



August 08, 2023

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WASHINGTON DC 20009-5728 US

In Reply refer to
FOIA Control #:
2023-6839

Requester reference:
FDA Lead in FCM #2

Dear Requester:

The Food and Drug Administration (FDA) has received your Freedom of Information Act (FOIA) request for records regarding:

Any information, including correspondence, emails, and other documents, generated or received by FDA since January 1, 2020 regarding lead, arsenic, cadmium, antimony, or cobalt in food contact substances, food contact materials, or food contact articles. It includes information related to product certifications such as those in NSF/ANSI 51 and NSF/ANSI 61.

In processing your FOIA request, FDA will apply, as appropriate, the FOIA exemptions in 5 USC 552(b) and the foreseeable harm standard in 5 USC 552(a)(8)(i). We will respond as soon as possible and may charge you a fee for processing your request. If your informational needs change, and you no longer need the requested records, please contact us to cancel your request, as charges may be incurred once processing of your request has begun. For more information on processing fees, please see <http://www.fda.gov/RegulatoryInformation/FOI/FOIAFees/default.htm>. PLEASE NOTE: HOURLY RATES FOR SEARCH AND REVIEW INCREASED FOR ALL REQUESTS RECEIVED ON OR AFTER JUNE 1, 2023.

Due to an increase in the number of incoming requests, we may be unable to comply with the twenty-working-day time limit in this case, as well as the ten additional days provided by the FOIA. The actual processing time will depend on the complexity of your request and whether sensitive records, voluminous records, extensive search, and/or consultation with other HHS components or other executive branch agencies are involved. Please note that requests for medical device approval records (e.g. 510K, PMA, DEN) may take up to 18 to 24 months to process.

If you have any questions about your request, please call Wilson M. Russ, Freedom Of Information Specialist, at (301) 796-8981 or write to us at:
Food and Drug Administration
Division of Freedom of Information
5630 Fishers Lane, Room 1035
Rockville, MD 20857

If you call or write, use the FOIA control number provided above which will help us to answer your questions more quickly.

You also have the right to seek dispute resolution services from:

Office of Government Information Services
National Archives and Administration
8601 Adelphi Road – OGIS
College Park, MD 20740-6001
Telephone: 202-741-5770
Toll-Free: 1-877-684-6448
Email: ogis@nara.gov
Fax: 202-741-5769

and/or

FDA FOIA Public Liaison
Office of the Executive Secretariat
US Food and Drug Administration
5630 Fishers Lane, Room 1050
Rockville, MD 20857
Email: FDAFOIA@fda.hhs.gov

Sincerely,

SARAH KOTLER
Director

Submitted online

August 6, 2023

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 Lead, Arsenic, Cadmium, Antimony, and Cobalt in Food Contact Materials

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. Part. 20.

I. RECORDS REQUESTED

Any information, including correspondence, emails, and other documents, generated or received by FDA since January 1, 2020 regarding lead, arsenic, cadmium, antimony, or cobalt in food contact substances, food contact materials, or food contact articles. It includes information related to product certifications such as those in NSF/ANSI 51 and NSF/ANSI 61.¹

For this FOIA request, the following terms apply:

- A *food contact substance* (FCS) is any substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.² FDA has an inventory of food contact substances listed in 21 CFR³ and an inventory of food contact substance notifications.⁴
- A *food contact material* is made with FCSs. It is often (but not necessarily) a mixture. The composition may be variable.⁵ The materials may include metals, metal alloys, ceramics, glass, clay, solder, paper, paperboard, or polymers.
- A *food contact article* is the finished film, bottle, conveyor belt, or whatever that is formed out of the FCM.⁶ It includes food packaging, food processing equipment, food preparation surfaces, cookware, cutlery, and foodware.
- *Metals* includes but are not limited to copper, iron, tin, zinc, and aluminum.
- *Metal alloys* include but are not limited to brass, bronze, pewter, and steel.

¹ See <https://www.nsf.org/knowledge-library/nsf-ansi-51-and-nsf-ansi-61-product-certifications-for-food-and-drinking-wa>.

² See 21 C.F.R. § 170.3

³ See <https://www.fda.gov/food/packaging-food-contact-substances-fcs/inventory-food-contact-substances-listed-21-cfr>.

⁴ See <https://www.fda.gov/food/packaging-food-contact-substances-fcs/inventory-effective-food-contact-substance-fcs-notifications>.

⁵ See <https://www.fda.gov/food/food-ingredients-packaging/food-ingredient-packaging-terms>.

⁶ *Id.*

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 the characteristics and potential health and environmental impacts of food contact substances made by food and additive manufacturers. EDF is well-positioned to enhance the public’s understanding of potential toxic exposures to food contact substances and safer alternatives 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 and correspondence regarding the safety assessment of lead, arsenic, cadmium, antimony, and cobalt in food contact materials. 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). Review of the agency’s communications

regarding the safe level of lead, arsenic, cadmium, antimony, and cobalt in food contact materials and how to assess the risk 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 the basis and rationale of FDA’s scientists regarding concerns or lack thereof about lead, arsenic, cadmium, antimony, and cobalt in food contact materials. This information is meaningful because there is wide public concern about exposure to potentially unsafe lead, arsenic, cadmium, antimony, and cobalt in food and food packaging. 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 safety assessment conducted by FDA had and how the notifiers responded to potential concerns raised by FDA 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 and understand their potential exposures to chemicals like lead, arsenic, cadmium, antimony and cobalt. 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 safer alternatives and how the public can protect itself from potentially unsafe toxic chemicals in FCS. 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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