Submitted online

August 18, 2021

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 Selected Generally Recognized as Safe (GRAS) Notifications**

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

For the 46 GRAS notifications (GRNs) listed below and posted on its website at https://www.cfsanappsexternal.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices, EDF is requesting any correspondence between FDA and the companies. We are also requesting any toxicology, chemistry or environmental assessment reports prepared by FDA in its evaluation of the notices. The response may be provided in parts as they are available.

GRN No.	GRAS Substance	Notifier	Date of closure
924	2'-fucosyllactose	Jennewein Biotechnologie GmbH	11/23/2020
973	Mapple wood fiber	Renmatrix, Inc.	5/13/2021
961	β-glucan derived from Agrobacterium sp. CCTCC No. M2010020	Sichuan Synlight Biotech, Ltd.	5/19/2021
958	Fungal oil (≥40% arachidonic acid) from Mortierella alpina strain AF	Hubei Fuxing Biotechnology Co., Ltd.	3/26/2021
942	Whey permeate	ProLiant Dairy, LLC	12/21/2020
893	D-psicose	Tate & Lyle	6/5/2020
890	Corn oil derived from distillers grains	Corn oil ONE	12/23/2020
889	Spermidine rich wheat germ extract	TLL The Longevity Labs GmbH	3/20/2020
874	Corn protein	Cargill, Inc.	4/29/2020
859	2'-fucosyllactose	Advanced Protein Technologies, Corp.	9/6/2019
830	Chicory flour	Blue Prairie Brands, Inc.	3/22/2019
820	Lactobacillus fermentum CECT5716	Biosearch, S.A.	4/3/2019
794	Shiitake, pea, and rice protein fermented with Lentinula edodes	MycoTechnology Inc.	11/9/2018
782	L-arabinose	Sensus America, Inc.	8/29/2018
762	Carnobacterium divergens M35 preparation	Fumoir Grizzly, Inc.	8/14/2018
748	Tomato powder	IBR LTD	4/19/2018
723	Benzalkonium chloride	Marvel Technologies USA, LLC	12/18/2017
718	Calcium acid pyrophosphate	Chemische Fabrik Budenheim KG	10/17/2017

716	Bovine milk osteopontin	Arla Foods Ingredients Group P/S	2/1/2018
712	Calcium acetate	Niacet Corporation	2/5/2018
710	Basic methacrylate copolymer	Ramboll Environ	12/8/2017
704	Corn oil (by-product of ethanol production)	CoPack Strategies, LLC	10/10/2017
698	Paramylon isolate from Euglena gracilis	Kemin Foods, L.C.	7/19/2017
697	Dried biomass of Euglena gracilis	Kemin Foods, L.C.	7/19/2017
692	Quinoa sprout extract	VIS VITALIS gmbh	11/3/2017
690	Fruit and vegetable vitamin extract	Hogan Lovells US LLP	8/1/2017
687	Inulin from Agave tequilana	IIDEA (Industrializadora Integral del Agave SA de CV)	5/8/2017
678	Alpha-cyclodextrin	Wacker Chemical Corporation	4/14/2017
665	Lactoperoxidase system	Taradon Laboratory	12/14/2016
658	Grapefruit extract	Chemie Research and Manufacturing	9/28/2016
655	Rice bran wax	J.M. Smucker Company	9/20/2016
643	Phosphatidylserine derived from fish	ECA Healthcare, Inc.	7/1/2016
637	Phosphatidylserine derived from soy lecithin	ECA Healthcare, Inc.	8/4/2016
636	Phosphatidylserine derived from sunflower lecithin	ECA Healthcare, Inc.	7/1/2016
622	Emulsified fish oil	MyCell Technologies, LLC	5/13/2016
621	Emulsified algal oil	MyCell Technologies, LLC	5/13/2016
612	Fractionated whey protein isolate containing cows milk derived lactoferrin, lactoperoxidase, and transforming growth factor β2	Armor Protéines S.A.S	5/16/2016
611	Fractionated whey protein isolate containing cows milk derived lactoferrin, lactoperoxidase, and transforming growth factor β2	Armor Protéines S.A.S	4/15/2016
595	gamma-aminobutyric acid	Pharma Foods International Co., LTD.	11/10/2015
570	Magnesium lactate	Exponent	1/26/2016
568	Apoaequorin	Quincy Bioscience Manufacturing, Inc.	10/21/2015
562	Bacillus subtilis	BiOWiSH Technologies, Inc.	4/2/2015
549	Sodium salts of fatty acids from Mortierella alpina oil	Jost Chemical Company	6/5/2015
539	Fish meal-based lipid extract	Enzymotec Ltd.	6/15/2015
530	Extract of Apocynum venetum leaves	Tokiwa Phytochemical Co., LTD	11/5/2014
513	Dried biomass of Euglena gracilis containing beta-1,3-glucan from Euglena gracilis	Algaeon, Inc.	7/9/2014

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 generally recognized as safe (GRAS) determinations made by food and additive manufacturers and is well-positioned to enhance the public's understanding of potential exposures to GRAS substances that FDA has already singled out as of safety concerns 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 safety assessment of 46 GRAS substances voluntarily submitted to the agency for review and that the notifier requested the agency to cease to evaluate. 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 the safety of GRAS substances directly added to the food 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 reasons FDA's scientists had concerns about the safety of the requested 46 GRAS substances if they were added to foods. This information is meaningful because there is wide public concern about exposure to

potentially unsafe substances declared GRAS by its manufacturers who, when confronted with questions by FDA's reviewers withdrew the notification. 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 concerns FDA had and how the notifiers responded to those concerns 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 that doesn't contain the GRAS substances listed in this request. 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 the public can protect itself from potentially unsafe GRAS ingredients added to food. This information will contribute to the numerous other public interest organizations looking at self-determined GRAS substances. 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,

Tom Neltner

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