UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

CENTER FOR FOOD SAFETY and ENVIRONMENTAL DEFENSE FUND, *Plaintiffs*, *v.* ALEX M. AZAR II, SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES, NED SHARPLESS, ACTING COMMISSIONER, UNITED STATES FOOD AND DRUG ADMINISTRATION, and UNITED STATES FOOD AND DRUG ADMINISTRATION, *Defendants*.	)	No. 1:17-cv-3833 (VSB) (BCM)

MEMORANDUM OF LAW
IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION AND SUMMARY OF ARGUMENT

This case is about the safety of our food. More specifically, it asks whether the U.S. Food and Drug Administration ("FDA" or the "Agency") may allow companies to determine—in secret—that a substance they have manufactured for use in food is "generally recognized as safe" ("GRAS") within the meaning of the Federal Food, Drug and Cosmetic Act ("FFDCA") and, thus, exempt from the pre-market approval process for food additives required by the statute.

Plaintiffs Center for Food Safety and Environmental Defense Fund challenge *Substances Generally Recognized as Safe*, 81 Fed. Reg. 54,960 (Aug. 17, 2016) (codified at 21 C.F.R. pts. 20, 25, 170, 184, 186 & 570) ("GRAS Rule"), a final rule adopted by FDA, because it violates the U.S. Constitution, the FFDCA, and the Administrative Procedure Act ("APA"). By subdelegating to self-interested manufacturers the authority to decide the safety of substances added to our food without agency oversight, public participation, judicial review, or sufficient protections to ensure food safety, FDA created a regulatory scheme that eviscerates its ability to fulfill its statutory obligations in three ways.

First, in the GRAS Rule, FDA unlawfully subdelegates to private parties its core statutory duty to keep food safe—despite the lack of express statutory authorization to do so. This subdelegation eliminates FDA oversight, public accountability, and judicial review—all constitutional necessities. The result is a complete erosion of the FFDCA's structure and purpose with respect to food additives. *Second*, by allowing self-interested private parties to make GRAS determinations in secret, the GRAS Rule keeps FDA in the dark about many of the substances used in foods, preventing the Agency from carrying out its statutory duty to ensure the safety of food both before substances enter our food supply and after food safety problems occur. *Third*, despite clear evidence documenting serious safety concerns about GRAS certifications made by

private entities, the GRAS Rule unreasonably fails to include even minimal criteria to ensure that manufacturers' GRAS determinations are sound.

In sum, the GRAS Rule offends core precepts of democratic accountability for agency actions, contradicts the language and goals of the FFDCA, impedes FDA from doing its job, and permits self-interested private parties to be the guardians of our food safety. This Court should vacate the rule and require FDA to promulgate a rule implementing the FFDCA faithfully and in compliance with constitutional principles and statutory mandates.

LEGAL AND PROCEDURAL BACKGROUND

The Federal Food, Drug, and Cosmetic Act

The FFDCA directs FDA to "protect the public health by ensuring that . . . foods are safe." *Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. § 393(b)(2). Twenty years after adopting the FFDCA, Congress expanded upon this requirement by "prohibit[ing] the use in food of additives which have not been adequately tested to establish their safety." Food Additives Amendment of 1958, Pub. L. No. 85-929, 72 Stat. 1784, 1784. The Amendment was motivated by Congress's concern with the growing use of chemicals in food production, and health risks posed by such uses. H.R. Rep. No. 82-2356 (1952), at 27. As amended, the statute commands that any additive "shall . . . be deemed to be *unsafe*" unless used "in conformity with[] a regulation . . . prescribing the conditions under which such additive may be safely used." 21 U.S.C. § 348(a)(2) (emphasis added).[1]

The revised FFDCA establishes a comprehensive process for the premarket review of proposed food additives. FDA must evaluate the safety of the proposed additive by considering, *inter alia*: (1) "the probable consumption of the additive and of any substance formed in or on

[1] The FFDCA includes a limited exception for the investigational use of unapproved additives, *see* 21 U.S.C. § 348(j), not at issue here.

food because of the use of the additive" and (2) "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." *Id.* §§ 348(c)(5)(A), (B). In addition, the statute directs FDA to publish notice of a food additive petition and invites thorough participation in the process, authorizing members of the public to file objections to and request hearings on FDA's decisions on such petitions. *See id.* §§ 348(b)(5), (e), (f)(1). Pursuant to that process, FDA may not authorize use of a food additive "if a fair evaluation of the data before [the Agency] . . . fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe." *Id*. § 348(c)(3)(A).[2] The Agency's final decision to enact (or decline to enact) a food additive regulation is subject to judicial review. *See id*. § 348(g).

The FFDCA's definition of "food additive" includes an important exception. "Food additive" is defined as "any 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." *Id*. § 321(s) (internal quotation marks omitted). The term "food additive" is defined to exclude substances that are:

> generally recognized, among experts qualified by scientific training and experience to evaluate its 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 its intended use.

Id. Because GRAS substances must be safe *by definition*, Congress did not require these substances to undergo the FFDCA's rigorous process for premarket review for food additives.

[2] Under the FFDCA's mandate, Congress intended to "require[] proof of a reasonable certainty that no harm will result from [the] use" of a proposed food additive. H.R. Rep. No. 85-2284, at 4 (1958); S. Rep. No. 85-2422, at 6 (1958), *as reprinted in* 1958 U.S.C.C.A.N. 5300, 5305.

The GRAS Rule

The GRAS Rule purports to establish processes for implementing the GRAS exception to the premarket food additive review process. It sets forth criteria for whether a planned use of a chemical substance is "generally recognized as safe" and it describes in detail the optional process manufacturers *could* use to notify FDA about their GRAS determinations.[3] 81 Fed. Reg. 54,960. Although FDA did not issue the final GRAS Rule until August 2016, the policies and processes set forth in the final GRAS Rule have actually been in operation for more than twenty years: FDA first proposed the GRAS Rule in 1997, and instructed food and chemical manufacturers to begin complying with its provisions at that time despite its not yet being final. *See* 81 Fed. Reg. at 54,967-68. FDA then delayed nearly two decades before litigation led to issuance of the final GRAS Rule. *See Ctr. for Food Safety v. Burwell*, No. 14-cv-00267-RC (D.D.C. Oct. 20, 2014), ECF No. 15 (consent decree establishing final rule deadline).

Central to the GRAS Rule are the criteria for "eligibility for classification as [GRAS]." 21 C.F.R. § 170.30. The Rule provides that GRAS status may be based only on "the views of experts qualified by scientific training and experience" to evaluate the safety of food additives. *See id.* § 170.30(a). However, the Rule does not limit or prescribe who can serve as an "expert" responsible for GRAS determinations, and does not provide a process for verifying expertise.[4] These "experts" must base the "general recognition of safety" determination on "the application of generally available and accepted scientific data, information, or methods, which *ordinarily* are

[3] Under the FFDCA, it is a substance under conditions of its intended use, rather than the substance generally, that is eligible for the GRAS exemption. However, for ease of reference, we refer to GRAS substances throughout this brief.

[4] FDA proposed, but never finalized, non-binding voluntary guidance regarding conflicts of interest. *Best Practices for Convening a Generally Recognized As Safe Panel: Draft Guidance for Industry; Availability*, 82 Fed. Reg. 53,433 (Nov. 16, 2017) (codified at 21 C.F.R. pts. 170 & 570). This non-binding draft does not cure conflicts of interest infecting GRAS determinations.

published, as well as the application of scientific principles, and may be corroborated by the application of *unpublished* scientific data, information, or methods." *Id.* § 170.30(b) (emphases added). In other words, the Rule allows manufacturers to base GRAS determinations on the "expertise" of their own consultants or employees relying on unpublished information corroborated by unpublished information.

Most of the GRAS Rule is devoted to the *optional* process for manufacturers to notify FDA if they self-certify use of a substance as GRAS. *See, e.g., See* 21 C.F.R. § 170.205 ("Any person *may* notify FDA of a view that a substance" is GRAS) (emphasis added); 81 Fed. Reg. at 55,043 ("Specifically the final rule establishes a *voluntary* administrative procedure for notifying FDA" that a substance is GRAS) (emphasis added). However, in many cases, manufacturers never notify FDA of GRAS determinations. *See* AR 008629 (finding that approximately 1,000 GRAS determinations were self-certified with no notice to FDA). In those cases, FDA has no opportunity to express safety concerns before the manufacturers classify the substances as GRAS or use it in food. And the Rule also does not require manufacturers to preserve records documenting the basis of any secret GRAS determinations. 81 Fed. Reg. at 55,044.

Food Safety Under the GRAS Rule

Implementation of the GRAS Rule has resulted in widespread uncertainty about the identity and safety of chemical substances in our food. In 2010, after industry had been following the procedures set forth in the 1997 proposed GRAS Rule for more than a decade, the U.S. Government Accountability Office ("GAO") issued a report titled: *FDA Should Strengthen Its Oversight of Food Ingredients Generally Recognized as Safe* ("GAO Report"). AR 008470-8543. GAO 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. FDA itself "acknowledged that [its database purporting to track all

substances added to food] is incomplete because companies are not required to participate in the GRAS notification program or even inform FDA of their GRAS determinations, and FDA officials cannot estimate the number of determinations that occur about which they are not notified." AR 008486. The GAO found that FDA's lack of information about substances in our food supply impedes the Agency's ability to ensure food safety. *See, e.g.*, AR 0084845 (because FDA does not know what substances "ha[ve] been determined to be GRAS," it is "difficult" for FDA to determine what substances are "the potential source of a food safety problem")]; AR 008486. ("Without information about all GRAS determinations, FDA has less awareness of substances in the nation's food supply and less knowledge of the potential cumulative dietary exposure of GRAS substances."). GAO also expressed concern about FDA's failure to impose recordkeeping requirements to facilitate enforcement, as well as its failure to develop guidance that would help manufacturers avoid conflicts of interest. AR 008488-89.

Additional studies identified significant shortcomings with FDA's GRAS Rule. For example, a 2011 study focusing on conflicts of interest in GRAS decisions found that, among 451 GRAS notices *voluntarily* submitted to FDA, *all* the GRAS determinations were made by either an employee of an additive manufacturer, an employee of a consulting firm selected by a manufacturer, or by an expert panel selected by the manufacturer or a firm that was a consultant to the manufacturer. AR 008220. The study uncovered "no instances where a manufacturer who submitted a GRAS notice to the FDA used a standing expert panel selected by a third party . . . to establish whether an additive met the GRAS criteria." AR 008220-21.

Another safety problem highlighted in the record is that the GRAS Rule does not prohibit manufacturers who submit food additive petitions or voluntary GRAS notices to FDA from subsequently withdrawing those petitions or notices and proceeding to self-certify the safety of

their products in secret, *even after* FDA raises questions about the safety of those products. AR 008272. And some manufacturers appear to have done just that, for substances including: epigallocatechin-3-gallate, used in teas, sport drinks, and juices, for which FDA identified concerns based on evidence that it might cause leukemia in fetuses, and that it has affected the thyroid, testis, spleen, pituitary, liver, and gastrointestinal tract in rats, *id.*; gamma-amino butyric acid, used in beverages, chewing gum, and candy, for which FDA found that cumulative consumer exposure would exceed the levels that the manufacturer considered to be safe, *id.*; and theobromine, used in beverages, candy, and yogurt and fruit smoothies, for which FDA concluded that some consumers would likely ingest more than five times the safe level reported by the manufacturer's consultant. AR 008273.

PROCEDURAL HISTORY

Plaintiffs filed their Complaint on May 22, 2017. Dkt. 1. Defendants moved to dismiss the Complaint for lack of standing, Dkt. 30, and this Court denied Defendants' motion as to Plaintiffs Center for Food Safety ("CFS") and Environmental Defense Fund ("EDF"). Dkt. 44 at 17-18. Following the Court's Order, Defendants filed their Answer. Dkt. 50. The parties submitted a proposed scheduling order, Dkt. 51, which they subsequently agreed to clarify after a lapse in government funding. Dkt. 63. Plaintiffs now move for summary judgment.

STANDING

Based on the well-pleaded allegations in the Complaint, this Court found that Plaintiffs have standing to sue on behalf of their members who "have been and will be exposed to potentially dangerous substances that were introduced into the food supply without FDA oversight, public participation, or the opportunity for judicial review," that Plaintiffs' "reasonably anticipate" that "dangerous substances" "will be introduced into the food supply under the GRAS Rule," and that Plaintiffs' "injuries are ongoing and imminent." Dkt. 44 at 13-

14. The declarations submitted along with this Memorandum of Law confirm the allegations set forth in the Complaint: as a direct result of the GRAS Rule's unlawful shortcomings (as described below), Plaintiffs' members have been exposed and will continue to risk exposure to potentially dangerous substances added to food without FDA oversight or accountability and absent any opportunity for public participation or judicial review.

STANDARD OF REVIEW

In a case like this where "a party seeks judicial review of an agency action, 'summary judgment is appropriate since whether an agency action is supported by the administrative record and consistent with the APA standard of review is decided as a matter of law.'" *Schwebel v. Crandall*, 343 F. Supp. 3d 322, 327 (S.D.N.Y. 2018) (quoting *Residents for Sane Trash Solutions, Inc. v. U.S. Army Corps of Eng'rs*, 31 F. Supp. 3d 571, 586 (S.D.N.Y. 2014)).

ARGUMENT

I. The GRAS Rule Unlawfully Subdelegates FDA's Statutory Authority to Manufacturers in Violation of the U.S. Constitution, the APA, and the FFDCA.

Congress delegated to FDA the responsibility of ensuring that our nation's food is safe and free from harmful substances. *See* Pub. L. No. 85-929, 72 Stat. 1748; 21 U.S.C. § 393(b). Pursuant to the GRAS Rule, FDA 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. 21 C.F.R. § 170.205. For the reasons below, FDA's subdelegation of GRAS determinations to self-interested, for-profit corporations violates fundamental constitutional principles, the FFDCA, and the APA because Congress has not expressly authorized it, it insulates FDA from democratic accountability for decisions about

food safety, and it denies citizens their right to seek judicial review of decisions about the safety of substances that may be added to food.[5]

A. FDA's Subdelegation to Manufacturers of Its Food Safety Responsibility Is Not Expressly Authorized and Is Therefore Impermissible.

According to the Second Circuit, "absent statutory authorization," subdelegation of statutory responsibility by federal agencies and officers to outside parties "is impermissible." *Fund for Animals v. Kempthorne*, 538 F.3d 124, 132 (2d Cir. 2008); *accord U.S. Telecom Ass'n v. FCC*, 359 F.3d 554, 565 (D.C. Cir. 2004). The reason for this is clear: when an agency "shifts to another party 'almost the entire determination of whether a specific statutory requirement . . . has been satisfied,' or . . . abdicates its 'final reviewing authority,'" then "lines of accountability may blur, undermining an important democratic check on government decision-making." *Fund for Animals*, 538 F.3d at 132 (internal citations omitted) (alterations in original). In addition, while agencies are charged with acting in the public interest, "outside parties . . . might not 'share the agency's national vision and perspective.'" *Id.* (quoting *U.S. Telecom*, 359 F.3d at 566). Thus subdelegation to private parties damages the function, purpose, and system of accountability for government actions.

Nothing in the FFDCA states that FDA may subdelegate to regulated entities decisions about whether chemical substances are safe, or that it can outsource decisions that are fundamental to FDA's core responsibility for ensuring food safety. Because Congress did not expressly authorize it, the GRAS Rule's subdelegation of authority for making GRAS

[5] Petitioners challenge FDA's action directly under the Constitution, as well as under the APA, which provides an additional means to challenge the constitutionality of agency actions. *See* 5 U.S.C. § 706(2)(B).

determinations to manufacturers is flatly impermissible.[6] *Id.* at 133; *U.S. Telecom Ass'n*, 359 at F.3d at 565.

B. FDA's Subdelegation of Statutory Authority to Self-Interested Manufacturers Violates Fundamental Constitutional Principles and the FFDCA, and Is Thus Unlawful.

Even if Congress implicitly authorized some subdelegation of GRAS determinations to private parties, the subdelegation codified in the GRAS Rule cannot stand. Irrespective of congressional authorization, courts must carefully scrutinize subdelegations to ensure that they do not erode constitutional checks on an agency's authority or interfere with an agency's fulfillment of its statutory obligations. *See, e.g.*, *U.S. Telecom Ass'n*, 359 F.3d at 565. As discussed below, the GRAS Rule impermissibly does both.

This Circuit has held that even with statutory authorization, subdelegation to private parties is permissible only where the agency retains sufficient oversight so that "lines of accountability [do not] blur," and "democratic check[s] on government decision-making" are not undermined. *Fund for Animals*, 538 at 132 (quoting *U.S. Telecom*, 359 F.3d at 565); *see also Nat'l Ass'n of Regulatory Util. Comm'rs v. FCC*, 737 F.2d 1095, 1143 n.41 (D.C. Cir. 1984) (a key purpose of prohibiting delegation to private entities is preventing "the harm done thereby to principles of political accountability"). Thus, in *Fund for Animals*, the Second Circuit upheld an agency's subdelegation because "the discretion granted to . . . third parties [wa]s limited and subject to adequate oversight." 538 F.3d at 132; *accord Cooling Water Intake Structure Coal. v. EPA*, 905 F.3d 49, 80 (2d Cir. 2018) (allowing subdelegation because EPA would independently

[6] "A general delegation of decision-making authority to a federal administrative agency does *not*, in the ordinary course of things, include the power to subdelegate that authority beyond federal subordinates." *U.S. Telecom Ass'n*, 359 F.3d at 566 (emphasis in original). "[S]tatutory 'silence' simply leaves that lack of authority untouched," and "the failure of Congress to use 'Thou Shalt Not' language doesn't create a statutory ambiguity. . . ." *Id.*

determine applicability of the statute). By contrast, subdelegations that render agency oversight "neither timely nor assured" cannot stand. *U.S. Telecom Ass'n*, 359 F.3d at 567.

Unlike the subdelegations at issue in *Fund for Animals* and *Cooling Water Intake Structure Coalition*, the GRAS Rule fails to ensure that FDA retains oversight of GRAS determinations. Private companies can self-certify their chemical additives as GRAS without notifying FDA. *See* 21 C.F.R. § 170.205 ("Any person *may* notify FDA" of a GRAS determination) (emphasis added); 81 Fed. Reg. at 55,043 (noting the "*voluntary* administrative procedure for notifying FDA" of GRAS determinations under the Rule) (emphasis added). Moreover, even if a company does voluntarily notify FDA of a GRAS determination, if FDA questions the substance's safety, the manufacturer may withdraw its notice and proceed to secretly self-certify the chemical as GRAS. *See supra* at 6-7; AR 08272-73 (describing several chemical substances self-certified as GRAS by manufacturers after FDA raised safety concerns). Thus, FDA oversight is by no means "assured," and the public cannot hold FDA accountable for the safety of the substances that have secretly entered the food system under the guise of GRAS without FDA's knowledge or approval. *U.S. Telecom Ass'n*, 359 F.3d at 567.

Further compounding the problem, under the GRAS Rule, manufacturers can secretly certify a substance as GRAS based entirely on unpublished material, precluding the public from accessing the studies or evidence purportedly showing that the substance is "generally recognized" "with reasonable certainty" to be safe. This impermissibly shields the manufacturers' decisions not only from FDA review, but also from public scrutiny.

The GRAS Rule's erosion of FDA accountability is best demonstrated by looking at the opportunity for public oversight that is lost when a substance enters the food supply through the GRAS exception, rather than through the food additive petition process. If a manufacturer

submits a food additive petition seeking FDA approval, the public has a statutory right to participate in the process, including the right to seek judicial review of food additive approvals. *See* 21 U.S.C. § 348(b)(5) (FDA must publish notice of a proposed food additive approval); *id*. § 348(f)(1) (public may file objections to proposed food additive approval and request a public hearing); *id*. § 348(g) (food additive approval is subject to judicial review). Yet the GRAS Rule permits manufacturers to bypass this process by self-certifying chemical substances as GRAS without genuine safeguards for assuring that those substances do, in fact, meet the statutory criteria for GRAS. *See infra* Section III (explaining that the GRAS Rule does not prohibit manufacturers from certifying as GRAS substances that are, *e.g*., novel, carcinogenic, not described in peer review literature, or based on unpublished material, and for these reasons the Rule is arbitrary and capricious). In so doing, the GRAS Rule unlawfully shields safety decisions about substances that should be considered "food additives" from both public participation and judicial review, leaving the public with no recourse. *See* AR 002256.[7] This is the very definition of lack of accountability and judicial oversight, undermining an essential check on agency rulemaking. Therefore, the GRAS Rule cannot stand. *Fund for Animals*, 538 F.3d at 132.

The GRAS Rule also strips the public of its ability to seek recourse in the courts because GRAS determinations made by private parties are not "agency action" within the meaning of the judicial review section of the APA. 5 U.S.C. § 706(2); *see Anglers Conservation Network v. Pritzker*, 809 F.3d. 664, 669 (D.C. Cir. 2016) (holding that the Mid-Atlantic Council is not a

[7] The GAO alerted Congress of this deficiency, reporting that the Rule precludes FDA from oversight because the agency "generally does not have information about [non-voluntary] GRAS determinations." AR 008471*; accord* AR 008218 ("The lack of independent review in GRAS determinations raises concerns about the integrity of the process and whether it ensures the safety of the food supply"); AR 008634 ("FDA also lacks clear authority to order companies to test the safety of chemicals they add to food.").

federal agency and its actions cannot be attributed to a federal agency, so the APA does not apply). In contrast, if FDA makes a final determination that a substance is GRAS, it could be challenged under the APA. *See Bennett v. Spear*, 520 U.S. 154, 175 (1997); *Bowen v. Mich. Acad. of Family Physicians*, 476 U.S. 667, 672-73, 682 n.3 (1986) (explaining the strong presumption that agency action is subject to judicial review). When 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. *Connecticut v. Am. Elec. Power Co., Inc.*, 406 F. Supp. 2d 265, 267 (S.D.N.Y. 2005), *vacated and remanded on other grounds*, 582 F.3d 309 (2d Cir. 2009), *rev'd*, 564 U.S. 410, 131 (2011) ("The Framers based our Constitution on the idea that a separation of powers enables a system of checks and balances, allowing our Nation to thrive under a Legislature and Executive that are accountable to the People, subject to judicial review by an independent Judiciary.") (citing Federalist Paper No. 47 (1788)); *cf. Defs. of Wildlife v. Gutierrez*, 532 F.3d 913, 926 (D.C. Cir. 2008) (declining to find that the Coast Guard was not accountable for traffic schemes devised by entity to which the Coast Guard had delegated this duty because such a construction would leave citizens with no recourse to sue the Coast Guard).

The lack of accountability and judicial review created by the GRAS Rule are all the more concerning because manufacturers have a clear financial incentive to self-certify their own substances as GRAS. This profit motive creates a conflict of interest that has pervaded GRAS determinations since the GRAS Rule initially went into effect. *See, e.g.*, AR 008218-25 (report finding that "financial conflicts of interest were ubiquitous" in GRAS determinations); *see also* AR 002039 (FDA's conflict of interest guidelines "do not extend to expert panels convened by private companies to establish consensus for GRAS determinations").

These conflicts of interest may incentivize the manufacturers' reviewing "experts" to conduct a more rapid and less rigorous review process than what FDA or independent experts might carry out. And these conflicts may generate differing and even self-serving views of food safety, and may lead manufacturers to "pursue goals inconsistent with" what the FFDCA requires, rendering the subdelegation unlawful. *U.S. Telecom Ass'n*, 359 F.3d at 565-66; *see also Nat'l Park & Conservation Ass'n v. Stanton*, 54 F. Supp. 2d 7, 20 (D.D.C. 1999) (finding unlawful agency's subdelegation to a council comprised partly of private landowners because the council's "dominant private local interests" were likely to conflict with the agency's statutory duties to the general public); *Sierra Club v. Sigler*, 695 F.2d 957, 962 n.3 (5th Cir. 1983) ("an agency may not delegate its public duties to private entities . . . particularly private entities whose objectivity may be questioned on grounds of conflict of interest.").

C. The GRAS Rule's Subdelegation Is Not an Attempt by FDA to Seek Legitimate Outside Input.

Finally, 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. *See U.S. Telecom Ass'n*, 359 F.3d at 566. This is not a situation in which the agency permissibly "condition[s] a grant of permission on the decision of another entity" because here, FDA "delegated to another actor almost the entire determination of whether a specific statutory requirement [here, the safety of a particular substance in food] has been satisfied." *Id.* at 567. Nor is it the case that FDA is permissibly using the manufacturers to provide it with factual information while retaining for itself sufficient oversight over the final decisions on food safety. *Id.* And the subdelegation can hardly qualify as seeking "advice and policy recommendations" from an outside entity given that the Rule renders FDA unaware of many of the GRAS determinations made by the companies. *Id.* at 568.

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In sum, the GRAS Rule's subdelegation of statutory authority to private self-interested parties to make decisions crucial to the safety of our food unlawfully removes fundamental checks on FDA's responsibility to keep our food safe. FDA's lack of accountability engenders a system that precludes the public from seeking judicial recourse to challenge food safety determinations, in violation of the FFDCA and separation of power principles. For these reasons, the Court should conclude that FDA acted unlawfully by subdelegating GRAS decisionmaking to private parties without express statutory authorization and in violation of the FFDCA and fundamental constitutional limitations.

II. The GRAS Rule Conflicts with Statutory Mandates, Exceeds FDA's Statutory Authority, and Constitutes Arbitrary and Capricious Agency Action in Violation of the FFDCA and APA.

Not only does the GRAS Rule constitute an unlawful subdelegation of authority in violation of fundamental constitutional principles and the FFDCA, but it also must be "h[e]ld unlawful and set aside" as an agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" or "in excess of statutory . . . authority." 5 U.S.C. § 706(2)(A), (C).

To determine whether an action exceeds agency authority or fails to accord with governing law, courts first examine "whether Congress has directly spoken to the precise question at issue." *Chevron U.S.A., Inc. v. Nat. Res. Def. Council*, 467 U.S. 837, 842 (1984); *Lawrence & Mem'l Hosp. v. Burwell*, 812 F.3d 257, 264 (2d Cir. 2016). "If the intent of Congress is clear, that is the end of the matter." *Lawrence & Mem'l Hosp.*, 812 F.3d at 264 (quoting *Chevron*, 467 U.S. at 842-43). "[I]f the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute." *Id*. (quoting *Chevron*, 467 U.S. at 843). To determine whether

agency action is arbitrary and capricious, courts look to see whether "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." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Applying these tests to the GRAS Rule leaves no doubt that it is unlawful.

A. The GRAS Rule Conflicts with the FFDCA's Plain Text and Intent and Thus Exceeds FDA's Authority and Violates the FFDCA.

Under the first step of the *Chevron* analysis, the Court must determine whether the GRAS Rule conflicts with the intent of Congress as set forth in the FFDCA. To evaluate Congress's intent, the Court must look at the statute's language as well as its purpose. The language of the FFDCA requires FDA to evaluate a number of factors in assessing the safety of any proposed use of a food additive. Specifically, the FFDCA mandates that 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) (emphasis added). FDA has no discretion to disregard this unambiguous statutory command. *See, e.g.*, *Katz v. Cellco P'ship*, 794 F.3d 341, 345 (2d Cir. 2015) ("Congress's 'use of a mandatory ''shall" . . . impose[s] discretionless obligations.'") (quoting *Lopez v. Davis*, 531 U.S. 230, 241 (2001)).

The GRAS Rule contravenes this plain statutory language. Because it allows manufacturers to make secret safety determinations, FDA does not have a list of every GRAS substance added to our food. *See* AR 008486; *see also* AR 008088 (admitting that FDA cannot "vouch for the safety of many of [these substances]"). As a result, FDA cannot determine our "potential cumulative dietary exposure [to] GRAS substances." AR 008486. Without information

about current exposures to substances *already* used in food, 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. 21 U.S.C. § 348(c)(5)(B). Thus, the GRAS Rule contravenes the plain terms of the FFDCA, which require FDA to consider the cumulative effects of substances added to food when making GRAS determinations.

Moreover, in at least three key respects, the GRAS Rule is incompatible with the FFDCA's core purpose of ensuring food safety.

First, FDA cannot ensure food safety if manufacturers are allowed to secretly self-certify substances as GRAS. "FDA, as the administrative agency created by Congress to administer the [FFDCA], cannot intelligently and rationally perform its regulatory duties unless *it* determines what products are 'food additives' under 21 U.S.C. s. 321(s) and what products, because of their GRAS status, are exempt from regulation." *Se. Minerals, Inc. v. Harris*, 622 F.2d 758, 767 (5th Cir. 1980) (emphasis added). Because FDA does not retain oversight over manufacturers' secret GRAS determinations (and, indeed, may not know these determinations have occurred at all), FDA cannot verify the safety of substances manufacturers secretly deem to be GRAS. As a result, FDA cannot fulfill the FFDCA's core purpose of "*ensuring*" food safety. *See* 21 U.S.C. § 393(b)(2) (emphasis added); *see also Waterkeeper All., Inc. v. EPA*, 399 F.3d 486, 499 (2d Cir. 2005) (EPA rule "[did] nothing to *ensure*" that regulated entities would comply with statutory restrictions because it failed to require EPA oversight) (emphasis added); *Envtl. Def. Ctr., Inc. v. EPA*, 344 F.3d 832, 855 (9th Cir. 2003) (EPA rule authorizing regulated entities to determine operating standards without agency review did not satisfy the Agency's responsibility to "require" protections).

Second, FDA cannot ensure food safety if it does not receive notice of manufacturers' secret GRAS determinations. The secrecy prevents FDA from ensuring the safety of chemical substances *before* they enter our food supply, and also impedes FDA's ability to remedy food safety problems *after* they occur. As the GAO recognized:

> Once a GRAS substance has entered the marketplace, FDA would find it difficult to identify that substance as the potential source of a food safety problem, especially if FDA is unaware that the substance has been determined to be GRAS. Food products may contain numerous ingredients, including GRAS substances, making it difficult, if not impossible, for public health authorities to attribute a food safety problem to a specific GRAS substance.

AR 008485. Indeed, FDA acknowledges that requiring notice of manufacturers' GRAS determinations would "provide additional food safety protection and would allow FDA to be more fully informed about food in the marketplace." AR 008492. Yet, despite this recognition, FDA enacted the GRAS Rule, permitting secrecy and undermining transparency. This impedes FDA's ability to ensure food safety.

As a result of this secrecy, the GRAS Rule deprives FDA of the ability to verify manufacturers' GRAS determinations through spot checks or random audits. *See* AR 008489. And it precludes the public—"including academic experts, consumer groups, and scientific organizations—[from] play[ing] a useful role in helping FDA oversee the safety of GRAS ingredients." AR 008497. Because it is difficult (if not impossible) to discover what substances manufacturers have secretly certified as GRAS, the public "do[es] not have the opportunity to investigate the potential health effects of such GRAS substances, leaving an additional gap in the oversight of their continued safety." *Id.*

Third, FDA cannot ensure food safety if it cannot obtain records pertaining to manufacturers' GRAS determinations. The GRAS Rule's lack of any recordkeeping

requirements further undercuts FDA's ability to ensure food safety both before and after substances enter the food supply. 81 Fed. Reg. at 55,004. Almost plaintively, FDA suggests that it would be "prudent" for manufacturers to preserve "the data and information that are the basis for the conclusion of GRAS status," *id.* at 54,992, 55,028, and expressed its "belie[f]" that manufacturers would do so. *Id*. This unenforceable hope cannot take the place of the effective oversight Congress demanded. The total lack of transparency about manufacturers' GRAS determinations—including the bases for those determinations—impedes FDA's ability to enforce the FFDCA's food safety requirements and, thus, contravenes the Act's core purpose of ensuring food safety. *See, e.g.*, *New York v. EPA*, 413 F.3d 3, 35 (D.C. Cir. 2005) (remanding an EPA rule that exempted certain industrial entities from recordkeeping but failed to explain how enforcement would occur in the absence of industry records).[8]

B. The GRAS Rule Reflects an Impermissible, Arbitrary and Capricious Construction of the FFDCA.

Even if this Court concludes that the language of the FFDCA is ambiguous, the GRAS Rule nevertheless is unlawful because a) it rests on an impermissible statutory construction, and b) it fails to address important aspects of food safety documented in the record.

FDA's construction of the FFDCA, allowing manufacturers to secretly self-certify substances as GRAS, is not "permissible," *Chevron*, 467 U.S. at 843, because it prevents FDA from "intelligently and rationally perform[ing] its regulatory duties" insofar as "*it* [does not] determine[] what products are 'food additives' . . . and what products . . . [are] GRAS." *Se. Minerals, Inc.*, 622 F.2d at 767 (emphasis added). Indeed, in 2014, FDA's then-Deputy

[8] Indeed, although FDA once recognized that "it would be prudent . . . [to] monitor compliance with the essence of the statutory requirements for GRAS status" by conducting random audits of manufacturers' secret GRAS determinations, the Agency now admits that it has never conducted a random audit—and it does not intend to do so in the future. 81 Fed. Reg. at 55,030.

Commissioner for Foods Michael Taylor admitted that, as a consequence of the secret GRAS system, "[FDA] simply do[es] not have the information to vouch for the safety of many of the[] chemicals [added to food]." AR 008088. He also acknowledged that, under the secret GRAS system, important food safety decisions could be made by "three employees sitting in a room looking at information that is only available to them," AR 008092, and concluded that this lack of transparency is "the *opposite* of what [Congress] intended" when it amended the FFDCA to *increase* FDA's oversight of chemicals added to food. *Id.* (emphasis added).

FDA's construction of the FFDCA also 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. *Nat. Res. Def. Council v. EPA*, 658 F.3d 200, 215 (2d Cir. 2011); *see also Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43.

At the time FDA finalized the GRAS Rule, FDA had more than 20 years of evidence documenting its shortcomings. Indeed, the record is replete with serious and well-justified concerns—from FDA itself, as well as others—about the Rule's negative effects on FDA's ability to ensure food safety. For example, the 2010 GAO report discussed above concluded that "FDA's oversight process does not help ensure the safety of all new GRAS determinations," and "FDA is not systematically ensuring the continued safety of current GRAS substances." [9] AR

[9] Additional record evidence raised similar concerns about the GRAS Rule's erosion of FDA's ability to keep our food safe. For example, following a three-year comprehensive assessment of FDA's oversight of substances added to food, analysts working with the Pew Charitable Trusts concluded that the GRAS Rule does not foster consensus within the scientific community because it allows manufacturers to keep their determinations secret and "[t]here can be no such consensus if [a] chemical's use is unknown to the scientific community and to FDA." *See, e.g.*, AR 008637. Pew also warned that "[t]he experts charged with assessing whether a scientific consensus exists should not have a relationship with the company that makes and sells the chemical additive" and "the experts must fairly represent the diversity of the scientific

008481, 008493. Yet despite overwhelming evidence that FDA's GRAS approach was flawed, the Agency did nothing to fix the Final Rule.

FDA's decision to finalize the Rule without meaningfully grappling with these concerns and without including safety protections despite the overwhelming weight of the record evidence showing that additional protections were necessary to ensure the safety of our food is classic arbitrary and capricious agency action in violation of the APA. *See Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43.

III. The GRAS Rule's Criteria for Determining GRAS Status Are Inconsistent With the FFDCA and Render the Rule Arbitrary and Capricious.

Even if FDA could subdelegate its responsibility to ensure food safety to manufacturers, and even if it could permit these manufacturers to make food safety determinations in secret without any oversight, the GRAS Rule still is unlawful because it fails to establish appropriate criteria for determining GRAS status. Under the FFDCA, a substance is eligible for GRAS status *only* if that substance is "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). The GRAS Rule provides that "[g]eneral recognition of safety through scientific procedures shall be based upon the application of generally available and accepted scientific data, information, or methods, which ordinarily are published . . . and may be corroborated by the application of unpublished scientific data, information or methods." 21 C.F.R. § 170.30(b). As explained below, however, the Rule's criteria do not meaningfully constrain manufacturers' GRAS determinations. Indeed, the criteria do not even require that manufacturers employ the practices FDA itself considers necessary to

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community." *Id.*; *see also supra*, at 5-7. And commenters renewed these and other concerns during the rulemaking process. *See, e.g.*, AR 007903–84.

assess the validity of GRAS determinations. As such, the Rule's criteria contravene the FFDCA and render the Rule arbitrary and capricious for five key reasons:

First, 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." For example, FDA does not require that scientific investigations in support of manufacturers' GRAS determinations undergo peer review, even though the publication of peer-reviewed investigations contributes to general recognition and "bears on the objectivity and scientific merit of study." 81 Fed. Reg. at 54,973.[10] In fact, FDA does not require that manufacturers' investigations be published *at all*, *see, e.g.*, *id.* at 54,976, even though information that is unpublished and, in effect, hidden from general view cannot be "generally recognized."[11] In failing to require that manufacturers ground their secret GRAS determinations in peer-reviewed, published investigations or even explain that peer-reviewed, published investigations are entitled to greater weight, the GRAS Rule conflicts with the FFDCA's core purpose of protecting food safety and constitutes arbitrary and capricious agency action.

Second, the GRAS Rule does not include criteria to ensure that manufacturers' GRAS determinations are free from conflicts of interest. The Rule requires that GRAS determinations reflect "common knowledge throughout the scientific community knowledgeable about the

[10] When manufacturers *choose* to notify FDA about GRAS determinations, the Agency considers whether the underlying investigations have been published in a peer-reviewed journal as "a variable . . . in determining whether experts accept the report of [an] investigation as a credible report and whether there is general knowledge of the . . . investigation." 81 Fed. Reg. at 54,976.

[11] The 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 FFDCA. 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. *Premo Pharm. Labs., Inc. v. U.S.*, 629 F.2d 795, 804 (2d Cir. 1980).

safety of substances directly or indirectly added to food." 21 C.F.R. § 170.30(a). As FDA is aware, however, this scientific community includes many individuals with "corporate or financial affiliations that could bias their decisions." AR 008488. In fact, the record shows that potentially biased individuals are very often responsible for manufacturers' GRAS determinations. According to one analysis of 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. *See* AR 008220. Despite this known risk of bias, the GRAS Rule does not include any criteria requiring manufacturers to prove or affirm that their GRAS determinations reflect the opinions of experts without financial conflicts of interest. This omission renders the Rule arbitrary and capricious.[12] *Nat. Res. Def. Council*, 658 F.3d at 215.

Third, 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. As discussed *supra*, manufacturers have taken advantage of this omission, withdrawing voluntarily-submitted notices and instead proceeding to self-certify substances as GRAS rather than addressing FDA's questions or concerns about the substances' safety. This is fundamentally at odds with the FFDCA's goal of ensuring food safety.

Fourth, FDA finalized the GRAS Rule without including any criteria to prevent manufacturers from secretly self-certifying newly synthesized or novel substances as GRAS, even though the record shows that these substances raise safety concerns. *See, e.g.* AR 008492 (FDA officials acknowledged that receiving information about secret GRAS determinations involving novel substances or uses would help ensure food safety). For example, FDA declined

[12] FDA not only failed to address these known pervasive conflicts of interest, but it also mistakenly suggests that a goal of the GRAS Rule is to "support the marketing of a food substance." 81 Fed. Reg. at 54,966.

to require that manufacturers wait any set amount of time before concluding that novel substances are GRAS, despite acknowledging that the scientific community would require "at least some gap" following synthesis of a novel substance to arrive at a general recognition of that substance's safety. 81 Fed. Reg. at 54,976 (although the passage of time alone is not a sufficient basis for concluding that general recognition exists, general recognition among disinterested experts is almost impossible to achieve before peer-reviewed, published investigations about a novel substance appear in the scientific literature). As a result of this omission, manufacturers have made GRAS determinations about little known novel substances—including, for example, "soybean leghemoglobin protein," a newly synthesized synthetic biology ingredient used in some vegetarian burgers. *See* AR 010880. Similarly, the GRAS Rule would allow a particular class of novel substances known as "engineered nanomaterials" to be deemed GRAS by a manufacturer,[13] even though the Agency acknowledged that these substances fail to satisfy the statutory criteria for GRAS status and, thus, "warrant formal premarket review and approval by FDA." 81 Fed. Reg. at 54,964.

Fifth, the GRAS Rule fails to include criteria clarifying that carcinogenic substances can *never* be deemed safe for use in food. The FFDCA expressly prohibits FDA from approving food

[13] Nanomaterials are materials that measure approximately 1–100 billionths of a meter, which have "novel properties compared with the same materials at their natural scale," such as enhanced abilities to react with other substances or move across biological membranes. AR 008480-81. Although some nanomaterials occur in nature or as inadvertent by-products, *engineered* nanonmaterials are deliberately manufactured. AR 008481. In 2010, GAO concluded that the "safety of [engineered nanomaterials] is uncertain." AR 008507. And FDA noted that "nanotechnology and emerging technologies . . . could be so new as to preclude a consensus among experts that the use of a food substance manufactured using that technology is safe, thus precluding a determination that the use of the food substance is GRAS." FDA, *Guidance For Industry Relating to Assessing the Effects of Emerging Technologies on the Safety and Regulatory Status of Food Substances* (2014), https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm300661.htm.

additives found to induce cancer. 21 U.S.C. § 348(c)(3)(A). However, as FDA is aware, some manufacturers have determined cancer-causing substances to be GRAS. *See* AR 000466-514 (certifying uses of certain substances, including six flavors subsequently shown to cause cancer, as GRAS). Although FDA recently revoked approval for the use of six cancer-causing substances as food additives, the Agency failed to articulate the common-sense conclusion that the GRAS status of those substances is also void. *See Food Additive Regulations; Synthetic Flavoring Agents and Adjuvants*, 83 Fed. Reg. 50,490 (Oct. 9, 2018) (revoking approval for six flavors found to cause cancer, but not expressly revoking the flavors' GRAS status).

For these reasons, this Court should find that the GRAS criteria contravene the FFDCA and the APA, rendering the GRAS Rule unlawful.

CONCLUSION

For the foregoing reasons, the GRAS Rule is unlawful. Accordingly, this Court should vacate the Rule. *See* 5 U.S.C. 706(2) (noting that courts "shall . . . hold unlawful and set aside" agency action that violates the APA); *see also New York v. U.S. Dep't of Commerce*, 351 F. Supp. 3d 502, 671-675 (S.D.N.Y. 2019) (vacating agency action for APA violation, providing detailed discussion of vacatur remedy and precedent), *cert. granted on different grounds, In re Dep't of Commerce*, 139 S.Ct. 953 (2019).

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CERTIFICATE OF SERVICE

I hereby certify that on March 26, 2019, I caused the foregoing MEMORANDUM OF LAW to be electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

/s/ Carrie Apfel
Carrie Apfel