EARTHJUSTICE

Submitted online

December 3, 2018

Food and Drug Administration
Division of Freedom of Information
Office of the Executive Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857

Re: **FOIA Request for Records Related to Phthalate Exposure and Safety Information**

Breast Cancer Prevention Partners ("BCPP"), Environmental Defense Fund ("EDF") and Learning Disabilities Association of America ("LDA") (the "Requesters") submit this request for information under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, and the Food and Drug Administration ("FDA") FOIA regulations, 21 C.F.R. pt. 20.

I. RECORDS REQUESTED

Request 1: In a press release,[1] the Flexible Vinyl Alliance (FVA) stated that:

> Concurrently, the FVA also provided exposure data to FDA on four ortho-phthalates that remain relevant in food contact applications: DIDP, DINP, DEHP and DCHP. Exposure assessments and safety data on these four plasticizers was provided in confidence to FDA in an accompanying document.

We request any exposure or safety data regarding the four ortho-phthalates referenced above – diisodecyl phthalates (DIDP), diisononyl phthalate (DINP), di(2-ethylhexyl) phthalate (DEHP), and dicyclohexyl phthalates (DCHP) – that FVA submitted to the agency.

Request 2: We also request any exposure or safety data on five additional ortho-phthalates with one or more uses that are not affected by FVA's abandonment petition: diallyl phthalate (as used as a component of paper or paperboard in contact with aqueous and fatty foods), and the four phthalates with prior sanctioned uses not covered by the petition (diethyl phthalates (DEP), ethyl phthalyl ethyl glycoloate, butyl phthalyl butyl glycolate, and diisooctyl phthalates (DIOP)). The information requested relates only to ortho-phthalates or uses of ortho-phthalates that have *not* been abandoned.

We note that FDA has stated that safety data "is not relevant to abandonment" and will not be considered by the agency when evaluating the abandonment petition. *See* 83 Fed. Reg. at 56,758. Thus, the exposure and toxicology information essential to evaluating safety is not relevant to FVA's abandonment petition and therefore should not be protected from release under 21 C.F.R., pt. 171.

[1] The press release is available at: https://www.prnewswire.com/news-releases/fda-to-consider-petition-to-abandon-26-ortho-phthalates-300750727.html

II. A FEE WAIVER IS APPROPRIATE

Pursuant to 5 U.S.C. § 552(a)(4)(A)(iii) and 21 C.F.R. § 20.46, Requesters ask that FDA waive all fees associated with responding to this request because Requesters seek this information in the public interest and will not benefit commercially from this request.

FOIA provides that fees shall be reduced "if disclosure of the information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester." 5 U.S.C. § 552(a)(4)(A)(iii). FDA's FOIA regulations contain a nearly identical requirement and identify six factors to assess whether a requester is entitled to a waiver of fees under FOIA. 21 C.F.R. § 20.46.

FOIA carries a presumption of disclosure, and the fee waiver was designed specifically to allow nonprofit, public-interest groups, such as Requesters, access to government documents without the payment of fees. The courts have stated that the statute "is to be liberally construed in favor of waivers for noncommercial requesters." *See Judicial Watch v. Rossotti*, 326 F.3d 1309, 1312 (D.C. Cir. 2003). As explained below, Requesters meet the criteria for a fee waiver established in FOIA and outlined in FDA's implementing regulations.

A. Disclosure of this information is in the public interest because it will likely contribute significantly to public understanding of the operations or activities of the government.

Requesters qualify for a fee waiver because, as discussed below, the requested information will contribute significantly to public understanding of the operations or activities of the federal government. *See* 21 C.F.R. § 20.46(b). BCPP, EDF, and LDA possess the ability to disseminate the information to the general public, and, in fact, such dissemination is routine to their operations.

Requesters are active in informing their constituencies about ortho-phthalate exposure and are well-positioned to enhance the public's understanding of potential exposures through food by analyzing and disseminating the requested information to members and the general public.

1. The Subject Matter of the Requested Documents Pertains to Operations or Activities of the Federal Government

Under the first factor used to consider fee waivers, FDA must consider "[w]hether the records to be disclosed pertain to the operations or activities of the Federal Government." 21 C.F.R. § 20.46(b)(1). Requesters seek documents regarding exposure assessments and safety data on four ortho-phthalates and five uses of ortho-phthalates that remain relevant in food contact applications: DIDP, DINP, DEHP and DCHP, as well as diallyl phthalate (as used as a component of paper or paperboard in contact with aqueous and fatty foods), and the four phthalates with prior sanctioned uses not covered by the abandonment petition (DEP, ethyl phthalyl ethyl glycoloate, butyl phthalyl butyl glycolate, and DIOP). The Federal Food, Drug, and Cosmetic Act requires FDA to "protect the public health by ensuring that … foods are safe, wholesome, sanitary, and properly labeled[.]" 21 U.S.C. § 393(b). FDA thus has a legal duty to consider information and data reflecting on the safety of food additives and food contact materials. Given FDA's obligation to ensure the safety of our food, exposure assessments and safety data submitted to FDA on ortho-phthalates that continue to be used in food contact applications clearly implicate "the operations and activities of the government," 5 U.S.C. § 552(a)(4)(A)(iii); *see also Citizens for Responsibility & Ethics in Washington v. U.S. Dep't of Health & Human Servs.*, 481 F. Supp. 2d 99, 107-08 (D.D.C. 2006); *Judicial*

Watch v. Dep't of Transp., Civ. No. 02-566-SBC, 2005 WL 1606915, at *4 (D.D.C. July 7, 2005).

Moreover, we are requesting the records with reasonable specificity. *See Rossotti*, 326 F.3d at 1313 (D.C. Cir. 2003) (quoting *Larson v. Cent. Intelligence Agency*, 843 F.2d 1481, 1483 (D.C. Cir. 1988)) (noting that to satisfy the first prong of a fee waiver request, government operations or activities must only be identified with "'reasonable specificity'—all that FOIA requires"). Here, Requesters request a reasonably specified set of records.

2. The Disclosure Would Likely Reveal Meaningful Information about Government Operations or Activities that is not Already Public Knowledge

Under the second factor used to consider fee waivers, FDA must consider "[w]hether disclosure of the records would reveal any meaningful information about Government operations or activities that is not already public knowledge." 21 C.F.R. § 20.46(b)(2). Disclosure of the requested records is likely to reveal "meaningful information" about government operations or activities by allowing the public to see exposure assessments and safety data on four ortho-phthalates and five ortho-phthalates uses currently used in food contact applications that industry does not intend to abandon – data that FDA has before it when determining whether use of these chemicals in these ways remain safe. This information is meaningful because there is wide public concern about exposure to ortho-phthalates given recent attention to the hazards of this chemical in food contact materials. Considering that this exposure and safety data was submitted to FDA, and given FDA's obligation to ensure the safety of our food, the requested documents reveal meaningful information about what FDA had before it when determining whether these food-related uses of these chemicals remain safe. Therefore, the foregoing request for documents meets the second factor for a fee waiver by seeking "meaningful information about government operations or activities" that is not already public knowledge.

3. The Disclosure Will Advance the Understanding of the General Public as Distinguished from a Narrow Segment of Interested Persons

Under the third factor, FDA regulations state that it "may consider whether the requester has such knowledge or expertise as may be necessary to understand the information" and "whether the requester's intended use of the information would be likely to disseminate the information to the public." 21 C.F.R. § 20.46(b)(3). In determining whether the disclosure of requested information will advance the understanding of the general public, a guiding test is whether the disclosed documents will reach "a reasonably broad audience of persons interested in the subject." *Carney v. U.S. Dep't of Justice*, 19 F.3d 807, 815 (2d Cir. 1994). Requesters use a variety of platforms to disseminate information to the public. For example, EDF has the capacity to write a report analyzing and summarizing information obtained through the FOIA request, and publicize the report to its two million members and activists through its blog and other publications. BCPP maintains a webpage translating available scientific information on phthalate exposure and breast cancer risk for members of the public. LDA disseminates information on the prevention of risk factors for learning disabilities and other neurodevelopmental disorders; exposure to phthalates is one such risk factor..

Requesters' use of a variety of platforms ensures that the requested information will reach a "reasonably broad" audience of people.

4. The Contribution to the General Public Will Likely Be Significant

As described above, Requesters communicate with supporters, members and the general public through a variety of means. Requesters plan to disseminate the pertinent information contained in the requested records to affected communities and stakeholders across the country. This type of dissemination has been held sufficient to satisfy this prong of the fee waiver determination. *See Judicial Watch, Inc. v. Gen. Servs. Admin.*, CIV.A. 98-2223 (RMU), 2000 WL 35538030, at *9 (D.D.C. Sept. 25, 2000) (holding that an organization satisfied FOIA's requirement that information be disseminated to a reasonably broad segment of the public where the organization had an established history of disseminating information and proposed to post disclosed information for public review on its website); *see also D.C. Technical Assistance Org., Inc. v. U.S. Dep't of Hous. & Urban Dev.*, 85 F. Supp. 2d 46, 49 (D.D.C. 2000) ("In this Information Age, technology has made it possible for almost anyone to fulfill [FOIA's dissemination requirement]."); *see also Or. Natural Desert Ass'n v. U.S. Dep't of Interior*, 24 F. Supp. 2d 1088, 1095-96 (D. Or. 1998) (relying on *Friends of the Coast Fork v. U.S. Dep't of the Interior*, 110 F.3d 53, 55-56 (9th Cir. 1997)) (finding that the organization established a prima facie case that "contribution to public understanding" was significant where organization sought a fee waiver request for monitoring data and gave a "lengthy articulation of its reasons for requesting the information," explained "what it would do with that information," "how [it] would disseminate" the information, and "to whom").

Furthermore, information about the exposure to and safety of ortho-phthalates is not readily available to the public. Disclosure and dissemination of this information would enhance the public's ability to make fully informed purchases of food. The current absence of the FDA's data in the public domain, coupled with Requesters' ability and intent to disseminate the records upon disclosure, is sufficient to satisfy the significance prong of a fee waiver request. *See Fed. CURE v. Lappin*, 602 F. Supp. 2d 197, 205–06 (D.D.C. 2009) (finding that, even in the absence of a "specific plan for interpreting [] information before disseminat[ion]," the public's understanding will be significantly enhanced by disseminating information otherwise not in the public domain).

B. Obtaining the Information Is of No Commercial Interest to Requesters

The fifth and sixth factors FDA must consider relate to the possible existence and magnitude of a commercial interest in disclosure. *See* 21 C.F.R. § 20.46(c). Two questions must be addressed when determining whether the information requested is "primarily in the commercial interest of the requester." 5 U.S.C. § 552(a)(4)(A)(iii). The first question is whether the requester has a commercial interest that would be furthered by the requested disclosure. Here, as 501(c)(3) nonprofit entities, Requesters have no commercial, trade, or profit interest in the material requested. Requesters will not be paid for or receive other commercial benefits from the publication or dissemination of the material requested. The requested material will be disseminated solely for the purpose of informing and educating the public and will not be used for commercial use or gain.

The final factor hinges on the primary interest in the disclosure. FDA must assess whether any commercial interest "outweighs the advancement of the public interest." 21 C.F.R. § 20.46(c). There is great public interest in the release of the materials sought because they will allow for a more thorough understanding of how the public can protect itself from exposure to ortho-

phthalates. This information will contribute to the work of numerous other public interest organizations looking at ortho-phthalates exposure through various pathways throughout the country. The disclosure of the requested information is therefore "not primarily in the commercial interest of" Requesters, and a fee waiver is appropriate. 5 U.S.C. § 552(a)(4)(A)(iii).

Under these circumstances, Requesters fully satisfy the criteria for a fee waiver.

III. CONCLUSION

Pursuant to FOIA and FDA's FOIA regulations, the agency has **20 working days** from the date of its receipt of this request to decide whether to grant the request, and it must notify the requester of the decision. *See* 5 U.S.C. § 551(a)(6)(A)(i); 21 C.F.R. § 20.41(b). Please produce the requested records by emailing or mailing them to the address listed below. The agency should provide the information as it becomes available. Because our first request is a discrete set of documents recently submitted by FVA, we would anticipate that FDA can – and will – produce the responsive documents relatively quickly.

If you have any questions about the records we are seeking, you can contact me at the information below. We also welcome the opportunity to clarify our request with FDA's FOIA Officer(s) via phone.

If for some reason the fee waiver is denied, please contact me before incurring any costs related to this request. If the fee waiver is not granted and costs are incurred prior to approval by Requesters, Requesters will not be responsible for those costs.

Thank you in advance for your prompt reply.

Sincerely,

Carrie Apfel
Staff Attorney
Earthjustice
1625 Massachusetts Ave, NW, Suite 702
Washington, DC 20036
202-797-4310
capfel@earthjustice.org