Submitted online

July 30, 2019

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 Per- and Polyfluoroalkyl Substance**

Environmental Defense Fund ("EDF"), Environmental Working Group ("EWG"), and Environmental Health Strategy Center ("EHSC") submits this request for information under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, and the Food & Drug Administration ("FDA") FOIA regulations, 21 C.F.R. pt. 20.

I. RECORDS REQUESTED

EDF, EWG, and EHSC are requesting documents describing the analytical results of per- and polyfluoroalkyl substances (PFAS) studies described on its webpage at https://www.fda.gov/food/chemicals/and-polyfluoroalkyl-substances-pfas. Using the descriptions on the webpage. The studies are:

- Dairy, 2018-2019;
- Produce, 2018; and
- Produce, meat, dairy, and grain products, 2019.

For each of the studies, we request documents related to the following:

- Sample selection and collection including for the "Produce, meat, dairy, and grain products, 2019" study the identity of the cities and retail outlets in the mid-Atlantic region where the samples were collected in October 2017 and the description and photos of the 91 items collected from each of the cities;
- Analysis including calculations of the detectable limit or Limit of Detection (LOD) and the Limit of Quantitation (LOQ) or lower LOQ (LLOQ);
- Analytical results between the LOD and either the LOQ or the LLOQ;
- Reference dose (RfD), acceptable dietary intake (ADI), estimated dietary intake (EDI) for the 16 PFAS analyzed individually or in combination; and
- Evaluation, including calculations, supporting FDA's statement on the webpage regarding each of the three studies that "Based on the best available current science, the FDA has no indication that these substances at the levels found in the limited sampling present a human health concern."

II. A FEE WAIVER IS APPROPRIATE

Pursuant to 5 U.S.C. § 552(a)(4)(A)(iii) and 21 C.F.R. § 20.46, EDF, EWG, and EHSC request that FDA waive all fees associated with responding to this request because EDF, EWG, and EHSC 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 EDF, EWG, and EHSC, 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, EDF, EWG, and EHSC 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.

EDF, EWG, and EHSC qualify for a fee waiver because 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). EDF, EWG, and EHSC possess the ability to disseminate the information to the general public, and, in fact, such dissemination is routine to their operations.

EDF, EWG, and EHSC are active in informing their constituencies about PFAS 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 Pertain 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). EDF, EWG, and EHSC seek documents regarding the presence of PFAS in the three most recent studies described on FDA's website as of July 28, 2019. The Federal Food, Drug, and Cosmetic Act requires the FDA to "protect the public health by ensuring that … foods are safe, wholesome, sanitary, and properly labeled[.]" 21 U.S.C. § 393(b). Sampling showing that food contains detectable levels of PFAS clearly implicates "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, EDF, EWG, and EHSC 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 which products have been found to contain PFAS and the product manufacturers. This information is meaningful because there is wide public concern about exposure to PFAS given recent attention to the hazards of PFAS in drinking water. Therefore, the foregoing request for documents meets the

second factor for a fee waiver by seeking "meaningful information" 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). EDF, EWG, and EHSC use a variety of platforms to disseminate information to the public. For example, EDF, EWG, and EHSC have the capacity to write a report analyzing and summarizing information obtained through the FOIA request, and publicize the report to members and activists, which total more than two million, through their blogs and other publications. EDF's and EWG's use of a variety of platforms ensure 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, EDF, EWG, and EHSC communicate with supporters, members and the general public through a variety of means. EDF, EWG, and EHSC 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 brands of food that have been identified as containing PFAS in the three studies 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 EDF's and EWG's 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 EDF, EWG, and EHSC

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 a 501(c)(3) nonprofit entity, EDF, EWG, and EHSC have no commercial, trade, or profit interest in the material requested. EDF, EWG, and EHSC 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 consumers can best protect themselves and their families from PFAS. This information will contribute to the numerous other public interest organizations looking at PFAS exposure through various pathways throughout the country. The disclosure of the requested information is therefore "not primarily in the commercial interest of" EDF, EWG, and EHSC, and a fee waiver is appropriate. 5 U.S.C. § 552(a)(4)(A)(iii).

Under these circumstances, EDF, EWG, and EHSC 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. Please also produce the records on a rolling basis; at no point should FDA's search for, or deliberations concerning, certain records delay the production of others that FDA has already retrieved and elected to produce.

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 EDF, EWG, and EHSC, it will not be responsible for those costs.

Thank you in advance for your prompt reply.

Sincerely,

Tom Neltner, Chemicals Policy Director
Environmental Defense Fund
1875 Connecticut Ave. NW, Suite 600
Washington, DC 20009
tneltner@edf.org
202-572-3263

Melanie Benesh
Environmental Working Group
1436 U St. NW, Suite 100
Washington, DC 20009
mbenesh@ewg.org
(202) 667-6982

Patrick MacRoy
Environmental Health Strategy Center
565 Congress Street
Portland, Maine 04101
pmacroy@preventharm.org