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

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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

[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

the substance was not GRAS and therefore a food additive. *Id.* § 170.35(c)(5), (c)(6). This GRAS affirmation process "involved the resource-intensive rulemaking process." 81 Fed. Reg. at 54,964.

In April 1997, FDA proposed "to: (1) [c]larify the criteria for eligibility for classification as GRAS;" "and (2) replace the GRAS affirmation petition process with a notification procedure whereby any person may notify [the FDA] of a conclusion that a particular use of a substance is GRAS." *Id.* From 2008 to 2010, the Government Accountability Office ("GAO") conducted a study related to ingredients used in human food on the basis of the GRAS provision. *Id.* In 2010, GAO issued a report ("GAO Report") that raised concerns about the proposed GRAS Rule and proposed recommendations for FDA, including that FDA finalize the proposed GRAS Rule and seek to minimize the potential for conflicts of interest in GRAS determinations. (*See* AR 008470–8543); U.S. Gov't Accountability Off., GAO-10-246, *FDA Should Strengthen Its Oversight of Food Ingredients Determined to Be Generally Recognized as Safe (GRAS)* (2010). In 2010, the comment period for the proposed rule was reopened to update comments and seek additional comments on specific issues, including those raised by GAO. 81 Fed. Reg. at 54,964. The proposed rule "invited interested persons to notify [FDA] about their conclusions of GRAS status as described in the proposed rule." *Id.*

FDA operated under the proposed GRAS Rule for nineteen years before publishing the final GRAS Rule on August 17, 2016. (Compl. ¶¶ 51, 53); *see* 81 Fed. Reg. 54,960. The final GRAS Rule codified FDA's practice of allowing any person to notify FDA that a particular use of a substance is GRAS. *See id.* at 54,966.

C. *The GRAS Rule*

Under the GRAS Rule, "[a]ny person may notify FDA of a view that a substance is not subject to the premarket approval requirements of section 409 of the Federal Food, Drug, and Cosmetic Act based on that person's conclusion that the substance is GRAS under the conditions of its intended use." 21 C.F.R. § 170.205. The GRAS Rule provides two ways for demonstrating GRAS status. The first is through "scientific procedures," which must be "the same quantity and quality of scientific evidence as is required to obtain approval of a food additive." 21 C.F.R. § 170.30(b). GRAS conclusions under this provision "shall be based upon the application of generally available and accepted scientific data, information, or methods, which ordinarily are published, as well as the application of scientific principles, and may be corroborated by the application of unpublished scientific data, information, or methods." *Id.* The second mechanism is for substances used in food prior to January 1, 1958, and requires that a showing be made "through experience based on common use in food." *Id.* § 170.30(a).

If a person chooses to submit a GRAS notice,[4] the person providing such notice must include the following information: (1) signed statements identifying the substance, its intended conditions of use, the basis for the GRAS status, and a certification that the notice is a complete, representative, and balanced submission, 21 C.F.R. § 170.225; (2) the identity, method of manufacture, specifications, and physical or technical effects, *id.* § 170.230; (3) information about dietary exposure, *id.* § 170.235; (4) information about any self-limiting levels of use, including a level at which the substance would become unpalatable or technologically impractical, *id.* § 170.240; (5) if applicable, information about experience based on common use

[4] GRAS notice refers to the submission to FDA that "informs [FDA] of [a person's] view that a substance is not subject to the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act based on [a person's] conclusion that the substance is GRAS under the conditions of its intended use in accordance with § 170.30." 21 C.F.R. § 170.203. A GRAS notice has seven parts, *id.* § 170.220, which are described above.

in food before 1958, *id.* § 170.245; (6) a narrative of the basis for the GRAS conclusion, *id.* § 170.250; and (7) a list of supporting data and information in the notice, specifying which data are generally available, *id.* § 170.255.

Within 180 days of a GRAS notice, with the opportunity for a 90-day extension, the FDA will respond to the person who provided notice based on its "evaluation of [the] notice." *Id.* § 170.265(b). FDA will respond in one of three ways: (1) a letter stating FDA does not question the basis for the GRAS determination; (2) a letter stating that FDA concludes that the notice does not provide a sufficient basis for a GRAS determination; or (3) a letter stating that at the notifier's request, FDA has ceased to evaluate the GRAS notice. *About the GRAS Notification Program*, U.S. Food and Drug Admin., https://www.fda.gov/food/generally-recognized-safe-gras/about-gras-notification-program (last visited Sept. 30, 2021). Before FDA's response, a person who submitted notice may request in writing that FDA cease to evaluate her GRAS notice. 21 C.F.R. § 170.260(b). Under the GRAS Rule, FDA makes publicly available "[a] list of filed GRAS notices, including [certain] information" included in the notice and "[t]he text of any letter" FDA issues, including any letter issued when granting a request to cease evaluating a notice. *Id.* § 170.275(b). Other information in a GRAS notice is subject to disclosure under the Freedom of Information Act. *Id.* § 170.275(a).

The GRAS Rule's notification process is voluntary. *See* 81 Fed. Reg. 54,960 (FDA noted that it was "amending [its] regulations to replace the voluntary GRAS affirmation petition process with a voluntary notification procedure under which any person may notify [FDA] of a conclusion that a substance is GRAS under the conditions of its intended use."). FDA, however, retains authority to take various actions, including issuing warnings and stopping distribution, when a substance does not qualify for GRAS status. *Id.* at 54,980–81.

II. Procedural History

On May 22, 2017, Plaintiffs—a group of nonprofit advocacy organizations—filed this action seeking a declaratory judgment that the GRAS Rule (1) violates fundamental principles of separation of powers; (2) exceeds FDA's statutory authority; (3) does not accord with the law; (4) is arbitrary and capricious; and (5) is an abuse of discretion. (Compl. ¶¶ 14, 19–28.) Plaintiffs also seek equitable relief vacating the GRAS Rule and directing FDA to reissue a rule that is in accordance with the FDCA. (*Id.* ¶ 14.)

On September 22, 2017, the Government filed a motion to dismiss for lack of jurisdiction pursuant to Federal Rule of Procedure 12(b)(1), (Doc. 30), which was fully briefed in November 2017, (*see* Docs. 31, 35, 36). On September 12, 2018, I issued an Opinion & Order denying the Government's motion as to Plaintiffs CFS and EDF because they had standing to pursue their claims based on harm to their members, and granting the Government's motion as to Plaintiffs Breast Cancer Prevention Partners, Center for Science in the Public Interest, and Environmental Working Group. (Doc. 44.)

After extending the Government's time to answer, (Doc. 47), the Government answered on October 4, 2018, (Doc. 50). I subsequently endorsed the parties' proposed schedule for production of the Record and summary judgment briefing. (Doc. 52.) Thereafter, I granted Plaintiffs' request for an extension of time to advise the Government that they were satisfied that the Record was complete. (Doc. 59). In December 2018, this case was stayed due to a lapse in funding to the United States Department of Justice. (Doc. 60.) The government shutdown ended on January 25, 2019, and funding was restored. On February 19, 2019, the Government filed a joint letter stating that "Plaintiffs [] advised the government that they will not file any motions to complete or supplement the record", and proposing that Plaintiffs' summary judgment deadline

be set for March 26, 2019, which was 60 days after the government shutdown ended. (Doc. 63.) I granted this request. (Doc. 64.)

On March 26, 2019, Plaintiffs filed a motion for summary judgment, a memorandum of law in support of their motion, and five declarations in support. (Docs. 65–71.) Subsequently, I extended the remaining briefing deadlines. (Doc. 73.) On June 17, 2019, the Government filed a cross motion for summary judgment and a memorandum of law in support. (Docs. 74–75.) In July of 2019, Safe Food Ingredients Coalition ("SFIC") requested that I grant it leave to file a brief as *amicus curiae* in support of the Government's cross-motion. I granted the request and directed SFIC to file it amicus brief by July 26, 2019, (Doc. 76), which it did, (Doc. 83.) On August 23, 2019, Plaintiffs filed their opposition to the Governments' cross-motion. (Doc. 85.) After granting the Government's extension request, (Doc. 87), and request to file excess pages, (Doc. 89), the Government filed its reply, (Doc. 90). On October 2, 2020, Plaintiffs requested oral argument, (Doc. 91), and I denied Plaintiffs' request on October 7, 2020, (Doc. 92).

On July 23, 2021, I issued an order explaining that it was unclear based on the docket whether the parties provided me with the Record. (Doc. 95.) I directed the parties to inform me whether they did in fact provide me with the Record, and if so, to provide me with another copy of the Record, by on or before July 30, 2021. (*Id.*) If the parties had not provided me with the record, I directed them to file a certified index of the Record, and a joint appendix containing only the cited portions of the Record, by on or before August 6, 2021. The parties filed a letter indicating that after reviewing the case file, the Government could not conclusively determine whether it previously provided a copy of the administrative record to chambers. (Doc. 96.) The Government indicated it would file the index of the complete administrative record, including a certification; and a special appendix including only those documents in the record that either

party cited in their briefing. (*Id.*) The parties also proposed to provide a copy of the full record on compact disk ("CD") to chambers and to send an additional copy of the same CD to the Clerk of Court to maintain. (Doc. 96.) I endorsed the parties' proposed plan for submitting the record. (Doc. 98.) The Government filed the appendix containing cited excerpts of the record and a certified index of the complete administrative record. (Docs. 97, 99.) The entire Record was provided to me on a CD.

III. Legal Standard

Under Federal Rule of Civil Procedure 56, summary judgment is appropriate when "the parties' submissions show that there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law." *Fay v. Oxford Health Plan*, 287 F.3d 96, 103 (2d Cir. 2002); *see also* Fed. R. Civ. P. 56(a). "When a party seeks review of agency action under the APA, the 'entire case on review is a question of law' such that 'judicial review of agency action is often accomplished by filing cross-motions for summary judgment.'" *Just Bagels Mfg., Inc. v. Mayorkas*, 900 F. Supp. 2d 363, 372 (S.D.N.Y. 2012) (quoting *Connecticut v. U.S. Dep't of Commerce*, No. 3:04cv1271 (SRU), 2007 WL 2349894, at *1 (D. Conn. Aug. 15, 2007)). Accordingly, "the usual Rule 56 summary judgment standard does not apply in such cases, because the court is resolving legal questions when it determines if the agency acted in excess of statutory authorization, not in accordance with law, arbitrarily and capriciously, or in some other way that violates 5 U.S.C. § 706." *New York v. U.S. Dep't of Health & Human Servs.*, 414 F. Supp. 3d 475, 516 (S.D.N.Y. 2019) (internal quotation marks omitted). "Generally, a court reviewing an agency decision is confined to the administrative record compiled by the agency when it made the decision." *Id.* at 517 (internal quotation marks omitted).

IV. Discussion

Plaintiffs argue that the GRAS Rule (1) unlawfully subdelegates FDA's duty to ensure food safety in violation of the Constitution, the APA, and the 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. The Government cross-moves for summary judgment essentially arguing the opposite: that the GRAS Rule is a lawful exercise of FDA's authority under the FDCA and is not unconstitutional.

A. *Subdelegation Challenge*

1. Applicable Law

"An agency impermissibly delegates its authority where, without statutory authorization, 'it shifts to another party almost the entire determination of whether a specific statutory requirement . . . has been satisfied, or where it abdicates its final reviewing authority.'" *Cooling Water Intake Structure Coal. v. U.S. Envtl Prot. Agency*, 905 F.3d 49, 79 (2d Cir. 2018) (quoting *Fund for Animals v. Kempthorne*, 538 F.3d 124, 133 (2d Cir. 2008)); *see also United States Sec. & Exch. Comm'n v. Alpine Sec. Corp.*, 982 F.3d 68, 81 (2d Cir. 2020). Although "[a]gencies may seek advice and policy recommendations from outside parties, . . . they may not '"rubber-stamp" decisions made by others under the guise of seeking their "advice".'" *Fund for Animals*, 538 F.3d at 133 (quoting *U.S. Telecom Ass'n v. FCC*, 359 F.3d 554, 568 (D.C. Cir. 2004)).

As the D.C. Circuit has explained, there is a distinction between a subdelegation to a subordinate federal officer or agency and subdelegation to an outside party. *See U.S. Telecom Ass'n*, 359 F.3d at 565.

> [W]hen an agency delegates power to outside parties, lines of accountability may blur, undermining an important democratic check on government decision-making.

> Also, delegation to outside entities increases the risk that these parties will not share the agency's national vision and perspective, and thus may pursue goals inconsistent with those of the agency and the underlying statutory scheme.

Id. at 565–66 (internal citations and quotation marks omitted). In other words, "subdelegation to outside entities aggravates the risk of policy drift inherent in any principal-agent relationship." *Id.* at 566.

2. Application

Plaintiffs argues that "Congress delegated to FDA the responsibility of ensuring that our nation's food is safe and free from harmful substances" and that the GRAS Rule "unlawfully *sub*delegates—or shifts—to manufacturers this core governmental duty, allowing them to decide for themselves, in secret, whether the chemical substances they have synthesized may be added to food." (Pls.' Mot. 8.)[5] Plaintiffs broadly assert separation of powers concerns. (*See id.* at 8–14.) The Government responds that contrary to Plaintiffs' framing of the issue, subdelegation claims are treated as statutory, not constitutional claims, and regardless, Plaintiffs' claim fails because the GRAS Rule does not subdelegate agency authority.[6] (Govt. Mot. 18.)[7]

In *Fund for Animals*, the Second Circuit held that a depredation order which authorized "State fish and wildlife agencies, Federally recognized Tribes, and State Directors of the Wildlife Services program . . . to prevent depredations on the public resources of fish . . . , wildlife, plants, and their habitats by taking without a permit double-crested cormorants found committing or about to commit, such depredations" did not unlawfully subdelegate the responsibility of the Fish

[5] "Pls.' Mot." refers to Plaintiffs' memorandum of law in support of Plaintiffs' motion for summary judgment, filed on March 26, 2019. (Doc. 66.)

[6] I note at the outset that I do not resolve whether Plaintiffs' claim should be treated as constitutional or statutory because I find that the GRAS Rule is not an unlawful subdelegation of FDA's authority.

[7] "Govt. Mot." refers to the Government's memorandum of law in support of their cross-motion for summary judgment and opposition to Plaintiffs' motion for summary judgment, filed on June 17, 2019. (Doc. 75.)

and Wildlife Service ("FWS") to regulate migratory birds under the Migratory Bird Treaty Act ("MBTA"). 538 F.3d at 130, 133 (internal quotation marks omitted). The Second Circuit explained that:

> the authority delegated by Congress to the FWS under the MBTA bears little resemblance to the far narrower band of discretion afforded to those acting under the Depredation Order. The MBTA requires the Secretary "to determine when, to what extent, if at all, and by what means, it is compatible with the terms of the conventions" to permit takings and killings of migratory birds. By contrast, third parties acting pursuant to the Depredation Order are limited to takings of cormorants, and cormorants only, and even then, solely "to prevent depredations on the public resources of fish . . . , wildlife, plants, and their habitats."

Id. at 133. Additionally, the Second Circuit observed that unlike the process for issuing depredation permits, which requires that FWS affirmatively issue a permit or order before any depredation control occurs, the Depredation Order allows the parties to provide such information after the fact. *Id.*; *see id.* at 130 (Depredation Order requires a yearly notice for those years in which the agency intends to act and annual reports describing their activities under the Depredation Order). The Second Circuit noted, "[t]here is, however, no statutory requirement that the FWS provide *prior* authorization in the form of a permit for specific takings of migratory birds. The MBTA mandates only 'suitable regulations permitting and governing' takings. The regulations restricting the taking of migratory birds, even in the absence of an advance permitting scheme, satisfy this statutory requirement." *Id.* at 133 (internal citation omitted).

As the Government correctly points out, "the FDCA does not impose mandatory GRAS notification on manufacturers or require FDA to review industry GRAS conclusions in advance of marketing." (Govt. Mot. 18.) Instead, FDA has the power to take enforcement action if it does not agree with a person's GRAS determination. *See* 81 Fed. Reg. at 54,980–81. Like the statute at issue in *Fund for Animals*, "there is . . . no

statutory requirement that the [FDA] provide *prior* authorization [that a substance is GRAS]." 538 F.3d at 131. Although in *Fund for Animals*, the FWS did retain some authority to regulate takings before they occurred, Plaintiffs are incorrect that the Second Circuit "premised its approval on the existence of pre-violation oversight mechanisms," (Pls.' Opp. 9)[8]; instead, the court explicitly held that "[t]he regulations restricting the taking of migratory birds, even in the absence of an advance permitting scheme, satisfy th[e] statutory requirement," *Fund for Animals*, 538 F.3d at 133.[9]

Plaintiffs' argument here is even less compelling than plaintiffs' argument in *Fund for Animals*. Congress delegated "to FDA the responsibility of ensuring that our nation's food is safe and free from harmful substances." (Pls.' Mot. 8 (citing 72 Stat. 1784; 21 U.S.C. § 393(b)).) If the FDA has delegated anything at all to manufacturers, it is simply the ability to notify FDA of a GRAS determination, with which FDA can agree or disagree. "[T]he authority delegated by Congress to the [FDA] . . . bears little resemblance to the far narrower band of discretion afforded to those acting under the [GRAS Rule]." *Fund for Animals*, 538 F.3d at 133. As the Government aptly notes, "[i]f

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[8] "Pls.' Opp." refers to Plaintiffs' opposition to Defendants' cross-motion for summary judgment and reply to Defendants' opposition to Plaintiffs' motion for summary judgment, filed on August 23, 2019. (Doc. 85.)

[9] Plaintiffs argue that FDA "invokes one of two independent Second Circuit tests set forth in *Fund for Animals* for determining whether a subdelegation is permissible," and "completely ignores the Second Circuit's second, independent test for determining whether an unlawful subdelegation has occurred. Under this test, an agency subdelegates authority when it abdicates 'final reviewing authority,' or pre-violation oversight." (Pls.' Opp. 7–8) (quoting *Fund for Animals*, 538 F.3d at 133).) While the test does include determining whether an agency abdicated its "final reviewing authority," *Fund for Animals* makes clear that is not equivalent to "pre-violation oversight"; Plaintiffs' citation to a sentence from a non-binding case that was cited in *Fund for Animals* is misleading, (*see* Pls.' Opp. 8–9), and is inconsistent with the holding in *Fund for Animals* that "[t]he regulations restricting the taking of migratory birds, even in the absence of an advance permitting scheme, satisfy th[e] statutory requirement," *Fund for Animals*, 538 F.3d at 133.

Cooling Water, 905 F.3d at 80, cited to by both parties, (*see* Pls.' Mot. 10–11; Govt. Mot. 18), held that an unlawful delegation did not occur where the agency retained oversight and the rule reflected a "cooperative arrangement specified by Congress in the [statute] and by the agencies in their [memorandum of agreement]." Although the regulatory scheme in *Cooling Water* is different than that at issue here, it did not establish that pre-violation oversight is required to survive a subdelegation challenge.

FDA had promulgated no rule at all, manufacturers would have the same option they have now: to act without notifying FDA and assume the risk of enforcement if FDA later determines that they violated the law. The Rule provides them no additional authority."[10] (Govt. Reply 9.)[11] This is due, at least in part, to the fact that the law does not require manufacturers to get preapproval before using a substance the manufacturer believes to be GRAS.

Plaintiffs contend that the GRAS Rule fails to ensure that FDA retains oversight over GRAS determinations and therefore the public cannot hold FDA accountable for the safety of substances, leaving the public with no recourse. (Pls.' Mot. 11–13.) Plaintiffs aver that "[w]hen actions that Congress delegated to an executive agency—such as decisions about what chemical substances can be added to food—are shielded from judicial review, separation of powers principles are violated." (*Id.* at 13.) According to Plaintiffs, this is exacerbated by the potential conflicts of interest that may arise during GRAS determinations. (*Id.*) Although Plaintiffs' assertions do raise legitimate concerns, here, FDA retains the power to disagree with manufacturers' GRAS determinations and bring enforcement actions. *See* 81 Fed. Reg. at 54,963; (AR 8649–56, 8662–66). The FDCA does provide for certain ways for the public to participate in the food additive

[10] Plaintiffs also contend that "FDA misstates the function of the Second Circuit tests as asking whether a subdelegation has occurred at all, rather than evaluating whether a subdelegation is permissible." (Pls.' Opp. 7 n.3 (internal quotation marks omitted)). In *Fund for Animals*, the Second Circuit explained that because the MBTA did not explicitly provide for delegation to third parties, the court's "inquiry focuses on whether the Depredation Order is, in fact, such a delegation" because any delegation would be impermissible. 538 F.3d at 132–33. Regardless of whether I ask whether a delegation occurred or whether a delegation was impermissible, my determination is the same—FDA has not unlawfully delegated its authority. Plaintiffs dedicate time to arguing that "FDA's subdelegation in no way qualifies as one of the three types of 'legitimate outside party input into agency decision-making processes' recognized by the courts." (Pls.' Mot. 14 (citing *U.S. Telecom Ass'n*, 359 F.3d at 566).) Given that I find that FDA has not unlawfully delegated its authority, I find it unnecessary to delve into whether the GRAS Rule falls within the exceptions laid out by Plaintiffs.

[11] "Govt. Reply" refers to the Government's reply memorandum of law in further support of its cross-motion for summary judgment, filed on September 19, 2019. (Doc. 90.)

process, *see* 21 U.S.C. § 348(b)(5), (f)(1), (g); however, there is nothing within the statutory scheme to require FDA to make GRAS determinations so that such determinations can be challenged in court. Other than prudential concerns and citations to inapposite case law, Plaintiffs provide no legal support for their argument that the GRAS Rule violates the Constitution by adopting a voluntary notification system and allowing post-violation, instead of pre-violation enforcement.[12] Moreover, FDA uses a similar voluntary notification system to regulate the marketing of cosmetics.[13] Accordingly, I find that the GRAS Rule is not an unlawful subdelegation of FDA's authority.

B. *Challenge Under the Administrative Procedure Act*

Plaintiffs appear to challenge the GRAS Rule under the standards set forth in *Chevron* and *State Farm*. (*See* Pls.' Opp. 22.) As explained more fully below, I will analyze the GRAS Rule under both standards.[14]

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[12] Plaintiffs' citations on this point are unpersuasive or non-binding. (*See, e.g.*, Pls.' Mot. 13–14 (citing *Connecticut v. Am. Elec. Power Co., Inc.*, 406 F. Supp. 2d 265, 267 (S.D.N.Y. 2005) (broadly describing the separation of powers principle), *vacated and remanded*, 582 F.3d 309 (2d Cir. 2009), *rev'd*, 564 U.S. 410 (2011); *Defs. of Wildlife v. Gutierrez*, 532 F.3d 913, 926 (D.C. Cir. 2008); *Nat'l Park & Conservation Ass'n v. Stanton*, 54 F. Supp. 2d 7, 18 (D.D.C. 1999)); Pls.' Opp. 10 (citing *R.H. Johnson & Co. v. SEC*, 198 F.2d 690, 695 (2d Cir. 1952) (no unconstitutional delegation of legislative power)).

[13] *See Voluntary Cosmetic Registration Program*, U.S. Food and Drug Admin., https://www.fda.gov/cosmetics/voluntary-cosmetic-registration-program (last visited Sept. 30, 2021) (explaining that the program "assists FDA in carrying out its responsibility to regulate cosmetics marketed in the United States. Because [cosmetic] product filings and establishment registrations are not mandatory, voluntary submissions provide FDA with the best estimate of information available about cosmetic products and ingredients, their frequency of use, and businesses engaged in their manufacture and distribution.").

[14] Although it may make sense to conduct a *State Farm* analysis before *Chevron* because if a "*State Farm* challenge is successful there is no need for the reviewing court to engage in *Chevron* analysis," *Catskill Mountains Chapter of Trout Unlimited, Inc. v. EPA*, 846 F.3d 492, 522 (2d Cir. 2017), here, because Plaintiffs' challenge is more properly a *Chevron* challenge, I consider it first. I also note that because I conduct a searching review of FDA's rationale during my *Chevron* analysis, I find it practical to conduct that analysis first.

1. *Chevron Analysis*

a. Applicable Law

Chevron sets forth a two-step framework. At *Chevron* Step One, the court asks "whether Congress has directly spoken to the precise question at issue." 467 U.S. at 842. "If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Id.* at 842–43. If, however, the statutory language is "silent or ambiguous," the court proceeds to *Chevron* Step Two, where "the question for the court is whether the agency's answer is based on a permissible construction of the statute." *Id.* at 843. "If it is—i.e., if it is not 'arbitrary, capricious, or manifestly contrary to the statute,'—[the court] will accord deference to the agency's interpretation of the statute so long as it is supported by a reasoned explanation, and 'so long as the construction is a reasonable policy choice for the agency to make.'" *Catskill Mountains Chapter of Trout Unlimited, Inc. v. EPA*, 846 F.3d 492, 507 (2d Cir. 2017) (quoting *Chevron*, 467 U.S. at 844 *and Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 986 (2005)). Therefore, the principal question, whether FDA's interpretation of the FDCA, as embodied in the GRAS Rule, is consistent with the FDCA, must be analyzed under the two-step framework set forth in *Chevron*.

b. Application

i. *Chevron Step One*

The question before me under *Chevron* Step One is whether the FDCA requires that FDA be made aware of GRAS conclusions. Plaintiffs contend that the GRAS Rule fails at Step 1 because it "contravenes . . . plain statutory language" by "allow[ing] manufacturers to make secret safety determinations." (Pls.' Mot. 16.) In other words, because manufactures do not

have to disclose GRAS determinations, "FDA cannot possibly assess the risks that new uses of food additives might pose in combination with 'chemically or pharmacologically related substances' in our diets, despite its statutory duty to do so." (*Id.* at 16–17 (quoting 21 U.S.C. § 348(c)(5)(B).) The Government argues that the FDCA is silent on whether the manufacturer must notify FDA of GRAS conclusions. (Govt. Mot. 10.)

To resolve this question, I employ "traditional tools of statutory construction," *Catskill Mountains*, 846 F.3d at 508 (internal quotation marks omitted), and "examine the statutory text, structure, and purpose as reflected in its legislative history," *id*. at 512. "As with any question of statutory interpretation, [I] begin with the text of the statute to determine whether the language at issue has a plain and unambiguous meaning." *Id.* (internal quotation marks omitted).

Plaintiffs argue that the statutory text specifically speaks on the issue because the Food Additives Amendment requires that in order to determine whether a food additive is safe, the FDA "shall consider . . . 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)(B), and the FDA cannot make this determination without information about current exposures to substances already present in food, (*see* Pls.' Mot. 16–17). Plaintiffs' strained interpretation is unpersuasive—this language does not have an "unambiguous meaning," *Catskill Mountains*, 846 F.3d at 512 (internal quotation marks omitted); it is dubious to think that Congress used such language to require manufacturers to inform FDA of GRAS determinations without explicitly saying so. Congress "does not, one might say, hide elephants in mouseholes." *Whitman v. Am. Trucking Ass'ns, Inc.*, 531 U.S. 457, 468 (2001).

The FDCA broadly 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). This mandate cuts in favor of Plaintiffs' argument, as FDA may be hindered in carrying out this objective if it does not have access to all GRAS determinations. On the other hand, the Food Additives Amendment establishes a rigorous statutory scheme for approving food additives, *see id*. § 348(b)–(g), but GRAS substances are specifically exempted from this scheme, *id*. § 321(s). This exemption lessens the requirements applicable to GRAS determinations. *See* 81 Fed. Reg. at 54,981–82 (responding to comments regarding mandatory GRAS notifications, and "agree[ing] that [FDA] lacks express statutory authority to require companies to submit GRAS notices."). In other words, the statutory text does not indicate that Congress "clearly spoke to the precise question at issue." *Catskill Mountains*, 846 F.3d at 514.

I next consider Congress's purpose in enacting the Food Additives Amendment. The purpose of the Amendment was "to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to prohibit the use in food of additives which have not been adequately tested to establish their safety," 72 Stat. 1784, and was "in response to public concern about the increased use of chemicals in foods and food processing and with the support of the food industry," 81 Fed. Reg. at 54,962. As Plaintiffs note, the GRAS Rule may undermine this purpose, as substances could potentially be included in food that have not been adequately tested, of which FDA is unaware. However, as noted above, although the Food Additives Amendment establishes a rigorous statutory scheme for approving food additives, GRAS substances are specifically exempted from this scheme. In addition, as the Government correctly points out, "no law pursues its purpose at all costs," *Rapanos v. United States*, 547 U.S. 715, 752 (2006), and the FDCA explicitly provides FDA "the authority to promulgate regulations for . . . efficient enforcement," 21 U.S.C. § 371(a). In short, an analysis of the "statutory text, structure, and

purpose as reflected in its legislative history," *Catskill Mountains*, 846 F.3d at 512, reveals that Congress did not in the FDCA speak directly to the question of whether GRAS notifications must be mandatory. The FDCA "is therefore silent or ambiguous as to this question, which means that this case cannot be resolved by the Step One analysis under Chevron." *Id.* at 519. Therefore, I proceed to Step Two.

ii. *Chevron Step Two*

Plaintiffs argue that the GRAS Rule is unlawful at Step Two because "it rests on an impermissible statutory construction" and "fails to address important aspects of food safety documented in the record." (Pls.' Mot. 19.) The Government responds that FDA is engaging in proper gap filling and "FDA has reasonably determined that a voluntary notice submission regime for GRAS substances, rather than a preapproval process with mandatory submissions, constitutes the best use of its resources to effectuate Congressional intent and the core statutory purpose." (Govt. Mot. 12.) The Government is correct.

At Step Two, I "deem Congress to have delegated the resolution of statutory ambiguity to the administering agency, so that [my] judicial task is simply to determine 'whether the agency's answer is based on a permissible construction of the statute.'" *New York v. FERC*, 783 F.3d 946, 954 (2d Cir. 2015) (quoting *Chevron*, 467 U.S. at 843). "That inquiry is deferential, asking only whether the agency's interpretation is 'reasonable,' while 'respecting legitimate policy choices' made by the agency." *Id.* (quoting *Chevron*, 467 U.S. at 866) (collecting cases); *Catskill Mountains*, 846 F.3d at 520 ("Generally, an agency interpretation is not arbitrary, capricious, or manifestly contrary to the statute if it is reasonable." (internal quotation marks omitted)).

First, I consider whether FDA has provided a reasoned explanation for its decision to not require mandatory GRAS notifications. *See id.* at 524. I find that FDA has done so. In

promulgating the GRAS Rule, FDA clearly considered whether to make GRAS notifications mandatory—an issue that was raised by numerous comments during consideration of the GRAS Rule. *See* 81 Fed. Reg. at 54,964–65, 54,979, 54,981–82. In response to comments asserting that a voluntary notification system would violate the Food Additives Amendment, FDA explained that although the FDCA provides for its review of food additives, "it is silent with respect to industry submissions to us on the use of GRAS substances." *Id.* at 54,971 (Response 1). In response to other similar comments, FDA explained:

> We agree that we lack express statutory authority to require companies to submit GRAS notices. In creating the premarket approval requirement for food additives in the 1958 amendment, Congress excluded a substance that is GRAS under the conditions of its intended use from the definition of food additive. The creation of this GRAS provision reflected Congress' determination that many substances intentionally added to food for a specific use do not need premarket review by FDA to ensure their safety, either because their safety has been established by a long history of use in food, or because their safety has been established by information that is generally available to and accepted by qualified experts, regarding the intended conditions of use of a substance in food.

Id. at 54,981–82.

FDA noted that even without express authorization from the FDCA, it could potentially make GRAS notifications mandatory, and commentators suggested that a mandatory system would increase GRAS filings. *See id.* FDA considered these concerns and observed that even under the voluntary system, the food industry had continued to actively submit GRAS notices. *Id.* at 54,981 (Response 26). Such submissions increased in the years after the proposed GRAS Rule was in place; between implementation of the proposed GRAS Rule and 2015, more than 600 GRAS notices were filed, resulting in an average of approximately 34 GRAS notices per year. *Id.* Between 1987 and 1996, FDA received a total of fewer than 100 GRAS affirmation petitions, with an average of approximately 8 GRAS affirmation petitions per year. *Id.* Additionally, FDA observed that a voluntary notification system compared to the previous

voluntary affirmation system would provide greater flexibility to respond to safety concerns. *Id*. at 54,980 (Response 25). Unlike the affirmation process, responding to a safety issue related to a GRAS substance would not require rulemaking. *Id.*

Finally, FDA concluded that mandatory submissions would consume FDA's resources, which could better be directed towards evaluating "more, and higher priority, substances." *See id*. at 54,961, 54,964 (observing that GRAS affirmation process "involved the resource-intensive rulemaking process"), 55,030. FDA explained that instead of conducting a pre-market review, safety concerns could be served by "issuing a [public] warning letter . . .; issuing a public alert; taking enforcement action . . . ; and issuing a declaratory order determining that the substance is not GRAS." *Id*. at 54,981. Not only those who submit GRAS notices are subject to FDA's enforcement authority. For example, in 2013, FDA published a notice in the Federal Register describing its findings that partially hydrogenated oils were not GRAS, and in 2015 issued a declaratory order issuing a final determination that such substances were not GRAS. *Id*. at 54,965. Additionally, FDA issued warning letters related to the use of caffeine in alcohol, resulting in the companies ceasing such distribution. *Id.*; (*see* AR 8649–56, 8662–66).

Based on the nineteen years operating under the proposed GRAS Rule, FDA concluded that the "filing of more than 600 GRAS notices for substances used in human food is evidence that the substitution of a GRAS notification procedure for the GRAS affirmation petition process has benefits for consumers, FDA, the regulated industry, and other stakeholders." 81 Fed. Reg. at 54,966. It found that the notification procedure "increased [its] awareness of the composition of the nation's food supply and the dietary exposure to GRAS substances, which helps [FDA] to ensure the safe use of substances added to food." *Id.* I find that FDA's rationale "was sufficiently reasoned to clear *Chevron*'s rather minimal requirement that the agency give a

reasoned explanation for its interpretation. [I] see nothing illogical in the [FDA]'s rationale." *Catskill Mountains*, 846 F.3d at 524 (finding EPA provided a reasoned explanation for its decision to interpret the Clean Water Act to not require certain permits where EPA based the rule on a "holistic interpretation of the Clean Water Act" taking into account "the statutory language, the broader statutory scheme, the statute's legislative history, [and] the EPA's longstanding position" on water transfers).

Next, I consider the reasonableness of FDA's interpretation of the FDCA, *see id.* at 525, and conclude that the FDA's interpretation is reasonable. First, as I have noted throughout my analysis, the FDCA is silent on whether GRAS notifications must be mandatory, and specifically exempts GRAS substances from the pre-market review regime to which food additives are subject. In promulgating the GRAS Rule, FDA noted that GRAS substances were excluded from the food additives process, and it is entirely reasonable that FDA would view this as suggesting Congress intended GRAS substances to be treated differently because Congress itself had done so.

Second, FDA operated under the proposed GRAS Rule for nineteen years and during that time, GRAS notices increased. When announcing the proposed GRAS Rule, FDA explained with regards to the GRAS affirmation process, "FDA believes that, in practice, this resource-intensive process deters many persons from petitioning the agency to affirm their independent GRAS determinations." 62 Fed. Reg. 18,938, 18,941 (1997). Based on FDA's history operating under the proposed GRAS Rule, it is reasonable that FDA would believe that such a rule would increase its awareness about the ingredients being put into food. Indeed, the increase in GRAS notices as compared to GRAS affirmation petitions bears this out.

Third, as *amicus curiae* SFIC points out in its brief, FDA has a "long-standing record" of

interpreting the FDCA to exempt GRAS substances from premarket review. (Amicus 6.)[15] Indeed, the system in place before the GRAS Rule was also voluntary. *See* 81 Fed. Reg. at 54,960. Similarly, as the Government notes, Congress has amended the Food Additives Amendment but has never amended the language to require mandatory GRAS submissions. (*See* Govt. Mot. 14 (citing as examples Food Quality Protection Act of 1996, Pub. L. 104-170, 110 Stat. 1489 (amending 21 U.S.C. § 342(a)); Dietary Supplement Health and Education Act of 1994, Pub. L. 103-417, 108 Stat. 4325 (amending § 342(f)); Act of June 29, 1966, Pub. L. 89-477, 80 Stat. 231 (amending § 342(d))). Plaintiffs respond that this argument fails because "FDA fails to identify subsequent congressional action bearing on the meaning of the GRAS exception or FDA's statutory responsibilities," and point out that the Government's examples occurred before the proposed GRAS Rule. (Pls.' Opp. 21.) I find it unnecessary here to resolve whether Congress has implicitly ratified FDA's interpretation, but find it persuasive that Congress has remained silent for more than sixty years on whether GRAS submissions should be voluntary, and has amended the statute at issue when a voluntary system was in place. *See Catskill Mountains*, 846 F.3d at 525 (noting that in the forty years since the passage of the Clean Water Act, water transfers were never subject to a general permit requirement and therefore "Congress . . . appears to have, however silently, acquiesced in this state of affairs.").

Finally, it was reasonable for FDA to determine that its resources could better be allocated to higher public health priorities. As SFIC's brief explains, FDA regulates a large percentage of the United States food supply, but less than a fifth of its budget is allocated to food regulatory activities.[16] (Amicus 11.) SFIC argues that "[t]he GRAS Notification program allows

[15] "Amicus" refers to SFIC's amicus brief, filed on July 26, 2019. (Doc. 83.)

[16] As of November 2020, FDA regulated around 78 percent of the United States food supply, and 19 percent of its budget is dedicated to food regulatory activities. *Fact Sheet: FDA at a Glance*, U.S. Food & Drug Admin. (last

FDA to best direct these limited resources. Specifically, it not only allows FDA to focus on higher priority food ingredients, but also other important health-related issues", including food-borne illness and the safety of imported food. (*Id.* at 12.) SFIC also notes that a change to the GRAS Rule would result in confusion and overwhelm FDA with reviewing the status of countless ingredients that are being used in food. (*Id.* 12–13.) FDA's determination that resources could be conserved by taking enforcement action after the fact, instead of requiring pre-market approval, is reasonable and commonplace in the administrative state. *See Nat. Res. Def. Council, Inc. v. U.S. Food & Drug Admin.*, 760 F.3d 151, 170–71 (2d Cir. 2014) ("Agencies have many responsibilities, and limited resources. Deciding whether and when to deploy those resources . . . is an important and difficult responsibility. It is rare that agencies lack discretion to choose their own enforcement priorities.").

In sum, I find FDA's interpretation reasonable given that GRAS substances are specifically exempted from the rigorous review applicable to food additives, GRAS submissions increased under the proposed GRAS Rule, in more than sixty years Congress has never required mandatory GRAS submissions, and that FDA has limited resources to allocate to food safety.

Plaintiffs assert numerous reasons why the GRAS Rule fails at *Chevron* Step Two. At their core, however, Plaintiffs' arguments boil down to the contention that if GRAS notifications were mandatory, FDA could obtain all of the information it needs to make food safety determinations before ingredients are placed into food. (Pls.' Opp. 19.) As Plaintiffs suggest, FDA could, for example, "require[e] any company that conducts a GRAS determination to provide FDA with basic information . . . such as the substance's identity and intended uses." (Pls.' Opp. 18 (quoting AR 008507).) However, this is not the law. FDA's interpretation need

updated Nov. 2020), https://www.fda.gov/about-fda/fda-basics/fact-sheet-fda-glance.

not be "the only possible interpretation, nor even the interpretation deemed *most* reasonable by the courts." *Entergy Corp. v. Riverkeeper, Inc.*, 556 U.S. 208, 218 (2009). Instead, it must simply be a reasonable interpretation of the FDCA.

In further support of their arguments, Plaintiffs point to a comment made by the FDA's deputy commissioner in 2014, when the proposed GRAS Rule was in place, that "[FDA] simply do[es] not have the information to vouch for the safety of many of the[] chemicals [added to food]", and that it is "the opposite of what [Congress] intended," (Pls.' Mot. 19–20 (quoting AR 008088, 8092) (alterations by Plaintiffs)[17], and the GAO Report. The language quoted by Plaintiffs comes from a 2014 Washington Post article exploring issues with the proposed GRAS Rule. I note that the quote excerpted from the deputy commissioner appears to refer not necessarily to the voluntary nature of the Rule being the problem, but rather the potential for conflicts of interest and backdoor dealings. (*See* AR 008092 ("Although informing the FDA is voluntary, he said, the law was meant to increase public scrutiny of additive safety by encouraging companies to publish their science in academic journals. 'The assessments need to be based on publicly available information where there is agreement among scientists,' he said. 'It has got to be more than three employees in a room looking at information that is only available to them.'").) Nevertheless, the article and comments from the FDA's deputy commissioner do raise potential issues with the GRAS Rule, (*see* AR 008088–94); however, these do not rise to the level of defeating *Chevron* deference. Instead, gap-filling the Food Additives Amendment "involves difficult policy choices that agencies are better equipped to make than courts." *Nat'l Cable*, 545 U.S. at 980.

[17] I note that the unaltered quotations read: "We simply do not have the information to vouch for the safety of many of these chemicals" and "This is the opposite of what the overight law intended." (AR 008088, 8092.)

The GAO Report, titled: "FDA Should Strengthen Its Oversight of Food Ingredients Generally Recognized as Safe," (*see* AR 008470–8543), was critical of the proposed Rule's voluntary nature, and reported that "FDA generally does not have information about . . . GRAS determinations because companies are not required to inform the agency of their GRAS determinations." (AR 008481.) GAO explained that without such information, FDA's ability to ensure food safety is hindered, and expressed concern over how FDA could conduct an audit of a company if manufacturers are not subject to recordkeeping requirements. (*See* AR 008485, 8486, 008489.) In characterizing FDA's response to the GAO Report, GAO noted that "[FDA's] comments suggest that FDA would prefer to make notifications mandatory," however, GAO also noted, that "[i]f this is FDA's intended strategy in response to our recommendation, we encourage the agency to seek legal authority from Congress, as needed, to implement this approach." (*Id.* at 8509.) After the GAO report, FDA reopened the comment period for the proposed GRAS Rule, in part due to the findings in the GAO report. *See* 75 Fed. Reg. 81,536, 81,537 (Dec. 28, 2010).

Plaintiffs argue that although the GAO Report alerted FDA to the problems inherent within the GRAS Rule, FDA ignored the Report, and "enacted the GRAS Rule, permitting secrecy and undermining transparency." (Pls.' Mot. 18.) This argument is unpersuasive and ignores the objective facts. As the Government correctly points out, FDA addressed the GAO Report numerous times when enacting the GRAS Rule. *See generally* 81 Fed. Reg. at 54,960–55,028 (mentioning GAO Report more than 10 times). In fact, FDA took steps recommended by GAO, including issuing guidance on the use of nanotechnology, announcing its intent to issue guidance on the potential for conflicts of interest, and reminding the food industry that the same standards apply to a GRAS determination, regardless of whether such a determination is

submitted to FDA. 81 Fed. Reg. at 54,964.

Finally, certain portions of the Record cited by Plaintiffs raise an issue inherent in this case—the increase in processed foods and food additives. (*See* AR 8088) ("In the five decades since Congress gave the FDA responsibility for ensuring the safety of additives in the food supply, the number has spiked from 800 to more than 9,000, ranging from common substances such as salt to new green tea extracts."). I am cognizant of this reality, and of the fact that circumstances have changed since the enactment of the Food Additives Amendment. Still, as was recognized by both FDA and GAO, it remains unclear under the statute whether FDA even has the authority to make GRAS notifications mandatory. I decline Plaintiffs' invitation to rewrite the statute. The remedy Plaintiffs seek lies with Congress, not me, and Congress has chosen not to act despite the increase in the number of food additives over the last five decades.

In sum, because the GRAS Rule is "a reasonable construction of the [FDCA] supported by a reasoned explanation, it survives deferential review under *Chevron*." *Catskill Mountains*, 846 F.3d at 533.

2. *State Farm Analysis*

a. Applicable Law

Pursuant to the APA, a reviewing court may "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary [or] capricious." 5 U.S.C. § 706(2)(A). In *State Farm* the Supreme Court explained that:

> an agency rule would be arbitrary and capricious [under § 706(2)(A)] if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

463 U.S. at 43.

In *Catskill Mountains*, the Second Circuit declined to incorporate the *State Farm* standard into the *Chevron* analysis. 846 F.3d at 521. The Court explained that "[a]n agency's initial interpretation of a statutory provision should be evaluated only under the *Chevron* framework, which does not incorporate the *State Farm* standard" and that "*State Farm* review may be appropriate in a case involving a non-interpretive rule or a rule setting forth a changed interpretation of a statute." *Id.* "*State Farm* is used to evaluate whether a rule is procedurally defective as a result of flaws in the agency's decisionmaking process. *Chevron*, by contrast, is generally used to evaluate whether the conclusion reached as a result of that process—an agency's interpretation of a statutory provision it administers—is reasonable." *Id.* (internal citations omitted).

A litigant may bring a challenge under either standard or both. *Id.* There is typically overlap between a *Chevron* Step Two analysis and *State Farm* analysis. *Id.* at 522 (collecting cases). The Second Circuit has "in many . . . cases, . . . applied *Chevron* Step Two without applying *State Farm* or conducting an exacting review of the agency's decisionmaking and rationale." *Id.* at 522–23; *see, e.g.*, *Stryker v. SEC*, 780 F.3d 163, 167 (2d Cir. 2015); *Florez v. Holder*, 779 F.3d 207, 211–12 (2d Cir. 2015); *Kar Onn Lee v. Holder*, 701 F.3d 931, 937 (2d Cir. 2012); *Adams v. Holder*, 692 F.3d 91, 95 (2d Cir. 2012).

b. Application

Plaintiffs argue that under *State Farm*, "FDA's construction of the [FDCA] . . . constitutes quintessential arbitrary and capricious rulemaking in violation of the APA because it ignores important aspects of food safety, and is inconsistent with the weight of the evidence in the record showing the dangers of this approach." (Pls.' Mot. 20; Pls.' Opp. 22.) Plaintiffs aver that FDA has more than 20 years of evidence of the GRAS Rule's shortcomings yet did nothing

to grapple with these concerns. (Pls.' Mot. 20–21.) Plaintiffs cite to *Nat. Res. Def. Council v. U.S. E.P.A.*, 658 F.3d 200, 215–16 (2d Cir. 2011) ("*NRDC*"), in which the Second Circuit held an agency's action was arbitrary and capricious under *State Farm* where the agency failed to provide an explanation for its action as was required by the statute at issue.

Plaintiffs' citation to *NRDC* is misplaced. FDA's actions here are not akin to those at issue in *NRDC*. As I detailed in my *Chevron* analysis, *supra* IV.B.1.b, FDA provided numerous cogent explanations for adopting the GRAS Rule—including the increase in GRAS submissions under the proposed GRAS Rule and that based on FDA's experience "streamlining [its] evaluation of conclusions of GRAS status will enable [FDA] to evaluate more, and higher priority, substances," 81 Fed. Reg. at 54,961. Additionally, FDA considered countless comments suggesting what Plaintiffs suggest here—that notifications should be mandatory—and considered the GAO Report, which Plaintiffs rely on heavily in building their argument. *See* 81 Fed. Reg. at 54,960–55,028. For the aforementioned reasons, I do not find FDA's actions to be arbitrary and capricious.[18]

C. *FDCA Challenge*

In a final attempt to strike down the GRAS Rule, Plaintiffs argue that the GRAS Rule is unlawful because its criteria for determining GRAS status contradicts the FDCA. (Pls.' Mot. 21–25.) In particular, Plaintiffs aver that the criteria within the GRAS Rule differs from the FDCA's requirement that a substance is eligible for GRAS status only if that substance is

[18] It bears noting that *Catskill Mountains* distinguished between *Chevron* and *State Farm* based in part on whether the agency's interpretation of the statute was its first. *See* 846 F.3d at 521 ("*State Farm* review may be appropriate in a case involving . . . a rule setting forth a changed interpretation of a statute."). Although FDA has previously interpreted the GRAS provision within the Food Additives Amendment, those prior interpretations, like the current GRAS Rule, provided only for voluntary submissions. *See* 81 Fed. Reg. at 54,963–64 (describing the history of FDA's approach). Therefore, there was no change in FDA's interpretation, which is the heart of Plaintiffs' challenge here.

"generally recognized, among experts qualified by scientific training and experience . . . as having been adequately shown through scientific procedures . . . to be safe under the conditions of its intended use." 21 U.S.C. § 321(s); (Pls.' Mot. 21.) Plaintiffs cite to five reasons: (1) the GRAS Rule fails to include sufficient criteria to ensure that the data, information, and methods upon which manufacturers base their GRAS determinations are "generally recognized"; (2) the GRAS Rule does not include criteria to ensure that manufacturers' GRAS determinations are free from conflicts of interest; (3) the GRAS Rule does not contain any criteria to ensure manufacturers do not self-certify substances as GRAS after FDA raises safety concerns about them; (4) FDA finalized the GRAS Rule without including any criteria to prevent manufacturers from secretly self-certifying newly synthesized or novel substances as GRAS; and (5) the GRAS Rule fails to include criteria clarifying that carcinogenic substances can never be deemed safe for use in food. (Pls.' Mot. 21–25.)

At the outset, I note that reasons three and four are essentially reiterations of the issues Plaintiffs flagged in their other challenges, and I do not restate my findings here. Regarding Plaintiffs' first reason, Plaintiffs make much of the fact that GRAS determinations can be based on unpublished material. (*Id.* at 22.) Plaintiffs argue that because the information is unpublished, it cannot be "generally recognized." (*Id.*) However, as the Government points out, general recognition is embodied within the GRAS Rule's criteria. (*See* Govt. Mot. 21.) For example, in general, GRAS determinations must be "based upon the application of generally available and accepted scientific data, information, or methods," 21 C.F.R. § 170.30(b), require "common knowledge throughout the scientific community," *id.* § 170.30(a), and require "the same quantity and quality of scientific evidence as is required to obtain approval of a food additive," *id.* § 170.30(b). In responding to a comment, FDA explained "the common

knowledge element of the GRAS standard precludes a GRAS conclusion if the data and information . . . are only available in files that are not publicly accessible, such as in confidential industry files." 81 Fed. Reg. at 54,973. Although FDA itself notes the material used in making GRAS determinations is "ordinarily . . . published," 21 C.F.R. § 170.30(b); *see* 81 Fed. Reg. at 54,973, this is not inconsistent with its choice not to ban unpublished evidence from being considered. Unpublished material is just one potential part of the GRAS determination. Additionally, the use of unpublished material is not inconsistent with the FDCA. There is no blanket prohibition on considering such material.[19]

Plaintiffs' second concern about conflicts of interest does not render the GRAS Rule inconsistent with the FDCA. Although Plaintiffs' concern may be valid, in 2017, FDA issued draft guidance on the issue, *see Best Practices for Convening a GRAS Panel: Guidance for Industry*, U.S. Food and Drug Admin., https://www.fda.gov/media/109006/download, and the FDCA is silent on what steps must be taken for addressing conflicts in GRAS determinations. Plaintiffs cite to a study in the Record, showing that in "more than 450 GRAS determinations voluntarily reported to FDA, every determination was made by experts with financial ties to the manufacturer of the substance at issue." (Pls.' Mot. 23 (citing AR 008220).) This study reports that of the 451 GRAS notices that were reviewed, "22.4% were made by an employee of an additive manufacturer, 13.3% were made by an employee of a consulting firm selected by a manufacturer, and 64.3% were made by an expert panel selected by the manufacturer or a firm

[19] Plaintiffs argue that "[t]he conclusion that the GRAS Rule's criteria fail to ensure true 'general recognition' is confirmed by long-standing interpretations of that term, as it appears elsewhere in the FDCA. For example, the Second Circuit has concluded that, in the absence of any 'published scientific literature,' qualified experts are likely unable to make any determination as to the 'general recognition' of a drug product's safety." (Pls.' Mot. 22 n.11 (quoting *Premo Pharm. Labs., Inc. v. U.S.*, 629 F.2d 795, 804 (2d Cir. 1980).) Plaintiffs, however, fail to point me to any provision within the FDCA that requires that general recognition be based on published material, and Plaintiffs' citation to a 40-year-old case involving a drug is inapposite.

that was a consultant to the manufacturer." (AR 008220.) The study, however, broadly uses the term "financial interest" and noted that the interest of a selected expert panel would be the interest in "[b]eing selected for more panels." (*Id.* at 8219–20.) Additionally, inherent in the GRAS Rule are certain safeguards, including that GRAS notices must have a signed statement certifying that the notice is a "complete, representative, and balanced submission that includes [known] unfavorable information." 21 C.F.R. § 170.225(c)(9).

Finally, I consider Plaintiffs' fifth reason: that the GRAS Rule is contrary to the Delaney Clause, a provision within the FDCA that prohibits FDA from approving food additives that are found to induce cancer. *See* 21 U.S.C. § 348(c)(3)(A). Plaintiffs state that FDA is aware that certain manufactures have determined cancer-causing substances to be GRAS, and has not articulated a position that "carcinogenic substances can never be deemed safe for use in food." (Pls.' Mot. 24–25.) The Government notes that the Delaney Clause governs food additives, not GRAS substances, and point to dicta from a D.C. Circuit case suggesting the Delaney Clause may not bar a finding that a substance with *de minimis* carcinogenicity is GRAS. (Govt. Mot. 24 (citing *Public Citizen v. Young*, 831 F.2d 1108, 1119–20 (D.C. Cir. 1987)).) Plaintiffs respond with a convoluted argument—"if a substance cannot be deemed 'safe' as a food additive, it certainly cannot qualify to be generally recognized as safe." (Pls.' Opp. 25.)

Inherent in the GRAS Rule are criteria that would likely prevent a carcinogenic substance from being deemed GRAS. *See* 21 C.F.R. § 170.30(a) ("General recognition of safety requires common knowledge throughout the scientific community . . . that there is a reasonable certainty that the substance is not harmful under the conditions of its intended use."). Additionally, if the Delaney Clause does in fact apply to GRAS determinations, then the criteria that Plaintiffs contend is missing from the GRAS Rule, is already present. In conclusion, I find that the GRAS

Rule does not unlawfully conflict with the FDCA.

V. Conclusion

Accordingly, because I find that the GRAS Rule (1) does not unlawfully subdelegate FDA's duty to ensure food safety; (2) does not exceed FDA's statutory authority; (3) does not constitute arbitrary and capricious agency action in violation of the FDCA and APA; and (4) does not conflict with the FDCA, Plaintiffs' motion for summary judgment is DENIED, and the Government's motion for summary judgment is GRANTED.

The Clerk of Court is respectfully directed to terminate docket entries 65 and 74, and to close this case.

SO ORDERED.

Dated: September 30, 2021
New York, New York

Vernon S. Broderick
United States District Judge