



FOIA Request Confirmation

Confirmation Number: FDA1737275

Requester:

General

Description of Requester:	Consumer
Max Amount Willing to Pay:	\$150

Organization

Organization Name: Environmental Defense Fund			
Primary Phone: 202-572-3263	Other Phone:	Email: tneltner@edf.org	

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City: Washington
State: DC
Zip Code: 20009

Billing Address

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Details

Requester Name: Tom Neltner		
Requester File #:	Request Letter: EDF FOIA Lead TDS and CFSAN Special Study 8-24-17.pdf	
Requested Date From: 10/01/2001	Requested Date To: 09/30/2016	
Subject of Request:	This request is a follow-up to two previous requests designated by FDA as FOI Request 2017- 2572 regarding the agency's study of infant and toddler foods	

Waiver of Fees

Justification: EDF requests that FDA waive all fees associated with responding to this request because it seeks this information in the public interest and will not benefit commercially from this request. See attach
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Expedited Processing

Reason: Other
Justification: This is a followup from previous incomplete or flawed responses.

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Within one business day of the submission of your online request, you will receive by electronic mail an FOIA Control Number. If you need to communicate with FDA regarding your request, please refer to this Control Number. Requests received after 4:00 P.M. E.S.T. will be considered to have been received on the following business day.

If your informational needs change, and you need to cancel your request, please contact the Division of Freedom of Information by telephone, mail, or fax. Please include your control number in the correspondence. For contact information, please see [FDA's FOIA page](#).

Submitted online

August 24, 2017

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 Samples for Lead in Two FDA Studies

Environmental Defense Fund (“EDF”) 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

This request is a follow-up to two previous requests designated by FDA as FOI Request 2017-2572 regarding the agency’s study of infant and toddler foods and FOI Request 2017-2639 regarding the agency’s Total Diet Study (TDS).

Regarding FOI Request 2017-2639, FDA’s Andrew Miller provided a partial response on June 20, 2017 by email to Eve Gartner. The email has included a spreadsheet with the file name of “Lead in TD Juices from MB2002-2016, 17may17 with FACTS Number.xlsx” with analytical results from TDS years 2002 to 2016 for 20 types of fruit juices. The file had a worksheet for each of the types of juices and included the results when composite samples were retested and when the individual samples that made up composite samples were analyzed.

Therefore, pursuant to 21 C.F.R. § 20.20(b), we request the same information in a spreadsheet for the other food types in the TDS. If more convenient, the information can be in a single worksheet instead of one for each food type and can include the 20 types of fruit juices.

Regarding FOI Request 2017-2572, FDA provided on June 22, 2017 a file named “CFSAN Quantitative Responsive Records (Redacted) 2017-2572.pdf” consisting of 10,288 pages. All of the pages seems to be generated from a PDF print rather than a scan of a hard copy printed from the database. From pages 5 to 1,115, the FOIA response is a series of PDF prints of spreadsheets that range from a handful to 44 pages in length. Many pages lack column or row headers or page numbers. We printed several of PDFs of the spreadsheets and attempted to piece them together but found pages missing. As a result, the FOIA response is unusable.

Therefore, pursuant to 21 C.F.R. § 20.20(b), we request that FDA provide the information on pages 5 to 1,115 in xls or cvs spreadsheet format as it did with FOI Request 2017-2639. If that is not possible, then we ask that FDA include column and row headings on each of the pages as well as page numbers.

In addition, our request was focused on the spreadsheet “Dataset for Lead and Cadmium in Infant Foods” FDA published on its website at <https://www.fda.gov/Food/FoodborneIllnessContaminants/Metals/ucm521427.htm>. The webpage says it was last updated September 23, 2016. However, the infant and toddler foods in the FOI response did not match the items in the dataset. For example, in the FOI response, FDA included results for carrageenan (which was not in the dataset) but not most of the quinoa samples (which was in the dataset). In addition the number of samples did not match those in the dataset. In addition, some of the high levels discussed in the emails exchanged between FDA scientists are not published in the spreadsheet. There is no explanation for the change in the emails. Therefore, pursuant to 21 C.F.R. § 20.20(b), we request that FDA provide a response for the full dataset that has been generated by the agency including both quinoa and carrageenan.

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 requests that FDA waive all fees associated with responding to this request because EDF seeks 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, 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 meets 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 qualifies 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 possesses the ability to disseminate the information to the general public, and, in fact, such dissemination is routine to their operations.

EDF is active in informing their constituencies about perchlorate 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 seeks documents regarding the presence of perchlorate in 47 food samples. 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 perchlorate 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 requests 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 perchlorate and the product manufacturers. This information is meaningful because there is wide public concern about exposure to perchlorate given recent attention to the hazards of perchlorate 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 uses 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. EDF's 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, EDF communicates with supporters, members and the general public through a variety of means. EDF plans 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 unusually high levels of perchlorate in the TDS sampling 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 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

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 has no

commercial, trade, or profit interest in the material requested. EDF 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 parents can protect their children from perchlorate. This information will contribute to the numerous other public interest organizations looking at perchlorate exposure through various pathways throughout the country. The disclosure of the requested information is therefore “not primarily in the commercial interest of” EDF, and a fee waiver is appropriate. 5 U.S.C. § 552(a)(4)(A)(iii).

Under these circumstances, EDF fully satisfies 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, it will not be responsible for those costs.

Thank you in advance for your prompt reply.

Sincerely,



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