4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-0571]

***Ortho*-phthalates for Food Contact Use; Request for Information**

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice; request for information.

SUMMARY: The Food and Drug Administration (FDA or we) is opening a docket to obtain data and information on the use of *ortho*-phthalates (or "phthalates") for food contact applications. Specifically, FDA is seeking scientific data and information on current uses, use levels, dietary exposure, and safety data of certain *ortho*-phthalates. The purpose of this request is to provide FDA with all sources of relevant information to support our review of the current use levels and safe use of these *ortho*-phthalates in food contact applications.

DATES: Submit either electronic or written comments and scientific data and information 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-2022-N-0571 for "*Ortho*-phthalates for Food Contact Use; Request for Information." Received comments, those filed in a timely manner (see ADDRESSES), 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, 240-402-7500.

- 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.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf

Docket: For access to the docket to read background documents or the electronic and written/paper 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, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Jessica Urbelis, Center for Food Safety and Applied Nutrition (HFS-275), Food and Drug Administration, 5001 Campus Dr., College Park,

MD 20740, 240-402-5187; or Meadow Platt, Office of Regulations and Policy (HFS-024), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

SUPPLEMENTARY INFORMATION:

I. Background

A. Introduction

Ortho-phthalates may be used as plasticizers for polymers, most commonly poly (vinyl chloride), to make the polymers less brittle or to soften them. These polymers are then used in a wide range of products, such as toys, vinyl flooring and wall covering, detergents, lubricating oils, food packaging, pharmaceuticals, blood bags and tubing, and personal care products. Our food additive regulations at parts 175, 176, 177, 178, and 181 (21 CFR parts 175, 176, 177, 178, and 181) provide for the safe use of certain *ortho*-phthalates as plasticizers for packaging used to contact food and for other food contact applications, such as components of adhesives, resins, lubricants, and sealants.

B. Recent Petitions

In the *Federal Register* of May 20, 2016 (81 FR 31877), we announced that we had filed a food additive petition (FAP 6B4815) in accordance with 21 CFR 171.130. The food additive petition (FAP 6B4815) proposed that we amend or revoke certain food additive regulations under parts 175, 176, 177, and 178 to no longer provide for the food contact use of specified *ortho*-phthalates. The petitioners based their petition on the claim that new evidence demonstrates the use of these *ortho*-phthalates in food contact applications is unsafe. Elsewhere in this issue of the *Federal Register*, we have published a final rule in response to FAP 6B4815 denying that petition.

On April 20, 2016, we received a citizen petition (Docket No. FDA-2016-P-1171) requesting that we initiate rulemaking to remove the prior sanctions in part 181 for the following five *ortho*-phthalates: di(2-ethylhexyl) phthalate (CAS No. 117-81-7), diethyl phthalate (CAS

No. 84-66-2), ethyl phthalyl ethyl glycolate (CAS No. 84-72-0), butyl phthalyl butyl glycolate (CAS No. 85-70-1), and diisooctyl phthalate (CAS No. 27554-26-3). FDA defined the term "prior sanction" in § 170.3(*l*) (21 CFR 170.3(*l*)) as an explicit approval granted with respect to use of a substance in food prior to September 6, 1958, by FDA or the United States Department of Agriculture (USDA), pursuant to the FD&C Act, the Poultry Products Inspection Act, or the Meat Inspection Act. The term "prior sanction" derives from section 201(s)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321(s)(4)), which excepts from the definition of a food additive any substance used in accordance with a sanction or approval granted before September 6, 1958, the date of enactment of the Food Additives Amendment to the FD&C Act. Before that date, we had approved specific uses of various food-contact materials or food ingredients by issuing letters and other statements that, in FDA's view, these substances were "not considered unsafe," that they did "not present a hazard," or that we "did not object to their use." The existence of a prior sanction exempts sanctioned uses from the food additive provisions of the FD&C Act but not from the other adulteration or the misbranding provisions of the FD&C Act (§ 181.5(b)). The prior sanction exists only for a specific use of a substance in food and delineates level(s), condition(s), and product(s) set forth by explicit approval by FDA or USDA before September 6, 1958 (§ 181.5(a)). Some prior sanctioned substances are codified in part 181. The citizen petition also requested that we add a new section to 21 CFR part 189 prohibiting the use of the following eight *ortho*-phthalates: diisobutyl phthalate (CAS No. 84-69-5), di-n-butyl phthalate (CAS No. 84-74-2), butyl benzyl phthalate (CAS No. 85-68-7), dicyclohexyl phthalate (CAS No. 84-61-7), di-n-hexyl phthalate (CAS No. 84-75-3), diisooctyl phthalate (CAS No. 27554-26-3), di(2-ethylhexyl) phthalate (CAS No. 117-81-7), and diisononyl phthalate (CAS No. 28553-12-0). We are denying this citizen petition.

In the *Federal Register* of November 14, 2018 (83 FR 56750), we announced that we had filed a food additive petition (FAP 8B4820) submitted in accordance with § 171.130. That FAP (8B4820) proposed to amend parts 175, 176, 177, and 178 to no longer provide for certain uses

of *ortho*-phthalates on the basis that the use of those *ortho*-phthalates in food contact applications has been abandoned. Elsewhere in this issue of the *Federal Register*, we have published a final rule in response to FAP 8B4820 granting that petition and amending parts 175, 176, 177, and 178 to no longer authorize the uses of the subject *ortho*-phthalates in food contact applications because those uses have been permanently and completely abandoned.

FAP 8B4820 includes the *ortho*-phthalates that are addressed in FAP 6B4815 except for the following: diisononyl phthalate (DINP) (CAS No. 28553-12-0), diisodecyl phthalate (DIDP) (CAS No. 26761-40-0), di(2-ethylhexyl) phthalate (DEHP) (CAS No. 117-81-7), and dicyclohexyl phthalate (DCHP) (CAS No. 84-61-7). These four phthalates are not included in the final rule for FAP 8B4820 because the petition does not claim that their uses have been abandoned. In addition, FAP 8B4820 does not include diallyl phthalate (CAS No.) 131-17-9. Diallyl phthalate is only authorized for use in these regulations as a monomer in the manufacture of polymers and not as a plasticizer.

C. Current Status of Information

The original safety assessments that resulted in the authorized uses of *ortho*-phthalates in food contact applications were based on exposure and toxicological information and data provided during the period of 1961 through 1985. As the food supply and packaging market has changed since that time, the use of *ortho*-phthalates in food contact materials has also evolved. Furthermore, the body of available toxicological information on phthalates has expanded since the food contact uses of *ortho*-phthalates were authorized. While FDA is generally aware of updated toxicological and use information on phthalates that is publicly available, we are also aware that stakeholders do not always make such information public. As such, we request all updated information regarding the food contact uses, use levels, and dietary exposure and safety data for the *ortho*-phthalates listed below that are currently in use in food contact applications. We may use this information to update the dietary exposure estimates and safety assessments for the permitted food contact uses of *ortho*-phthalates. While we are responding to the food

additive petitions and citizen petition based on the information provided in those petitions and other relevant and available data, the information we are requesting may add to our knowledge of *ortho*-phthalates that remain authorized for use.

II. Request for Information

FDA is requesting information on the current food contact uses, use levels, dietary exposure and safety data on *ortho*-phthalates currently used in food contact applications. FDA is not requesting this information for uses that have been abandoned. Specifically, FDA requests the following:

1. Information on any current specific food-contact uses and use levels for the following *ortho*-phthalates found in FDA's regulations (as food additives and/or prior sanctioned substances): diisononyl phthalate (DINP, CAS No. 28553-12-0), diisodecyl phthalate (DIDP, CAS No. 26761-40-0), di(2-ethylhexyl) phthalate (DEHP, CAS No. 117-81-7), dicyclohexyl phthalate (DCHP, CAS No. 84-61-7), butylphthalyl butyl glycolate (BPBG, CAS No. 85-70-1), diethyl phthalate (DEP, CAS No. 84-66-2), ethylphthalyl ethyl glycolate (EPEG, CAS No. 84-72-0) and diisooctyl phthalate (DIOP, CAS No. 27554-26-3);
2. Data, analyses, and any other information related to dietary exposure from the use of *ortho*-phthalates listed in item 1 currently in food contact applications;
3. Safety data for all *ortho*-phthalates listed in item 1 currently used in food contact applications; and/or
4. Information regarding any prior sanctioned uses of *ortho*-phthalates not listed in FDA's regulations. This includes documentation to support the prior sanction and the information requested in items 1 through 3 above on the current use(s), use levels, exposure, and safety information for any such prior-sanctioned *ortho*-phthalates currently in use.

Dated: May 11, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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