

January 14, 2019

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2018-F-3757, Flexible Vinyl Alliance: Filing of Food Additive Petition
Comments by Breast Cancer Prevention Partners, Center for Environmental Health, Center for Food Safety, Center for Science in the Public Interest, Consumer Federation of America, Environmental Defense Fund, Healthy Babies Bright Futures, Improving Kids' Environment, Learning Disabilities Association of America, and Natural Resources Defense Council

To Whom It May Concern:

Earthjustice, on behalf of Breast Cancer Prevention Partners, Center for Environmental Health, Center for Food Safety, Center for Science in the Public Interest, Consumer Federation of America, Environmental Defense Fund, Healthy Babies Bright Futures, Improving Kids' Environment, Learning Disabilities Association of America, and Natural Resources Defense Council, respectfully submits these comments on the July 3, 2018, petition filed by the Flexible Vinyl Alliance ("the Alliance") requesting that the Food and Drug Administration ("FDA" or the "Agency") revoke its approval of 26 ortho-phthalates that the Alliance claims are no longer used as food additives in food contact applications, Docket No. FDA-2018-F-3757.

In FDA's request for comments on the Flexible Vinyl Alliance petition in the November 14, 2018 *Federal Register* notice, the Agency described industry's claim that the food additive uses of these 26 ortho-phthalates have been permanently abandoned.¹ Because the Alliance has not chosen to allow the Agency to post its petition in the docket, we have no choice but to rely on the Agency's description of the documentation in the notice.² We ask that the Alliance immediately give FDA permission to make its petition public so we can comment on the industry's actual request.

Overview: Ortho-Phthalates and the Alliance's Abandonment Petition

There is currently a class of chemically- and pharmacologically-related food additives known as ortho-phthalates that are approved for use as plasticizers, binders, coating agents, defoamers, gasket closures, and slimicide agents in materials such as cellophane, paper and paperboard, and

¹ Flexible Vinyl Alliance; Filing of Food Additive Pet., 83 Fed. Reg. 56,750 (Nov. 14, 2008)..

² Note that several of the commenters filed a Freedom of Information Act (FOIA) request on December 3, 2018, to obtain a copy of the petition. FDA has not yet fully responded to that FOIA.

plastics that are approved to contact food.³ Exposure to ortho-phthalates can disrupt the endocrine system and result in a variety of reproductive, developmental, and neurological health effects, most notably in children and pregnant women.⁴ Prenatal exposure to ortho-phthalates has been linked to lower IQs in young children and to malformation of the genital tract.⁵ Food is a major source of exposure to these toxic chemicals.⁶

On July 3, 2018, the Alliance filed a petition with FDA requesting that the Agency revoke its approval for use as food additives of 26 ortho-phthalates that the Alliance represents are no longer used as food additives.⁷ The Agency published notice of the petition in the *Federal Register* on November 14, 2018. The petition itself has not been made available to the public.

The Agency seeks public comment on whether the food additive uses of these 26 ortho-phthalates that the Alliance claims have been abandoned have in fact been completely abandoned, or whether instead any food contact materials containing these substances are

³ The Alliance's petition references 30 chemicals designated as ortho-phthalates in food additive petition FAP 6B4815. See Breast Cancer Fund, Ctr. for Env'tl. Health, Ctr. for Food Safety, Ctr. for Sci. in the Pub. Interest, Clean Water Action, Consumer Fed'n of America, Earthjustice, Env'tl. Def. Fund, Improving Kids' Env't, Learning Disabilities Ass'n of America, & Nat. Res. Def. Council; Filing of Food Additive Pet. 81 Fed. Reg. 31,877 (May 20, 2016). Though FDA determined that 2 of the 30 chemicals claimed as ortho-phthalates in FAP 6B4815 did not meet the technical definition of an ortho-phthalate, the Alliance includes those two chemicals on its list of 26 abandoned ortho-phthalates.

⁴ See, e.g., Nat. Res. Def. Council et al., *Food Additive Pet.*, FDA 6 (March 18, 2016) [FAP 6B4815]. The toxicity of phthalates has been discussed in multiple reports by the National Academies. See, e.g., Nat'l Research Council of the Nat'l Acads., *Phthalates & Cumulative Risk Assessment: The Task Ahead* (2008), <https://www.nap.edu/read/12528/chapter/1#xii>; Nat'l Acads. of Scis., Engineering, & Medicine, *Application of Systematic Review Methods in an Overall Strategy for Evaluating Low-Dose Toxicity from Endocrine Active Chemicals* (2017), <https://www.nap.edu/read/24758/chapter/1>.

⁵ See, e.g., Pam Factor-Litvak et al., *Persistent Associations between Maternal Parental Exposure to Phthalates on Child IQ at Age 7 Years*, 9 PLoS ONE (2014), <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0114003>; Shanna H. Swan et al., *Prenatal Phthalate Exposure & Reduced Masculine Play in Boys*, 33 Int'l Journal of Andrology 259 (2010), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2874619/>; Shanna H. Swan et al., *First Trimester Phthalate Exposure & Anogenital Distance in Newborns*, 30 Human Reprod. 963 (2015), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4359397/>; Sally W. Thurston et al., *Phthalate Exposure & Semen Quality in Fertile U.S. Men*, 4 Andrology 632 (2015), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4879116/>.

⁶ CPSC, *Chronic Hazard Advisory Panel on Phthalates & Phthalate Alternatives* 82 (2014), <https://www.cpsc.gov/PageFiles/169902/CHAP-REPORT-With-Appendices.pdf>.

⁷ 83 Fed. Reg. 56,750.

currently being introduced, delivered, or used in the United States market.⁸ The comments below address questions and concerns related to the Agency's request.

Comment 1: The Agency Improperly Delayed Posting Notice of the Abandonment Petition in the *Federal Register*.

The Federal Food, Drug, and Cosmetic Act directs the Agency to post notice of a food additive petition in the *Federal Register* within 30 days of its filing.⁹ The Agency provides no explanation for why it took more than four months to post the notice in this case. The delay is of particular concern because the law also requires FDA to make a final decision on the petition within 180 days of filing.¹⁰ By our calculations, the deadline for a decision passed on December 31, 2018, creating an absurd situation where the decision was required during the public comment period. The delay in publishing the notice raises questions about the seriousness with which the Agency takes these statutory deadlines. We encourage FDA to make timely decisions consistent with the statute.

Comment 2: Nine of 30 Ortho-Phthalates Used in a Total of 28 Applications Are Not Covered by the Alliance's Petition.

Should the Agency grant the Alliance's petition and revoke its approval of the 26 ortho-phthalates contained therein, there would remain nine ortho-phthalates and 28 ortho-phthalates uses approved for use as food contact substances.¹¹ The Agency should clarify in the *Federal Register* notice accompanying any final rule on the abandonment petition that these uses of ortho-phthalates remain approved and must be considered in any future safety assessments for any ortho-phthalates. The nine ortho-phthalates and 28 uses not covered by the petition include:

- **Dicyclohexyl phthalate (DCHP)** (CASRN 84-61-7) at 21 C.F.R. § 175.105 (use in adhesives), *id.* § 176.170 (use in paper and paperboard in contact with aqueous and fatty foods), *id.* § 177.1200 (use in cellophane), and *id.* § 178.3740 (use as plasticizer in polymeric substances).
- **Di(2-ethylhexyl) phthalate (DEHP)** (CASRN 117-81-7) at *id.* § 175.105 (use in adhesives), *id.* § 175.300 (use in resinous or polymeric coatings), *id.* § 175.380 (use in xylene-formaldehyde resins condensed with 4,4'-isopropylidenediphenol-epichlorohydrin epoxy resins), *id.* § 175.390 (use in zinc-silicon dioxide matrix coatings), *id.* § 176.170 (use in paper and paperboard in contact with aqueous and fatty foods), *id.* § 176.180 (use in paper and paperboard in contact with dry food), *id.* § 176.210 (use as a defoaming agent in the manufacture of paper and paperboard), *id.* § 177.1010 (use in

⁸ *Id.* at 56,757.

⁹ Federal Food, Drug, & Cosmetic Act, 21 U.S.C. § 348(b)(5) (2018).

¹⁰ *Id.* § 348(c)(2). The agency has 90 days but can grant itself a 90-day extension.

¹¹ In FAP 6B4815, petitioners requested that FDA revoke its approvals of all 30 ortho-phthalates because their use is no longer safe, describing and providing scientific evidence that exposure to these chemicals – including through food contact applications – causes severe health effects. FDA filed that petition on April 12, 2016 and requested public comments on May 20, 2016. Despite a statutory deadline to decide a petition within 180 days of the petition's filing, the Agency still has not made a decision on that petition.

acrylic and modified acrylic rigid and semi-rigid plastics), *id.* § 177.1200 (use in cellophane), *id.* § 177.1210 (use in sealing gaskets for food containers), *id.* § 177.1400 (use in melamine-formaldehyde resins in molded articles), *id.* § 178.3910 (use in surface lubricants to manufacture metallic articles), and *id.* § 181.27 (use as a plasticizer).

- **Diisononyl phthalate (DINP)** / Bis(7-methyloctyl) phthalate (CASRN 28553-12-0) at *id.* § 178.3740 (use as plasticizer in polymeric substances).
- **Diisodecyl phthalate (DIDP)** / Bis(8-methylnonyl) phthalate (CASRN 26761-40-0) at *id.* § 175.105 (use in adhesives) and *id.* § 175.300 (use in resinous and polymeric coatings), *id.* § 177.1210 (use in sealing gaskets for food containers), *id.* § 177.2600 (use in rubber articles intended for repeated use), and *id.* § 178.3910 (use in surface lubricants to manufacture metallic articles).
- **Diallyl phthalate (DAP)** (CASRN 131-17-9) at *id.* § 176.170 (use as reactant in paper and paperboard in contact with aqueous and fatty foods).
- **Diethyl phthalate (DEP)** (CASRN 84-66-2) at *id.* § 181.27 (use as a plasticizer).
- **Diisooctyl phthalate (DIOP)** (CASRN 27554-26-3) at *id.* (use as a plasticizer).
- **Ethylphthalyl ethyl glycolate (EPEG)** / Ethyl carbethoxymethyl phthalate (CASRN 84-72-0) at *id.* (use as a plasticizer).
- **Butylphthalyl butyl glycolate (BPG)** / Butyl carbobutoxymethyl phthalate (CASRN 85-70-1) at *id.* (use as a plasticizer).

Although the Alliance claimed in its press release¹² that only the first four ortho-phthalates (DCHP, DEHP, DENP, and DIDP) remain relevant in food contact applications, the industry abandonment petition makes no reference to the approved use of the other five ortho-phthalates (DAP, DEP, DIIP, EPEG, and BPG) listed above. The status of these additional ortho-phthalates must be clarified in the *Federal Register* notice of the final rule.

FDA guidance recommends that when assessing risk posed by a food additive, the Agency must consider dietary exposure from *all* approved uses of that additive, including exposure from drinking water, dietary supplements, and naturally occurring substances.¹³ Therefore, the Agency is obligated to consider exposures from all nine remaining approved ortho-phthalates when making a determination as to the safety of ortho-phthalates, including when deciding FAP 6B4815. The Agency also must consider exposures to any other ortho-phthalates to the extent they continue to occur in the diet as a result of, inter alia, contamination.

¹² Flexible Vinyl Alliance, *FDA to Consider Petition to Abandon 26 Ortho-Phthalates*, Cision PR Newswire (Nov. 14, 2018), <https://www.prnewswire.com/news-releases/fda-to-consider-petition-to-abandon-26-ortho-phthalates-300750727.html>.

¹³ FDA, *Guidance for Industry: Estimating Dietary Intake of Substances in Food*, Section III.B. (2006), <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/IngredientsAdditivesGRASPackaging/ucm074725.htm#Bfoo>.

Comment 3: The Agency Does Not Explain How the Petition Affects Installed Food Handling Equipment Containing “Abandoned” Ortho-Phthalates.

As FDA states in the notice, “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. Such abandonment must be complete for any intended uses in the U.S. market.”¹⁴ Thus, to support its claims of abandonment, the Alliance must show that all uses of the 26 listed ortho-phthalates have been permanently abandoned.

According to the *Federal Register* notice, as evidence of its claims, the Alliance sent a survey to its members and other firms asking 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.”¹⁵

We are concerned that the survey questions do not clearly capture uses of these ortho-phthalates in conveyors, tubing, pumps, meters, tanks, chutes, and other equipment installed in facilities that produce food for sale to consumers. Each of these installed uses may release ortho-phthalates into the food that passes through them. And each is an ongoing use that is approved by the FDA. To qualify as abandoned, industry must not only cease to manufacture or sell the equipment containing an ortho-phthalate, but any such equipment must no longer be used in contact with food.

Based on the information in the *Federal Register* notice, it seems that only the last of the five survey questions attempts to address the issue of installed food-handling equipment. However, this question does not go far enough. Given the long life expectancy of some types of installed equipment, more is needed than someone’s statement that he or she does not possess knowledge of the use. For example, the Agency would need to know the most recent year that equipment containing ortho-phthalates was sold, as well as the life expectancy of that equipment, and whether the person completing the survey possesses sufficient knowledge of the food handling equipment materials and uses to answer the questions accurately.

If the Agency accepts the abandonment claim, then any company using installed equipment containing ortho-phthalates that come in contact with food would be violating the law. We

¹⁴ 83 Fed. Reg. at 56,757.

¹⁵ *Id.*

therefore request that when publishing the final rule, the Agency explicitly state that continued use of installed equipment with abandoned ortho-phthalates that come into contact with food is unlawful and that the food would be adulterated.

Alternatively, should public comments or other information before the Agency reveal that some of the 26 ortho-phthalates included in the Alliance's petition continue to be used in installed equipment that contacts food, the Agency should not revoke its approval of those substances. And it must continue to count the estimated migration of ortho-phthalates into food from each and every contact with the installed equipment as part of its safety evaluation of the remaining ortho-phthalates.

Comment 4: It Is Not Clear from the *Federal Register* Notice What Parts of Industry Were Not Included in the Alliance's Survey of Abandonment.

To support its claim for abandonment, the Alliance sent surveys and received information from the following entities: its members, who the Alliance describes as including "plasticizer manufacturers, compounders, formulators, molders and fabricators of polyvinyl chloride"; and "other industry stakeholders," including members of a number of industry associations.¹⁶ The Alliance claims its petition "captures the substantial majority of domestic and international phthalate manufacturers and users," and that the responses it received demonstrate that these chemicals have been permanently abandoned as food additives.¹⁷

From the information provided in the *Federal Register* notice, it is not clear what parts of industry were not included in the Alliance's survey.¹⁸ As a result, the Agency does not currently know whether and to what extent those left out of the survey continue to manufacture and/or use ortho-phthalates in food contact applications. Yet should the Agency grant the abandonment petition, all food contact uses of the subject ortho-phthalates by any food manufacturer will be unlawful. Accordingly, we request that FDA explicitly state in the *Federal Register* notice of the final rule that food contact use of an ortho-phthalate for which the Agency revokes its approval renders the product adulterated and thus illegal.

Comment 5: FDA should clarify that for any abandoned ortho-phthalates, all prior and future uses that have been or will be deemed "generally recognized as safe" are invalid.

If the Agency approves the Alliance's petition, there remains a risk that some subset of these substances may continue to be used by industry, or may be used by the industry in the future. Under the Federal Food, Drug, and Cosmetic Act, a substance is not categorized as a food additive if it is "generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures

¹⁶ 83 Fed. Reg. at 56,757.

¹⁷ *Id.*

¹⁸ The Alliance's statement that it included the "substantial majority" necessarily implies that there is some quantity of firms or stakeholders that were not surveyed as part of this petition. *Id.*

... to be safe under the conditions of its intended use.”¹⁹ The use of substances satisfying this showing are considered to be “generally recognized as safe,” or “GRAS.”

Under FDA’s current regulations, manufacturers can secretly certify substances as GRAS without any Agency oversight, public participation, or judicial review. *See* Substances Generally Recognized as Safe, 81 Fed. Reg. 54,960 (Aug. 17, 2016) (codified at 21 C.F.R. pts. 20, 25, 170, 184, 186 & 570).²⁰ As a result, if FDA accepts the petition and removes its approval from the food additive regulations, manufacturers might self-certify that certain ortho-phthalates or specific uses of ortho-phthalates are GRAS (and thus not food additives), and could thereby continue to use some subset of the abandoned ortho-phthalates in food contact applications. In this situation, neither FDA nor the public would necessarily receive notice of that ongoing use.²¹ Yet as FDA’s notice makes clear – and as the law requires – for any ortho-phthalate for which FDA grants the petition and revokes its approval, no food additive use of that substance will be permitted.²² Thus, allowing industry to continue any use of the otherwise abandoned ortho-phthalates under the GRAS system could allow unregulated use of substances that the Alliance has represented are permanently out of use.²³

This use under the GRAS system of any abandoned ortho-phthalate would also affect safety assessments of any ortho-phthalates for which FDA does not revoke its approval. Given that risk posed by ortho-phthalates is determined by cumulative exposure from all sources, any unknown or unreported use of ortho-phthalates (such as GRAS uses) would unknowingly and unlawfully be omitted from such risk assessments.

Thus, to ensure that industry has not and does not self-certify as GRAS uses of ortho-phthalates over which FDA revokes its approval in response to the Alliance’s abandonment petition, FDA should clarify in the *Federal Register* notice of the final rule that abandoned substances and uses cannot be GRAS. Such clarification is necessary to help ensure the Agency’s proper oversight over the food additive system, and to prevent skewing the risk assessments of the nine ortho-phthalates and 28 food application uses not covered by the petition.

¹⁹ 21 U.S.C. § 321(s).

²⁰ Several of the organizations submitting these comments have challenged FDA’s regulations in a different forum, arguing that allowing industry to self-certify substances as GRAS an unlawful delegation of authority and is arbitrary, capricious, and an abuse of discretion. *See* Complaint for Declaratory & Injunctive Relief, *Center for Food Safety et al v. Price et al*, No. 1:17-cv-03833-VSB (S.D.N.Y. 2017).

²¹ Once FDA revokes its approval of a food additive, there is no record of the process in the regulations. Thus, industry may not be aware that a particular ortho-phthalate was once – but no longer is – approved for use as a food additive.

²² 83 Fed. Reg. at 56,751.

²³ Any attempt by industry to certify an abandoned use as GRAS after representing to FDA that all uses were permanently abandoned would be disingenuous, deceitful, and an abuse of the abandonment process.

For more information or questions regarding these comments, please contact Carrie Apfel at 202-797-4310 or capfel@earthjustice.org.

Respectfully submitted,

/s/ Carrie Apfel

Carrie Apfel
Earthjustice
1625 Massachusetts Ave., N.W., Suite 702
Washington, D.C. 20036-2243
202-797-4310
capfel@earthjustice.org

Peter Lehner
Earthjustice
48 Wall Street, 15th Floor
New York, NY 10005
212-845-7389
plehner@earthjustice.org