

ENVIRONMENTAL DEFENSE FUND, BREAST CANCER PREVENTION PARTNERS,
ENVIRONMENTAL PROTECTION NETWORK, ENVIRONMENTAL WORKING GROUP,
AND HEALTHY BABIES BRIGHT FUTURES

June 19, 2022

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852.

Re: Objections to FDA's Decision to Partially Grant the Flexible Vinyl Alliance Ortho-Phthalates Abandonment Food Additive Petition at Docket No. FDA-2018-F-3757 for "Indirect Food Additives: Adhesives and Components of Coatings; Paper and Paperboard Components; Polymers; Adjuvants, Production Aids, and Sanitizers.

On May 20, 2022, the Food and Drug Administration (FDA) issued a final rule withdrawing its approval of various food contact uses of 25 ortho-phthalates¹ because the petitioner, the Flexible Vinyl Alliance (FVA), stated to the agency that the uses had been abandoned.² The agency 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.

We, the signatories below, make the following objection to and comments on FDA's decision. We do not request a hearing on the objection.

Objection #1: FDA improperly rejected the abandonment request for diallyl phthalate (CAS Reg. No. 131-17-9) and should remove its approved uses at §§ 175.105, 176.180, 176.300, and 177.1210.

In the food additive petition, the FVA claimed that the food contact uses of diallyl phthalate (CAS Reg. No. 131-17-9) were abandoned.³ FVA specifically asked survey recipients about "food contact applications" and not only about uses as a plasticizer.

Despite the survey results, in the May 20, 2022 *Federal Register* notice, the agency stated that:

"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 makes no claims in their petition that the use of polymers produced with diallyl phthalate for food contact applications have been abandoned. Thus, after following up with the petitioner, diallyl phthalate is no longer subject to this petition, and diallyl phthalate will not be discussed further." 87 FR 31080-81

¹ For these objections we will follow FDA's approach and refer to di(2-ethylhexyl) hexahydrophthalate and diphenylguanidine phthalate as ortho-phthalates because they were designated as such in Food Additive Petition 8B4820.

² FDA, Docket No. FDA-2018-F-3757 for "Indirect Food Additives: Adhesives and Components of Coatings; Paper and Paperboard Components; Polymers; Adjuvants, Production Aids, and Sanitizers," 87 *Federal Register* 31080, May 20, 2022. See <https://www.regulations.gov/document/FDA-2018-F-3757-0017>.

³ FDA, Flexible Vinyl Alliance; Filing of Food Additive Petition, 83 *Federal Register* 56750. See <https://www.regulations.gov/document/FDA-2018-F-3757-0001>.

As a result, diallyl phthalate (CAS Reg. No. 131–17–9) actually remains approved for use as a component in:

- **Adhesives** per [§ 175.105](#) without regard to its potential use as a plasticizer.⁴ If the rule intended to limit the chemical's use as a plasticizer, it would have done so in the second column of the table under paragraph (c)(5) in a similar manner to how it described the use of polypropylene glycol dibenzoate (CAS Reg. No. 72245-46-6) and propylene glycol dibenzoate (CAS Reg. No. 19224-26-1) when it said "For use as a plasticizer at levels not to exceed 20 percent by weight of the finished adhesive."
- **Paper and paperboard in contact with dry food** per [§ 176.180](#) without regard to its potential use as a plasticizer.⁵ If the rule intended to limit the chemical's use as a plasticizer, it would have done so in the second column of the table under paragraph (b)(2) in a similar manner to how it described the use of polypropylene glycol dibenzoate (CAS Reg. No. 72245-46-6), glyceryl tribenzoate (CAS Reg. No. 614-33-5), and diethylene glycol dibenzoate (CAS Reg. No. 120-55-8) when it said "For use only as plasticizer in polymeric substances."
- **Slimicides** used to manufacture paper and paperboard that contact food per [§ 176.300](#) without regard to its potential use as a plasticizer.⁶
- **Sealing gaskets** for food containers per [§ 177.1210](#) without regard to its potential use as a plasticizer.⁷ If the rule intended to limit the chemical's use as a plasticizer, it would have done so in the second column of the table under paragraph (b)(2) in a similar manner to how it described the use of diethylene glycol dibenzoate (CAS Reg. No. 120-55-8), dipropylene glycol dibenzoate (CAS Reg. No. 27138-31-4), and glyceryl tribenzoate (CAS Reg. No. 614-33-5) when it said "For use only as plasticizer in polymeric substances."

FDA's approach to diallyl phthalate is inconsistent with its handling of all of the ortho-phthalates for which the FVA stated abandoned uses, and whose functions were not described as or limited to plasticizer in the agency's rules. FDA provided no rationale for singling out diallyl phthalate for denial of abandonment other than its use was as a monomer to produce polymers.

As we reviewed FDA's description of the process FVA followed to document the abandonment of ortho-phthalate uses in the November 14, 2018 and the May 20, 2022 *Federal Register* notices as well as the supporting references in the docket, the petitioner did not single out diallyl phthalate for special treatment. In its petition, FVA clearly considered diallyl phthalate as abandoned, and FDA supported it in the filing notice for the food additive petition. We find nothing in the comments to contradict the fact that diallyl phthalate appeared to be abandoned.

Therefore, we maintain that FDA improperly rejected the abandonment request for diallyl phthalate and should remove all of its approved uses at §§ 175.105, 176.180, 176.300, and 177.1210. If the agency maintains the approval, FDA needs to demonstrate in the record that the process FVA used to demonstrate that diallyl phthalates are abandoned was flawed, improper, or inadequate. FDA's vague reference to undocumented "follow[] up with the petitioner" is insufficient to sustain this aspect of FDA's decision.⁸

⁴ Other than the general limit of good manufacturing practices.

⁵ Other than the general limit of good manufacturing practices.

⁶ Diallyl phthalates is permitted as a result of being listed in § 176.180. See FDA, Flexible Vinyl Alliance; Filing of Food Additive Petition, 83 *Federal Register* at 56754. See <https://www.regulations.gov/document/FDA-2018-F-3757-0001>.

⁷ Diallyl phthalate is permitted because the regulation authorizes its use by cross-referencing authorizations in 21 CFR parts 174-178 and § 179.45. See FDA, Flexible Vinyl Alliance; Filing of Food Additive Petition, 83 *Federal Register* at 56754-5. See <https://www.regulations.gov/document/FDA-2018-F-3757-0001>.

⁸ 87 *Federal Register* at 31,081.

We make two additional comments on FDA's decision.

Comment #1: FDA should remove the approvals of 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.

As we reviewed FDA's description of the process FVA followed to document the abandonment of ortho-phthalate uses in the November 14, 2018 and the May 20, 2022 *Federal Register* notices as well as the supporting references in the docket, the petitioner did not single out uses of these ortho-phthalates in § 181.27 for special treatment.

The FVA process treated all of the 26⁹ ortho-phthalates covered by its food additive petition similarly without regard to their status as food additive or as prior-sanctioned approved uses. The FVA process did not distinguish between the types of regulatory approvals. It is clear that FVA found all uses to be abandoned including diethyl phthalate's (CAS Reg. No. 84-66-2), diisooctyl phthalate's (CAS Reg. No. 27554-26-3), ethylphthalyl ethyl glycolate's (CAS Reg. No. 84-72-0), and butylphthalyl butyl glycolate's (CAS Reg. No. 85-70-1) use as a plasticizer at [§ 181.27](#).

While we understand that FDA maintains¹⁰ that food additive petitions do not apply to prior-sanctioned uses, we find the agency's decision to grant food additive abandonment yet its failure to also remove the prior-sanction uses flawed. It had sufficient evidence that the prior-sanctioned uses of the four ortho-phthalates as a plasticizer were abandoned and should have either removed the approvals at § 181.27 as part of its decision or initiated rulemaking to do so.

Comment #2: FDA should clearly communicate to food manufacturers and to food packaging and handling equipment manufacturers that the 26 abandoned ortho-phthalates are prohibited for food uses that may result in their migration into food.

We do not object to FVA's claim that the uses of the 26 ortho-phthalates covered by its petition are abandoned¹¹ or to FDA's decision to remove approval for food-additive uses of 25 of them. However, there is evidence based on two resources that these substances may be present in food, food packaging and food handling equipment.

The first resource is the FCCmigex database released in May 2022 by the Food Packaging Forum (FPF) at <https://www.foodpackagingforum.org/fccmigex>. The organization, based in Switzerland describes the database as follows:

The novel Database on Migrating and Extractable Food Contact Chemicals (FCCmigex) systematically maps the scientific evidence of food contact chemicals (FCCs) that have been measured in migrates and extracts of food contact materials and articles. It was compiled by a team of researchers from the Food Packaging Forum together with colleagues from eight academic institutions. The scientists analyzed 1,210 scientific studies that resulted from a

⁹ We include diallyl phthalate in our count. See Objection #1.

¹⁰ FDA, **Natural Resources Defense Council, et al.; Denial of Food Additive Petition; Denial Without Prejudice of Food Additive Petition**, 87 *Federal Register* 31066 at 67.

¹¹ We include the four that had prior-sanctioned use at § 181.27 as a plasticized in our count because the process FVA used found them to be abandoned. See Comment #1. We also include diallyl phthalate because FDA also found its use to be abandoned. See Objection #1.

systematic literature search and passed a two-phase screening process. In total, the database contains more than 3,000 food contact chemicals and over 22,000 database entries.

All FCCs in the database were investigated either for their presence in food contact materials, or for their propensity to transfer into food under real-world conditions,¹² thus making human exposure to these chemicals highly probable. Importantly, only one third of FCCs that were detected in these studies were previously known to be used in the manufacture of food contact materials. And of all the materials investigated, 60% of the studies were on plastics with 1,976 different chemicals detected.

The FCCmigex database is a product of the ongoing Food Contact Chemicals and Human Health (FCCH) [Project](#)¹³ led by the Food Packaging Forum. A peer-reviewed, open-access [article](#)¹⁴ in the scientific journal *Critical Reviews in Food Science and Nutrition* provides detailed information about the compilation of the database and summarizes some of the key information. All data are accessible via the interactive tool below.

We used the database and a search strategy based on the CAS Reg. Nos. for the 26 ortho-phthalates with studies published after 2017¹⁵ and found publicly available references of migration for 14 of the ortho-phthalates considered by FVA as abandoned. In the attached spreadsheet titled “EDF Comment on FCCmigex references for FDA allowed phthalates - Docket FDA-2018-F-3757 6-12-22.xlsx” we provided a description of each of the 14 ortho-phthalates and links to where the migration studies are published. Note that Food Packaging Forum submitted PDF copies of each of the available references in their comments on the citizen petition at docket FDA-2016-P-1171-006.¹⁶
<https://www.regulations.gov/comment/FDA-2016-P-1171-0006>.

We recognize that some of the studies may have been based on samples collected outside the United States or before 2018, but with a global food supply, they run a significant chance of showing up in food in our country.

The second resource consists of studies that analyzed food for ortho-phthalate contamination. We identified five studies, four published between 2013 and 2016 and a recent one of fast-food chains in San Antonio, Texas published in 2021.

- **United Kingdom Total Diet Study (TDS) 2013:** BRADLEY, E. L., BURDEN, R. A., BENTAYEB, K., DRIFFIELD, M., HARMER, N., MORTIMER, D. N., SPECK, D. R., TICHA, J. & CASTLE, L. 2013. Exposure to phthalic acid, phthalate diesters and phthalate monoesters from foodstuffs: UK total diet study results. *Food Addit Contam Part A Chem Anal Control Expo Risk Assess*, 30, 735-42. <https://doi.org/10.1080/19440049.2013.781684>

¹² Protocol for a systematic map of the evidence of migrating and extractable chemicals from food contact articles. 2018. <https://zenodo.org/record/2525277#.Yq9wunbMLYw>

¹³ FPF, Food Contact Chemicals & Human Health Project, Mapping the Evidence on FCCs, accessed on June 12, 2022 at <https://www.foodpackagingforum.org/fcch-project>.

¹⁴ Birgit Geueke, Ksenia J. Groh, Maricel V. Maffini, Olwenn V. Martin, Justin M. Boucher, Yu-Ting Chiang, Frank Gwosdz, Phoenix Jieh, Christopher D. Kassotis, Paulina Łańska, John Peterson Myers, Alex Odermatt, Lindsey V. Parkinson, Verena N. Schreier, Vanessa Srebny, Lisa Zimmermann, Martin Scheringer & Jane Muncke (2022) Systematic evidence on migrating and extractable food contact chemicals: Most chemicals detected in food contact materials are not listed for use, *Critical Reviews in Food Science and Nutrition*, DOI: [10.1080/10408398.2022.2067828](https://doi.org/10.1080/10408398.2022.2067828).

¹⁵ FVA submitted its petition to FDA in 2018. We assumed that the substances listed in the petition would not be found in more recent packaging and processing equipment testing.

¹⁶ FPF Letter to Dennis Keefe, April 2022 at <https://www.regulations.gov/comment/FDA-2016-P-1171-0006>.

- **Canada TDS 2013:** CAO, X.-L., ZHAO, W. & DABEKA, R. 2015. Di-(2-ethylhexyl) adipate and 20 phthalates in composite food samples from the 2013 Canadian Total Diet Study. Food Additives & Contaminants: Part A, 32, 1893-1901. <https://doi.org/10.1080/19440049.2015.1079742>.
- **Australia TDS 2016:** Food Standards Australia & New Zealand, 24th Australian Total Diet Study, 2016, <https://www.foodstandards.gov.au/publications/Pages/24th-Australian-Total-Diet-Study.aspx>.
- **New York State Supermarket Study 2013:** SCHECTER, A., LORBER, M., GUO, Y., WU, Q., YUN, S. H., KANNAN, K., HOMMEL, M., IMRAN, N., HYNAN, L. S., CHENG, D., COLACINO, J. A. & BIRNBAUM, L. S. 2013. Phthalate concentrations and dietary exposure from food purchased in New York State. Environ Health Perspect, 121, 473-94. <https://ehp.niehs.nih.gov/doi/10.1289/ehp.1206367>.
- **San Antonio Fast Food Chains Study 2021:** EDWARDS, L., MCCRAY, N. L., VANNOY, B. N., YAU, A., GELLER, R. J., ADAMKIEWICZ, G. & ZOTA, A. R. 2021. Phthalate and novel plasticizer concentrations in food items from U.S. fast food chains: a preliminary analysis. J Expo Sci Environ Epidemiol. <https://www.nature.com/articles/s41370-021-00392-8>.

These sources document that seven of the 26 ortho-phthalates covered by the FVA food additive petition were present in food. As with the first resource, we recognize that several studies were based on samples collected outside the United States and before 2018, but with a global food supply, they run a significant chance of showing up in food in our country. Note that the San Antonio Fast Food Chain Study of 2021 sampled fast food items from chains in two phases from 2017 to 2018.

The table below summarizes our findings from each of the resources.

Ortho-phthalates that may be in food supply or food contact materials
(sorted by number of references)

FDA Name (CAS No.)	Evidence of migration since 2018 (FPF FCCmigex database)	Found in the diet
Di-n-butyl phthalate (84-74-2)	42 references	Australia TDS 2016 Canada TDS 2013 United Kingdom TDS 2013 New York State Supermarket Study 2013 San Antonio Fast Food Chains Study 2021
Diisobutyl phthalate (84-69-5)	31 references	Canada TDS 2013 New York State Supermarket 2013 San Antonio Fast Food Chains Study 2021
Diethyl phthalate (84-66-2)	24 references	Australia TDS 2016 Canada TDS 2013 United Kingdom TDS 2013 New York State Supermarket Study 2013 San Antonio Fast Food Chains Study 2021
Butyl benzyl phthalate (85-68-7)	15 references	Canada TDS 2013 United Kingdom TDS 2013 New York State Supermarket Study 2013 San Antonio Fast Food Chains Study 2021
Di-n-octyl phthalate (117-84-0)	9 references	New York State Supermarket 2013 San Antonio Fast Food Chains Study 2021

Ortho-phthalates that may be in food supply or food contact materials
(sorted by number of references)

FDA Name (CAS No.)	Evidence of migration since 2018 (FPF FCCmigex database)	Found in the diet
Dimethyl phthalate (131-11-3)	9 references	Australia TDS 2016 New York State Supermarket Study 2013
Di(butoxyethyl) phthalate (117-83-9)	4 references	
Di-n-hexyl phthalate (84-75-3)	3 references	New York State Supermarket Study 2013
Diphenyl phthalate (84-62-8)	3 references	
Diallyl phthalate (131-17-9)	2 references	
Di-n-decyl phthalate (84-77-5)	2 references	
n-octyl n-decyl phthalate (119-07-3 / 1323-73-5)	2 references (for CAS 119-07-3)	
Diisooctyl phthalate (27554-26-3)	2 references	
n-butyl n-octyl phthalate (84-78-6)	1 reference (a thesis)	

Based on these findings, we recommend that FDA clearly communicate to food manufacturers and food packaging and handling equipment manufacturers that they are not permitted to use the 26 abandoned ortho-phthalates in food uses that may migrate into food without a specific food additive use approval or a specific authorization pursuant to a Food Contact Substance Notification.

We also urge the agency to conduct further analyses in food, including in its Total Diet Study, to verify that the 26 abandoned ortho-phthalates are indeed absent from foods.

We thank the agency for the opportunity to file these objections and comments. If you have questions, please contact Tom Neltner at tneltner@edf.org and Maricel Maffini at drmvma@gmail.com.

Sincerely



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