UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

CENTER FOR FOOD SAFETY, BREAST CANCER PREVENTION PARTNERS, CENTER FOR SCIENCE IN THE PUBLIC INTEREST, ENVIRONMENTAL DEFENSE FUND, and ENVIRONMENTAL WORKING GROUP,

Plaintiffs,

- against -

XAVIER BECERRA, SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES; JANET WOODCOCK, COMMISSIONER, UNITED STATES FOOD AND DRUG ADMINISTRATION; and UNITED STATES FOOD AND DRUG ADMINISTRATION,

Defendants.

17-CV-3833 (VSB)

OPINION & ORDER

Appearances:

Alexis Charlotte Andiman
Carrie Apfel
Peter Hans Lehner
Eve C. Gartner
Jonathan James Smith
Earthjustice
New York, New York
Counsel for Plaintiffs

George Kimbrell
Center for Food Safety
Portland, Oregon
Counsel for Plaintiffs

Michael James Byars
Peter Max Aronoff
U.S. Attorney's Office, SDNY
New York, New York
Counsel for Defendants

Devon Hill
Eric P. Gotting
Joseph Michael Dages
Keller and Heckman LLP
Washington, DC
Counsel for Amicus Curiae Safe Food Ingredients Coalition

VERNON S. BRODERICK, United States District Judge:

What do enzyme-treated pea protein, oat polar lipid extract, rice bran wax, and refined shea butter have in common? These are substances that manufacturers have concluded to be generally recognized as safe ("GRAS") for their prescribed uses in food.[1] Such substances—substances generally recognized as safe—are at the heart of this case.

Plaintiffs Center for Food Safety ("CFS") and Environmental Defense Fund ("EDF") bring this action seeking declaratory and injunctive relief with respect to a final rule promulgated by the United States Food and Drug Administration ("FDA") entitled "Substances Generally Recognized as Safe," 81 Fed. Reg. 54,960 (Aug. 17, 2016) (the "GRAS Rule"). Plaintiffs move for summary judgment on the grounds that the GRAS Rule (1) unlawfully subdelegates FDA's duty to ensure food safety in violation of the United States Constitution (the "Constitution"), the Administrative Procedure Act ("APA"), and the Federal Food, Drug, and Cosmetic Act ("FDCA"); (2) exceeds FDA's statutory authority and constitutes arbitrary and capricious agency action in violation of the FDCA and APA; and (3) conflicts with the FDCA. Defendants Xavier

[1] *See GRAS Notices*, Nos. 892, 941, 948, 962, U.S. Food and Drug Admin., https://www.cfsanappsexternal.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices&sort=GRN_No&order=DESC&startrow=1&type=basic&search= (last visited Sept. 30, 2021).

Becerra, Secretary of Health and Human Services; Janet Woodcock, Commissioner of Food and Drugs; and FDA, (collectively, the "Government"), cross-move for summary judgment arguing that the GRAS Rule is a lawful exercise of FDA's authority under the FDCA, and is not unconstitutional.[2]

Because I find that FDA did not unlawfully subdelegate its authority, that the GRAS Rule passes muster under the standards set forth in *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.* ("*Chevron*"), 467 U.S. 837, 845 (1984), and *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, ("*State Farm*"), 463 U.S. 29, 43 (1983), and that it does not conflict with the FDCA, the Government's motion for summary judgment is GRANTED. Plaintiffs' motion is DENIED.

I. Background[3]

A. *The Food Additives Amendment*

The FDCA requires FDA to "protect the public health by ensuring that . . . foods are safe, wholesome, sanitary, and properly labeled." 21 U.S.C. § 393(b)(2). In 1958, Congress enacted the Food Additives Amendment to the FDCA (the "Food Additives Amendment"), Pub. L. No. 85-929, 72 Stat. 1784 (1958), "in response to public concern about the increased use of

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[2] Xavier Becerra, Secretary of Health and Human Services and Janet Woodcock, Commissioner of Food and Drugs are automatically substituted as parties pursuant to Fed. R. Civ. P. 25(d).

[3] The following factual summary is drawn from the allegations in the Complaint for Declaratory and Injunctive Relief ("Complaint" or "Compl."), (Doc. 1), the special appendix, which contains the documents in the administrative record cited by the parties, (Docs. 97), and the administrative record ("Record") provided to my chambers on a compact disk ("CD"). I will cite to the special appendix and Record interchangeably as "AR". The parties previously agreed that Local Rule 56.1 statements of undisputed material fact were not necessary, and that the facts could be drawn from the Record. (Doc. 51.) My references to allegations within the Complaint should not be construed as a finding as to their veracity, and I make no such findings.

Plaintiffs submitted five declarations with their motion for summary judgment, (*see* Docs. 67–71); however, these declarations are not referenced in their papers, and I do not rely on them here—therefore, I do not consider whether submission of these declarations was proper, (*see* Govt Mot. 9 n.2). The parties debate whether I should consider certain citations to evidence outside of the administrative record, (*see* Pls.' Opp. 20); because these citations have no bearing on my resolution of the parties' motions, I find it unnecessary to resolve this dispute.

chemicals in foods and food processing," 81 Fed. Reg. at 54,963. The purpose of the Food Additives Amendment is "to prohibit the use in food of additives which have not been adequately tested to establish their safety." 72 Stat. 1784.

The Food Additives Amendment mandates that any "food additive" must go through an approval process. *See* 21 U.S.C. § 348(b)–(g). Under this process, "the burden is on the manufacturer to prove the safety of the use of the substance," and "FDA must review and approve the proposed use before the additive can be used in food." (Compl. ¶ 36.) FDA considers, among other things, "the probable consumption of the additive and of any substance formed in or on food because of the use of the additive," and "the cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substance or substances in such diet." 21 U.S.C. § 348(c)(5).

The Food Additives Amendment provides a role for the public in the approval of food additives. *See generally* 21 U.S.C. § 348. Specifically, it requires that FDA publish notice of a proposed food additive regulation and the agency's final decision on the underlying petition. *Id.* § 348(b), (c), (e). Any person adversely affected by FDA's final decision may file objections and request a public hearing, and the final decision is subject to judicial review. *Id.* § 348(f)–(g).

The Food Additives Amendment defines a "food additive" to include "substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food." 21 U.S.C. § 321(s). This definition exempts a category of substances that are:

> generally recognized, among experts qualified by scientific training and experience to evaluate [their] safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of [their] intended use.

Id. Based on the GRAS exemption to the Food Additives Amendment, described above, substances such as vinegar, vegetable oil, baking powder, and many spices, flavors, gums, and preservatives are lawfully marketed today. 81 Fed. Reg. at 54,963. After the passage of the Food Additives Amendment, FDA "clarified the regulatory status of a multitude of food substances that were used in food prior to 1958 and amended . . . regulations to include a list of food substances that, when used for the purposes indicated and in accordance with good manufacturing practice, are GRAS." *Id.*; *see* 21 C.F.R. § 184.1005 *et seq.* (listing GRAS substances). FDA, however, acknowledged that it would be impractical to list all GRAS substances. 81 Fed. Reg. at 54,963; *see* 21 C.F.R. § 182.1(a). Procedurally, the Food Additives Amendment does not require FDA to conduct a premarket review of whether the use of a substance is GRAS. *See* 81 Fed. Reg. at 54,963.

B. *History of the GRAS Rule*

Prior to the GRAS Rule, manufacturers could file a petition requesting a non-binding "'opinion letter,' in which Agency officials would render an informal opinion on the GRAS status of use of a substance." 81 Fed. Reg. at 54,963. Subsequently, FDA instituted a voluntary GRAS affirmation process under which manufacturers could ask FDA to affirm the GRAS status of a particular use of a substance, thereby confirming that the substance was not a food additive under the FDCA. 81 Fed. Reg. at 54,963–64. In so doing, manufacturers would provide FDA with certain information, including "information to establish the safety and functionality of the substance in food." 21 C.F.R. § 170.35(c)(1) (reserved by 81 Fed. Reg. 54,960). Within thirty days of the filing, FDA was required to publish a notice of filing in the Federal Register and allow a sixty-day comment period. *Id.* § 170.35(c)(2), (c)(4). FDA could then either publish an order that added the substance to the list of affirmed GRAS substances or publish a ruling that

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