117-84-0
Butyloctyl phthalate (n-butyl n-octyl phthalate)	84-78-6
Di(2-ethylhexyl) hexahydrophthalate	84-71-9
Butyl decyl phthalate (n-butyl n-decyl phthalate) ³	89-19-0
Decyl octyl phthalate (Octyldecyl phthalate/n-octyl n-decyl phthalate)	119-07-3
Dihydroabietyl phthalate	26760-71-4

¹ Although the petitioner refers to this substance as di-n-butyl phthalate in the petition, it is listed in § 175.105 as dibutyl phthalate. These terms are synonymous, referring to the same chemical substance.

² Although the petitioner refers to this substance as Butyl phthalyl butyl glycolate phthalate in the petition, it is listed in § 175.105 as Butyl phthalate butyl glycolate. These terms are synonymous, referring to the same chemical substance.

³ Although the petitioner refers to this substance as Butyl decyl phthalate in the petition, it is listed in § 175.105 as Butyldecyl phthalate. These terms are synonymous, referring to the same chemical substance.

The petition identifies § 175.300, "Resinous and polymeric coatings" (21 CFR 175.300), as being impacted by the FAP. Specifically, the petition identifies the use of the ortho-phthalates listed in table 3 as being impacted.

Table 3.--Ortho-phthalates Authorized by § 175.300 That Would be Affected by this FAP ("Resinous and polymeric coatings")

Food Additive	CAS No.
Diethyl phthalate	84-66-2
Ethyl phthalyl ethyl glycolate (Ethyl carbethoxymethyl phthalate)	84-72-0
Di-n-butyl phthalate ¹	84-74-2
Butyl phthalyl butyl glycolate (Butyl carbobutoxymethyl phthalate)	85-70-1
Diisooctyl phthalate	27554-26-3

¹ Although the petitioner refers to this substance as di-n-butyl phthalate in the petition, it is listed in § 175.300 as dibutyl phthalate. These terms are synonymous, referring to the same chemical substance.

The petition identifies § 175.320, "Resinous and polymeric coating for polyolefin films" (21 CFR 175.320), as being impacted by the FAP. Specifically, the petition identifies the use of the ortho-phthalates listed in table 4 as being impacted.

Table 4.--Ortho-phthalates Authorized by § 175.320 That Would be Affected by this FAP ("Resinous and polymeric coatings for polyolefin films")

Food Additive	CAS No.
Diethyl phthalate	84-66-2
Ethyl phthalyl ethyl glycolate (Ethyl carbethoxymethyl phthalate)	84-72-0
Butyl phthalyl butyl glycolate (Butyl carbobutoxymethyl phthalate)	85-70-1

The petition identifies § 175.380, "Xylene-formaldehyde resins condensed with 4,4'-isopropylidenediphenol-epichlorohydrin epoxy resins" (21 CFR 175.380), as being impacted by the FAP. Specifically, the petition identifies the use of the ortho-phthalates listed in table 5 as being impacted. Although the regulation in § 175.380 does not directly refer to these ortho-phthalates, the regulation authorizes their use by cross-referencing § 175.300(b)(3). Although use of ortho-phthalates authorized by § 175.380 would be affected by the FAP, the FAP would not require the regulatory text in § 175.380 to be amended.

Table 5.--Ortho-phthalates Authorized by § 175.380 That Would be Affected by this FAP ("Xylene-formaldehyde resins condensed with 4,4'-isopropylidenediphenol-epichlorohydrin epoxy resins")

Food Additive	CAS No.
Diethyl phthalate	84-66-2
Ethyl phthalyl ethyl glycolate (Ethyl carbethoxymethyl phthalate)	84-72-0
Di-n-butyl phthalate ¹	84-74-2
Butyl phthalyl butyl glycolate (Butyl carbobutoxymethyl phthalate) ²	85-70-1
Diisooctyl phthalate	27554-26-3

¹ Although the petitioner refers to this substance as di-n-butyl phthalate in the petition, it is listed in § 175.300(b)(3) as dibutyl phthalate. These terms are synonymous, referring to the same chemical substance.

The petition identifies § 175.390, "Zinc-silicon dioxide matrix coatings" (21 CFR 175.390) as being impacted by the FAP. Specifically, the petition identifies the use of the ortho-phthalates listed in table 6 as being impacted by the FAP. Although the regulation in § 175.390 does not directly refer to these ortho-phthalates, the regulation authorizes their use by cross-referencing § 175.300. Although use of ortho-phthalates authorized by § 175.390 would be affected by the FAP, the FAP would not require the regulatory text in § 175.390 to be amended.

Table 6.--Ortho-phthalates Authorized by § 175.390 That Would be Affected by this FAP ("Zinc-silicon dioxide matrix coatings")

Food Additive	CAS No.
Diethyl phthalate	84-66-2
Ethyl phthalyl ethyl glycolate (Ethyl carbethoxymethyl phthalate)	84-72-0
Di-n-butyl phthalate ¹	84-74-2
Butyl phthalyl butyl glycolate (Butyl carbobutoxymethyl phthalate)	85-70-1
Diisooctyl phthalate	27554-26-3

¹ Although the petitioner refers to this substance as di-n-butyl phthalate in the petition, it is listed in § 175.300 as dibutyl phthalate. These terms are synonymous, referring to the same chemical substance.

The petition identifies § 176.170, "Components of paper and paperboard in contact with aqueous and fatty foods" (21 CFR 176.170) as being affected by the FAP. Specifically, the petition identifies the use of the ortho-phthalates listed in table 7 as being impacted.

Table 7.--Ortho-phthalates Authorized by § 176.170 That Would be Affected by this FAP ("Components of paper and paperboard in contact with aqueous and fatty foods")

Food Additive	CAS No.
Butyl benzyl phthalate ¹	85-68-7
Di-n-butyl phthalate ²	84-74-2

¹ Although the petitioner refers to this substance as Butyl benzyl phthalate in the petition, it is listed in § 176.170 as Butylbenzyl phthalate. These terms are synonymous, referring to the same chemical substance.

² Although the petitioner refers to this substance as di-n-butyl phthalate in the petition, it is listed in § 176.170 as dibutyl phthalate. These terms are synonymous, referring to the same chemical substance.

The petition identifies § 176.180, "Components of paper and paperboard in contact with dry food" (21 CFR 176.180) as being impacted by the FAP. Specifically, the petition identifies the use of the ortho-phthalates listed in table 8 as being impacted. Although the regulation in § 176.180 does not directly refer to all of these ortho-phthalates, the regulation authorizes the use of all of them either directly or by cross-referencing § 176.170.

Table 8.--Ortho-phthalates Authorized by § 176.180 That Would be Affected by this FAP ("Components of paper and paperboard in contact with dry food")

Food Additive	CAS No.
Diallyl phthalate	131-17-9
Butyl benzyl phthalate	85-68-7
Di-n-butyl phthalate ¹	84-74-2
Didecyl phthalate (Di-n-decyl phthalate)	84-77-5
Dodecyl phthalate	21577-80-0

¹ Although the petitioner refers to this substance as di-n-butyl phthalate in the petition, it is listed in § 176.170 as dibutyl phthalate. These terms are synonymous, referring to the same chemical substance.

The petition identifies § 176.300, "Slimicides" (21 CFR 176.300), as being impacted by the FAP. Specifically, the petition identifies the ortho-phthalates listed in table 9 as being impacted, some of which are permitted as a result of being listed in §§ 176.170 and 176.180.

Table 9.--Ortho-phthalates Authorized by § 176.300 That Would be Affected by this FAP ("Slimicides")

Food Additive	CAS No.
Diallyl phthalate	131-17-9
Butyl benzyl phthalate	85-68-7
Di-n-butyl phthalate	84-74-2
Didecyl phthalate (Di-n-decyl phthalate)	84-77-5
Dodecyl phthalate	21577-80-0

The petition identifies § 177.1010, "Acrylic and modified acrylic plastics, semirigid and rigid" (21 CFR 177.1010) as being impacted by the FAP. Specifically, the petition identifies the use of the ortho-phthalate listed in table 10 as being impacted.

Table 10.--Ortho-phthalates Authorized by § 177.1010 That Would be Affected by this FAP ("Acrylic and modified acrylic plastics, semirigid and rigid")

Food Additive	CAS No.
Dimethyl phthalate (dimethyl orthophthalate)	131-11-3

The petition identifies § 177.1200, "Cellophane" (21 CFR 177.1200) as being impacted by the FAP. Specifically, the petition identifies the use of the ortho-phthalates listed in table 11 as being impacted.

Table 11.--Ortho-phthalates Authorized by § 177.1200 That Would be Affected by this FAP ("Cellophane")

Food Additive	CAS No.
Diisobutyl phthalate	84-69-5
Di-n-butyl phthalate ¹	84-74-2
Dimethylcyclohexyl phthalate	1322-94-7
Castor oil phthalate, hydrogenated	N/A
Castor oil phthalate with adipic acid and fumaric acid-diethylene glycol	68650-73-7

¹ Although the petitioner refers to this substance as di-n-butyl phthalate in the petition, it is listed in § 177.1200 as dibutylphthalate. These terms are synonymous, referring to the same chemical substance.

The petition identifies § 177.1210, "Closures with sealing gaskets for food containers" (21 CFR 177.1210), as being impacted by the FAP. Specifically, the petition identifies the first five ortho-phthalates listed in table 12 as being impacted based on the authorization of their use in § 177.1210. Although the regulation in § 177.1210 does not directly refer to these ortho-

phthalates, the regulation authorizes their use by cross-referencing authorizations in 21 CFR parts 174-178 and § 179.45 (21 CFR 179.45). In addition to the first five ortho-phthalates in table 12 that the petition identifies as being authorized under § 177.1210, § 177.1210 also authorizes the use of the remaining substances that are listed in table 12. We have listed these remaining substances in table 12 because the petition seeks to revoke the food additive approvals for these substances, and § 177.1210 authorizes their food additive use by cross-referencing authorizations in parts 174-178 and § 179.45. Although use of the substances authorized by § 177.1210 that are listed in table 12 would be affected by the FAP, the FAP would not require the regulatory text in § 177.1210 to be amended.

Table 12.--Ortho-phthalates Authorized by § 177.1210 That Would be Affected by this FAP ("Closures with sealing gaskets for food containers")

Food Additive	CAS No.
Diethyl phthalate	84-66-2
Ethyl phthalyl ethyl glycolate (Ethyl carbethoxymethyl phthalate)	84-72-0
Di-n-butyl phthalate	84-74-2
Butyl phthalyl butyl glycolate (Butyl carbobutoxymethyl phthalate)	85-70-1
Diisooctyl phthalate	27554-26-3
Dimethyl phthalate (dimethyl orthophthalate)	131-11-3
Diphenyl phthalate	84-62-8
Methyl phthalyl ethyl glycolate (1,2-Benzenedicarboxylic acid, 1-(2-ethoxy-2-oxoethyl) 2-methyl ester)	85-71-2
Diphenylguanidine phthalate	17573-13-6
Diallyl phthalate	131-17-9
Diisobutyl phthalate	84-69-5
Butyl benzyl phthalate	85-68-7
Diethyl phthalate (Di-n-hexyl phthalate)	84-75-3
Di(butoxyethyl) phthalate (Bis(2-n-butoxyethyl) phthalate)	117-83-9
Dimethylcyclohexyl phthalate	1322-94-7
Diethyl phthalate (Di-n-octyl phthalate)	117-84-0
Butyloctyl phthalate (n-butyl n-octyl phthalate)	84-78-6
Di(2-ethylhexyl) hexahydrophthalate	84-71-9
Amyl decyl phthalate (n-amyl n-decyl phthalate)	7493-81-4
Butyl decyl phthalate (n-butyl n-decyl phthalate)	89-19-0
Decyl octyl phthalate (Octyldecyl phthalate/n-octyl n-decyl phthalate)	119-07-3
Didecyl phthalate (Di-n-decyl phthalate)	84-77-5
Dodecyl phthalate	21577-80-0
Dihydroabietyl phthalate	26760-71-4
Castor oil phthalate, hydrogenated	N/A
Castor oil phthalate with adipic acid and fumaric acid-diethylene glycol	68650-73-7

The petition identifies § 177.1400, "Hydroxyethyl cellulose film, water-insoluble" (21 CFR 177.1400), as being impacted by the FAP. Specifically, the petition identifies the use of the ortho-phthalates listed in table 13 as being impacted. Although the regulation in § 177.1400 does not directly refer to these ortho-phthalates, the regulation authorizes their use by cross-referencing § 177.1200(c). Although use of the ortho-phthalates authorized by § 177.1400 would be affected by the FAP, the FAP would not require the regulatory text in § 175.1400 to be amended.

Table 13.--Ortho-phthalates Authorized by § 177.1400 That Would be Affected by this FAP ("Hydroxyethyl cellulose film, water-insoluble")

Food Additive	CAS No.
Diisobutyl phthalate	84-69-5
Di-n-butyl phthalate ¹	84-74-2
Dimethylcyclohexyl phthalate	1322-94-7
Castor oil phthalate, hydrogenated	N/A
Castor oil phthalate with adipic acid and fumaric acid-diethylene glycol	68650-73-7

¹ Although the petitioner refers to this substance as di-n-butyl phthalate in the petition, it is listed in § 177.1200 as dibutylphthalate. These terms are synonymous, referring to the same chemical substance.

The petition identifies § 177.1460, "Melamine-formaldehyde resins in molded articles" (21 CFR 177.1460), as being impacted by the FAP. Specifically, the petition identifies the use of the ortho-phthalate listed in table 14 as being impacted.

Table 14.--Ortho-phthalates Authorized by § 177.1460 That Would be Affected by this FAP ("Melamine-formaldehyde resins in molded articles")

Food Additive	CAS No.
Dioctyl phthalate (Di-n-octyl phthalate)	117-84-0

The petition identifies § 177.1590, "Polyester elastomers" (21 CFR 177.1590), as being impacted by the FAP. Specifically, the petition identifies the use of the ortho-phthalate listed in table 15 as being impacted.

Table 15.--Ortho-phthalates Authorized by § 177.1590 That Would be Affected by this FAP ("Polyester elastomers")

Food additive	CAS No.
Dimethyl phthalate (dimethyl orthophthalate)	131-11-3

The petition identifies § 177.2420, "Polyester resins, cross-linked" (21 CFR 177.2420), as being impacted by the FAP. Specifically, the petition identifies the use of the ortho-phthalates listed in table 16 as being impacted.

Table 16.--Ortho-phthalates Authorized by § 177.2420 That Would be Affected by this FAP ("Polyester resins, cross-linked")

Food Additive	CAS No.
Dimethyl phthalate (dimethyl orthophthalate)	131-11-3
Butyl benzyl phthalate	85-68-7
Di-n-butyl phthalate	84-74-2

¹ Although the petitioner refers to this substance as di-n-butyl phthalate in the petition, it is listed in § 177.2420 as dibutyl phthalate. These terms are synonymous, referring to the same chemical substance.

The petition identifies § 177.2600, "Rubber articles for repeated use" (21 CFR 177.2600), as being impacted by the FAP. Specifically, the petition identifies the use of the substances listed in table 17 as being impacted.

Table 17.--Ortho-phthalates Authorized by § 177.2600 That Would be Affected by this FAP ("Rubber articles intended for repeated use")

Food Additive	CAS No.
Diphenylguanidine phthalate	17573-13-6
Di-n-butyl phthalate ¹	84-74-2
Di-octyl phthalate (Di-n-octyl phthalate)	117-84-0
Amyl decyl phthalate (n-amyl n-decyl phthalate)	7493-81-4
Decyl octyl phthalate (Octyldecyl phthalate/n-octyln-decyl phthalate)	119-07-3
Didecyl phthalate (Di-n-decyl phthalate)	84-77-5

¹ Although the petitioner refers to this substance as di-n-butyl phthalate in the petition, it is listed in § 177.1200 as dibutyl phthalate. These terms are synonymous, referring to the same chemical substance.

The petition identifies § 178.3740, "Plasticizers in polymeric substances" (21 CFR 178.3740), as being impacted by the FAP. Specifically, the petition identifies the use of the ortho-phthalates listed in table 18 as being impacted.

Table 18.--Ortho-phthalates Authorized by § 178.3740 That Would be Affected by this FAP ("Plasticizers in polymeric substances")

Food additive	CAS No.
Diphenyl phthalate	84-62-8
Butyl benzyl phthalate	85-68-7
Di-hexyl phthalate (Di-n-hexyl phthalate)	84-75-3

The petition identifies § 178.3910, "Surface lubricants used in the manufacture of metallic articles" (21 CFR 178.3910), as being impacted by the FAP. Specifically, the petition identifies the use of the ortho-phthalate listed in table 19 as being impacted.

Table 19.--Ortho-phthalates Authorized by § 178.3910 That Would be Affected by this FAP ("Surface lubricants used in the manufacture of metallic articles")

Food Additive	CAS No.
Diethyl phthalate	84-66-2

II. Abandonment

Under section 409(i) of the FD&C Act, we 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 that the Commissioner of Food and Drugs, on his own initiative or on the petition of any interested person, under 21 CFR part 10, 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 that 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 appeal (§ 171.130(b)). New data must be furnished in the form specified in 21 CFR 171.1 and 171.100 for submitting petitions (id.). Under these regulations, a petitioner may propose that we amend a food additive regulation if the petitioner can demonstrate that there are "old uses abandoned" for the relevant food additive (id.). 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 regulatory authorization is no longer necessary because the use of that food additive has been 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 FAP seeks an amendment to a food additive regulation 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.

As support for the assertion that the food-contact use of the ortho-phthalates listed in the petition has been abandoned, the FAP includes the results of a survey petitioner sent to its members and other firms. The petitioner asked the recipients to verify that they do not:

- Currently manufacture the ortho-phthalates listed in table 1 for use in food contact applications in the United States;
- Currently import the ortho-phthalates listed in table 1 for use in food contact applications in the United States;
- Intend to manufacture or import the ortho-phthalates listed in table 1 for use in food contact applications in the United States in the future;
- Currently maintain any inventory of the ortho-phthalates listed in table 1 for sale or distribution into commerce that is intended to be marketed for use in food contact applications in the United States; or
- Possess any knowledge that the ortho-phthalates listed in table 1 are used in food contact applications in the United States.

The FAP describes the petitioner's members as including plasticizer manufacturers, compounders, formulators, molders and fabricators of polyvinyl chloride (PVC). The petition states that the surveys collected include the substantial majority of phthalate and PVC manufacturers, as well as the downstream compounders and users of the materials.

In addition, the FAP states that petitioner has confirmed with other industry stakeholders that no entities appear to be using or marketing the ortho-phthalates listed in table 1 in the food-contact applications referenced in tables 2-19. The petition states that other industry stakeholders include members of: (1) the Plastics Industry Association's (PIA's) Food, Drug and Cosmetic Packaging Materials Committee, (2) the Adhesives and Sealants Council, (3) the American Beverage Association, (4) the American Forest and Paper Association, (5) the Grocery Manufacturers Association, and (6) the High Phthalates Panel of the American Chemistry Council. The petition states that no member companies from the organizations indicated that they had any knowledge that the regulatory clearances in tables 2-19 are relied upon for use of the ortho-phthalates listed in table 1. With regard to PIA, the petition states that PIA asked its member companies to advise whether they have any knowledge that the subject ortho-phthalates are being used in food-contact applications.

The FAP states that the petition captures the substantial majority of domestic and international phthalate manufacturers and users.

We expressly request comments on FVA's request that we amend §§ 175.105, 175.300, 175.320, 176.170, 176.180, 176.300, 177.1010, 177.1200, 177.1460, 177.1590, 177.2420, 177.2600, 178.3740, and 178.3910 of the food additive regulations to no longer permit the food additive use of the substances listed in table 1 because these uses have been abandoned. Although the regulatory text in §§ 175.380, 175.390, 177.1210, and 179.1400 would not be

amended, these regulations would be affected because they authorize certain uses of substances listed in table 1 by cross-referencing other regulations. Accordingly, we request comments that address whether the use of the substances in table 1 (as authorized in the regulations identified in tables 2-19) have been completely abandoned. For example, we request information on whether food contact materials containing these substances are currently being introduced or delivered for introduction into the U.S. market. Any comments indicating that the specified uses of one or more of the 26 substances have not been abandoned should specify the ortho-phthalate(s) (or substances identified in the petition as ortho-phthalates). We also recommend including information about the use, any relevant regulation(s) authorizing the use, and a description of the product that contains the substance(s).

We are currently unaware of information demonstrating the continued use of these substances in the food contact applications listed. We are providing the public 60 days to submit comments. We anticipate that some interested persons may wish to provide us with certain information they consider to be trade secret or confidential commercial information (CCI) under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552). Interested persons may claim information that is submitted to us as CCI or trade secret by clearly marking both the document and the specific information as "confidential." Information so marked will not be disclosed except in accordance with the Freedom of Information Act and our disclosure regulations (21 CFR part 20). For electronic submissions to <https://www.regulations.gov>, indicate in the "comments" box of the appropriate docket that your submission contains confidential information. Interested persons must also submit a copy of the comment that does not contain the information claimed as confidential for inclusion in the public version of the official record.

Information not marked confidential will be included in the public version of the official record without prior notice.

We are not requesting comments on the safety of these uses of the substances in table 1 because such information is not relevant to abandonment, which is the basis of the proposed action. We will not consider any comments addressing safety in our evaluation of this FAP. In addition to our consideration of this petition, we are considering information on the safety of many of the ortho-phthalates listed in table 1 as part of our consideration of a petition designated for reference as FAP 6B4815 (see 81 FR 31877, May 20, 2016).

The petitioner has claimed that this action is categorically excluded under 21 CFR 25.32(m) because the petition requests an action that would prohibit or otherwise restrict or reduce the use of a substance in food, food packaging, or cosmetics. In addition, the petitioner has stated that, to petitioner's knowledge, no extraordinary circumstances exist. If FDA determines a categorical exclusion applies, neither an environmental assessment nor an environmental impact statement is required. If FDA determines a categorical exclusion does not apply, we will request an environmental assessment and make it available for public inspection.

Dated: November 6, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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