Submitted online

June 26, 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 Specific Total Diet Study Samples for Perchlorate**

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

Pursuant to 21 C.F.R. § 20.20(b), we request all records related to the collection, handling, and/or analysis of the 47 composite samples described in Table 1 for perchlorate in the Total Diet Study ("TDS") in study years 2008 to 2012. These composite samples consist of:

- Any food with perchlorate levels of 100 parts per billion (ppb) or higher; or
- Baby food with perchlorate levels of 20 ppb or higher.

The composite samples are based on "FDA's Survey Data on Perchlorate in Food – TDS Perchlorate Data for 2008-2012" posted online at https://www.fda.gov/downloads/Food/FoodborneIllnessContaminants/ChemicalContaminants/UCM555603.xls.

Table 1. Composite samples for which detailed information is requested.

EDF ID	Year	Market Basket	FDA Food #	Food Description	Result (ppb)
1	2008	1 (Northcentral)	335	Luncheon meat (chicken/turkey)	169.1
2	2008	1 (Northcentral)	244	Shrimp, boiled	147.2
3	2009	1 (Northcentral)	728	BF, vegetables and turkey	64.0
4	2010	1 (Northcentral)	728	BF, vegetables and turkey	38.0
5	2012	1 (Northcentral)	729	BF, macaroni and cheese	38.0
6	2012	1 (Northcentral)	123	Cucumber, peeled, raw	128.0
7	2008	2 (West)	725	BF, cereal, oatmeal w/ fruit, prepared w/	63.6
8	2008	2 (West)	324	BF, cereal, rice, dry, prepared w/ water	98.3
9	2008	2 (West)	17	Ham, cured (not canned), baked	125.8
10	2008	2 (West)	20	Pork bacon, oven-cooked	139.3
11	2008	2 (West)	244	Shrimp, boiled	111.2

12	2008	2 (West)	123	Cucumber, peeled, raw	139.6
13	2008	2 (West)	125	Pepper, sweet, green, raw	106.2
14	2009	2 (West)	700	BF, cereal, barley, dry, prepared w/ water	37.0
15	2009	2 (West)	123	Cucumber, peeled, raw	287.0
16	2009	2 (West)	109	Lettuce, iceberg, raw	265.0
17	2009	2 (West)	125	Pepper, sweet, green, raw	135.0
18	2009	2 (West)	117	Tomato, raw	178.0
19	2010	2 (West)	728	BF, vegetables and turkey	39.0
20	2010	2 (West)	123	Cucumber, peeled, raw	101.0
21	2010	2 (West)	124	Summer squash, fresh/frozen, boiled	118.0
22	2010	2 (West)	117	Tomato, raw	147.0
23	2011	2 (West)	218	BF, carrots	74.0
24	2011	2 (West)	123	Cucumber, peeled, raw	158.0
25	2011	2 (West)	125	Pepper, sweet, green, raw	201.0
26	2011	2 (West)	124	Summer squash, fresh/frozen, boiled	197.0
27	2011	2 (West)	117	Tomato, raw	169.0
28	2012	2 (West)	218	BF, carrots	30.0
29	2012	2 (West)	729	BF, macaroni and cheese	35.0
30	2012	2 (West)	125	Pepper, sweet, green, raw	142.0
31	2012	2 (West)	124	Summer squash, fresh/frozen, boiled	147.0
32	2008	3 (South)	700	BF, cereal, barley, dry, prepared w/ water	67.0
33	2008	3 (South)	108	Collards, fresh/frozen, boiled	264.0
34	2009	3 (South)	728	BF, vegetables and turkey	45.0
35	2009	3 (South)	357	Lettuce, leaf, raw	229.0
36	2011	3 (South)	108	Collards, fresh/frozen, boiled	677.0
37	2012	3 (South)	29	Bologna (beef/pork)	395.0
38	2012	3 (South)	218	BF, carrots	39.0
39	2012	3 (South)	30	Salami, luncheon-meat type (not hard)	686.0
40	2008	4 (Northeast)	701	BF, cereal, oatmeal, dry, prepared w/ water	24.0
41	2008	4 (Northeast)	725	BF, cereal, oatmeal w/ fruit, prepared w/	42.0
42	2008	4 (Northeast)	324	BF, cereal, rice, dry, prepared w/ water	173.0
43	2009	4 (Northeast)	317	BF, teething biscuits	21.0
44	2010	4 (Northeast)	113	Broccoli, fresh/frozen, boiled	102.0
45	2010	4 (Northeast)	108	Collards, fresh/frozen, boiled	1090.0
46	2012	4 (Northeast)	29	Bologna (beef/pork)	1557.0
47	2012	4 (Northeast)	728	BF, vegetables and turkey	33.0

These composite samples are a blend of individual samples were collected from cities listed in Table 2.

Table 2. Cities where food products were collected in each market basket year			
Year	Market Basket	Sample collection dates	Collection region and locations
2008	1 (Northcentral)	October-November 2007	Central (Toledo, OH; Detroit, MI; Minneapolis-St. Paul, MN)
2008	2 (West)	January-February 2008	West (Albuquerque, NM; Phoenix-Mesa, AZ; Reno, NV)
2008	3 (South)	March-May 2008	South (Baltimore, MD; Houston, TX; Tampa, FL)
2008	4 (Northeast)	July-August 2008	North (Buffalo, NY; Voorhees, NJ; Philadelphia, PA)
2009	1 (Northcentral)	October-November 2008	Central (Chicago, IL; Columbus, OH; Springfield, MO)
2009	2 (West)	January-February 2009	West (Colorado Springs, CO; Oakland, CA; Spokane, WA)
2009	3 (South)	April-May 2009	South (Greenville, NC; Austin, TX; Montgomery, AL)
2009	4 (Northeast)	July-August 2009	North (New York, NY; Newark, NJ; Concord, NH)
2010	1 (Northcentral)	October-November 2009	Central (Lansing, MI; Des Moines, IA; Madison, WI)
2010	2 (West)	January-February 2010	West (Riverside-San Bernardino, CA; San Francisco, CA; Yakama, WA)
2010	3 (South)	April-May 2010	South (Charleston, WV; Tampa-St. Petersburg-Clearwater, FL; New Orleans, LA)
2010	4 (Northeast)	July-August 2010	North (Boston, MA; Syracuse, NY; Pittsburg, PA)
2011	1 (Northcentral)	October-November 2010	Central (Chicago, IL; Youngstown-Warren, OH; Kalamazoo-Battle Creek, MI)
2011	2 (West)	January-February 2011	West (Salt Lake City-Ogden, UT; Los Angeles-Long Beach, CA; Boise, ID)
2011	3 (South)	April-May 2011	South (Atlanta, GA; Roanoke, VA; San Antonia, TX)
2011	4 (Northeast)	July-August 2011	North (Hartford, CT; Morris-Passaic, NJ; Scranton-Wilkes-Barre, PA)
2012	1 (Northcentral)	October-November 2011	Central (Peoria, IL; Wichita, KS; St. Cloud, MN)
2012	2 (West)	January-February 2012	West (Boulder, CO; Las Vegas, NV; Seattle, WA)
2012	3 (South)	April-May 2012	South (Raleigh, NC; West Palm Beach-Boca Raton, FL; Nashville, TN)
2012	4 (Northeast)	July-August 2012	North (Monmouth-Ocean, NJ; Albany, NY; Chester County, PA)

The records requested includes, but is not limited to, the following records described under Program 7304.839 of FDA's Compliance Program Guidance Manual:[1]

1. Collection reports for each city and collection week, including lists of stores visited and items collected from each store, including receipts, brands, UPC codes, country of origin, and other detailed product information of items collected, if available.
2. Logs of food samples received by the Kansas City Laboratory.
3. All analytical results for perchlorate in food samples, or composites thereof, reported into the Field Accomplishments and Compliance Tracking System ("FACTS").
4. All data related to "unusual analytical findings" for perchlorate in food samples, including, but not limited to, all data from analyses of original composite samples, all data from duplicate analyses of the reserve portions of composite samples, and all data from analyses of the intact samples from the three collection locations, as applicable.
5. Communications between the Kansas City Laboratory and the CFSAN TDS coordinator regarding unusual analytical findings for perchlorate in food products samples.
6. Communications between the TDS coordinator and the CFSAN contact for regulatory guidance regarding unusual analytical findings for perchlorate in food products samples.
7. Results of scientific reviews conducted by the CFSAN contact for regulatory guidance and/or program offices regarding unusual analytical findings for perchlorate in food products samples.
8. Records related to regulatory or administrative follow-up regarding unusual analytical findings for perchlorate in food products samples, including any summaries of district follow-up sent to the TDS monitor and/or the Kansas City Laboratory.
9. Communications between CFSAN and any food company regarding unusual analytical findings for perchlorate in food products samples.
10. Total Diet Market Basket Reports for perchlorate prepared by the Kansas City Laboratory.

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

[1] FDA, Compliance Program Guidance Manual, available at https://www.fda.gov/downloads/Food/ComplianceEnforcement/UCM073281.pdf (last accessed June 25, 2017).

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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