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; NORMAN E. SHARPLESS, , ACTING COMMISSIONER, UNITED STATES FOOD AND DRUG ADMINISTRATION;[1] and UNITED STATES FOOD AND DRUG ADMINISTRATION, Defendants.	No. 17 Civ. 3833 (VSB) (BCM)

DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF THEIR CROSS-MOTION FOR SUMMARY JUDGMENT AND OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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[1] Pursuant to Federal Rule of Civil Procedure 25(d), Acting Commissioner Sharpless has been automatically substituted in place of former Commissioner Gottlieb, who resigned effective April 5, 2019.

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Pursuant to Federal Rule of Civil Procedure 56, Defendants cross-move for summary judgment and oppose Plaintiffs' motion. The final rule that Plaintiffs challenge—the so-called "GRAS rule"—is a lawful exercise of Defendants' authority under the Federal Food, Drug, and Cosmetic Act ("FDCA") and is not unconstitutional.

PRELIMINARY STATEMENT

Since 1958, Congress has required "food additives" to undergo premarket FDA review for safety. 21 U.S.C. § 348. But the statutory definition of "food additive" specifically excludes substances that are "generally recognized as safe," or GRAS, under the conditions of their intended use. 21 U.S.C. § 321(s).[2] These substances do not require premarket review, and the statute says nothing about whether manufacturers must make any premarket submissions to FDA when they have concluded that the use of a particular substance is GRAS. Plaintiffs, two public interest groups, nonetheless argue that FDA's rule interpreting the statute is arbitrary, capricious, and unconstitutional because it does not mandate FDA's advance approval or oversight of industry GRAS conclusions.[3]

Plaintiffs are mistaken. The GRAS Rule should be upheld as a reasonable agency interpretation of a broad Congressional delegation of authority. FDA has reasonably chosen to enforce the GRAS provision by issuing regulations that establish criteria for GRAS conclusions and permit, but do not require, manufacturers to notify FDA of their GRAS conclusions. Nothing

[2] To be "GRAS," a substance must be generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use. As FDA has explained, "GRAS status is not an inherent property of a substance, but must be assessed in the context of the intended conditions of use of the substance." AR 8654-55. However, for ease of reference, this brief occasionally uses the phrase "GRAS substances" (and similar phrases) as shorthand for substances that are generally recognized as safe under the conditions of their intended use.

[3] FDA's final GRAS rule uses the term "conclude" rather than "determine" to clarify that the submission of a GRAS notice reflects the view of the notifier and may not necessarily provide an adequate basis for a GRAS determination. 81 Fed. Reg. at 54984; 75 Fed. Reg. at 81538. For the same reason, the rule does not use the term "self-certify."

in the statute unambiguously requires that the FDA enforce these standards in a particular way, let alone through the mandatory premarket notification mechanism that Plaintiffs propose.

Plaintiffs' arguments rely on the erroneous premise that FDA has somehow given manufacturers the ability to make legally conclusive determinations of GRAS status. That is simply not so. Under the GRAS rule, manufacturers have no more authority to make legally conclusive determinations that the use of a substance meets the definition of "food additive" than they have to make legally conclusive determinations of whether a substance meets the definition of "drug." *See* 21 U.S.C. § 321(g)(1). The FDCA regulates both food additives and drugs, giving the FDA broad authority to ensure their safety. Under the Act, a manufacturer need not notify the FDA that a substance is not a "drug" before marketing it; but if the FDA concludes otherwise, the agency can bring an enforcement action . Likewise, manufacturers need not notify the FDA that a substance is not a "food additive" (but instead is being used as GRAS) before marketing it. But if a manufacturer inappropriately markets an unapproved food additive, the FDA may take enforcement action. 81 Fed. Reg. 54,960, at 54,980-81. There is nothing unusual about an agency's choice to enforce regulatory requirements in this manner, and nothing in the statute requires otherwise.

Finally, Plaintiffs' argument that the GRAS rule's criteria "do not meaningfully constrain manufacturers' GRAS determinations" is without merit. Each of Plaintiffs' specific assertions—for example, that the criteria allow GRAS determinations to be made on the basis of "hidden" information—is belied by the text of the rule or was appropriately considered by the agency.

For all of these reasons, the Court should deny Plaintiffs' motion for summary judgment and grant Defendants' cross-motion for summary judgment.

STATUTORY AND REGULATORY FRAMEWORK

I. The 1958 Food Additives Amendment to the FDCA

In 1958, Congress enacted the Food Additives Amendment ("the 1958 Amendment") to the FDCA, Pub. L. No. 85-929, 72 Stat. 1784. The 1958 Amendment provides that any new "food additive" must undergo an FDA premarket approval process. *See* 21 U.S.C. § 348(b)-(g).[4] The amendment defined "food additive" to mean "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," subject to certain exceptions. 21 U.S.C. § 321(s). As relevant to this case, the term "food additive" does *not* include any substance that is

> *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. (emphases added). Many substances—such as vinegar, vegetable oil, baking powder, and certain spices—are lawfully used without premarket approval under this provision. 81 Fed. Reg. at 54,963. Congress determined that GRAS substances do not need premarket review by FDA to ensure their safety. Instead, the safety of a GRAS substance for its intended use is either established by a long history of use in food, or established by information that is generally available to, and accepted by, qualified scientific experts. 21 U.S.C. § 321(s); *see also* 81 Fed. Reg. at 54,963.

Procedurally, the statute does not require FDA to conduct a premarket review of whether the use of a substance is GRAS. Instead, the statute requires only that a GRAS conclusion be based on the opinions of "experts qualified by scientific training." 21 U.S.C. § 321(s). The statute also

[4] Food containing any unapproved additive is deemed to be adulterated within the meaning of 21 U.S.C. § 348. *See id.* § 342(a)(2)(C). The FDCA prohibits the introduction into interstate commerce of adulterated food, *see id.* § 331(a), and provides for enforcement through, for example, injunctive relief, seizure, and criminal penalties, *id.* §§ 332-334.

does not require manufacturers to notify FDA of GRAS conclusions. Rather, Congress's broad textual command leaves FDA discretion to determine how to best implement the GRAS provision.

II. FDA's Experience With GRAS Substances Under Prior Rules

In the more than sixty years since the 1958 Amendment was enacted, FDA has never interpreted the statute to require manufacturers to notify FDA of their GRAS conclusions or obtain FDA's premarket agreement that a use of a substance is GRAS. Indeed, the current GRAS Rule "replace[d] one voluntary administrative procedure . . . with a different voluntary administrative procedure." 81 Fed. Reg. at 54,965. And, as has always been the case since 1958, a manufacturer who markets an unapproved food additive on the incorrect belief that it is GRAS can face enforcement.

Shortly after the 1958 Amendment was passed, FDA published a list of food substances that, when used for the purposes indicated and in accordance with good manufacturing practice, were GRAS. *See* Substances that are Generally Recognized as Safe, 24 Fed. Reg. 9,368 (Nov. 20, 1959). FDA later added to this "GRAS List" in subsequent rulemakings. *See* Substances Generally Recognized as Safe; Spices, Seasonings, Flavorings, Essential Oils, Oleoresins, and Natural Extractives, 25 Fed. Reg. 404 (Jan. 19, 1960); Substances that are Generally Recognized as Safe, 30 Fed. Reg. 3,991-01 (May 9, 1961). However, the GRAS List is not, and was never intended to be, a comprehensive listing of all GRAS substances. Making such a list would be, in the agency's judgment, impracticable. *See* 21 C.F.R. § 182.1(a).

In 1970, FDA announced that it was undertaking a comprehensive study of the GRAS List in order to "evaluate by current standards the available safety information regarding each item on the list." Food Additives; Eligibility of Substances for Classification as Generally Recognized as Safe in Food, 35 Fed. Reg. 18,623 (Dec. 8, 1970). The agency explained that it intended to "repromulgate each item in a new GRAS list or in a food additive regulation or in an interim food

additive regulation pending completion of additional toxicity experiments." *Id.* At the same time, FDA also proposed criteria to establish whether these food substances should be listed as GRAS, clarify the differences between GRAS status and food additive status, and describe the procedures being used to conduct the review of food substances. 35 Fed. Reg. at 18,623-24. These criteria were later incorporated into agency regulations. *See* 35 Fed. Reg. at 18,623; Eligibility of Substances for Classification as Generally Recognized as Safe in Food, 36 Fed. Reg. 12,093 (June 25, 1971); General Recognition of Safety and Prior Sanctions for Food Ingredients; Notice of Proposed Rulemaking, 39 Fed. Reg. 34,194 (Sept. 23, 1974); General Recognition of Safety and Prior Sanctions for Food Ingredients, 41 Fed. Reg. 53,600 (Dec. 7, 1976).

However, the agency's review of the substances already on the GRAS List was not intended to cover all GRAS substances. 21 C.F.R. § 182.1. In an effort to relieve uncertainty about what other substances might be GRAS, FDA established a procedure through which (1) an interested party could—but only if it wished—petition the Commissioner to review the GRAS status of a substance, or (2) FDA could review a substance's GRAS status on its own initiative. GRAS and Food Additive Status; Proposed Procedures for Affirmation and Determination, 37 Fed. Reg. 6,207 (Mar. 25, 1972); *see also* GRAS and Food Additive Status Procedures, 37 Fed. Reg. 25,705 (Dec. 2, 1972); AR 2592. This voluntary administrative process—known as the GRAS affirmation petition process—provided a mechanism for "official recognition of lawfully made GRAS determinations." 62 Fed. Reg. at 18,941. It involved a resource-intensive rulemaking process for each substance. FDA published a notice in the Federal Register that a petition had been filed and requested comments; conducted a comprehensive review of the petition's data and information and the comments received; and drafted a detailed explanation of the GRAS determination for publication of a final rule in the Federal Register. 21 C.F.R. § 170.35(c) (1977).

III. The Challenged Rule

After more than twenty years of experience, FDA found that the GRAS affirmation petition process both deterred "many persons from petitioning the agency to affirm their independent GRAS determinations" and drained agency resources. 62 Fed. Reg. at 18,941. To address these problems, FDA issued a proposed rule that would replace the affirmation petition process, *id.* at 18,954, and implemented an interim policy reflecting the new voluntary procedure. Under the new voluntary notification procedure, an entity could notify FDA of its conclusion that a particular use of a substance is GRAS. *Id.* FDA also clarified the criteria used for concluding whether a particular use of a substance is GRAS. *Id.*

In February 2010, after more than a decade under the interim policy, the Government Accountability Office ("GAO") issued a report with recommendations for FDA's food ingredient program. AR 2022-2095 ("GAO Report"). Among other things, the GAO Report criticized FDA's "voluntary notification program" because it did not require manufacturers to inform the agency about substances manufacturers determined to be GRAS. Later that year, FDA reopened the comment period for the proposed rule, noting that it had identified a number of issues that required further clarification based on the experience during the interim period and the GAO recommendations. *See* 75 Fed. Reg. 81536, 81537 (Dec. 28, 2010).

FDA issued the final rule that is the subject of this litigation on August 17, 2016.[5] The final GRAS rule replaced the voluntary petition process with the voluntary notification procedure. 81 Fed. Reg. at 54,961. In adopting this rule, FDA concluded that the voluntary GRAS notification procedure has several advantages over the process it replaced. Critically, the current approach

[5] While the interim policy was still in effect, one of the Plaintiffs here sued FDA, alleging that the policy was an unlawful final rule. *See Center for Food Safety v. Sebelius et al.*, No. 14-267 (D.D.C.). The parties resolved the case without reaching the merits. *See* Consent Decree, ECF No. 15, *Center for Food Safety v. Sebelius et al.*, No. 14-267 (D.D.C. Oct. 20, 2014).

enables FDA to "evaluate more, and higher priority, substances." *Id*. FDA's experience with the two programs supports this conclusion: FDA averaged 34 GRAS notices per year from 1998 to 2015, but only 8 affirmation petitions per year from 1987 to 1996. *Id.* at 54,981.

Following the statutory text, the final rule provides two ways to show 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 through scientific procedures "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 way to demonstrate GRAS status is through experience based on common use in food prior to January 1, 1958. *Id.* § 170.30(c).

If a manufacturer ("notifier") chooses to submit a GRAS notice, it must include the following information: (1) signed statements identifying the substance, its intended conditions of use, whether the use is GRAS based on scientific procedures or through experience based on common use in food 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 (21 C.F.R. § 170.230); (3) information about dietary exposure (21 C.F.R. § 170.235); (4) information about any self-limiting levels of use, such as a level at which the substance would become unpalatable (21 C.F.R. § 170.240); (5) information about experience based on common use in food before 1958, if applicable (21 C.F.R. § 170.245); (6) a narrative of the basis for the GRAS conclusion, which must address the safety of the substance, considering all dietary sources and taking into account any chemically or pharmacologically related substances

in the diet (21 C.F.R. § 170.250); and (7) a list of supporting data and information in the notice, specifying which data are generally available (21 C.F.R. § 170.255).

When FDA receives a GRAS notice, it will generally respond by letter within 180 days of filing[6] by saying that it has no questions at this time, that the notice failed to provide a sufficient basis to support a GRAS conclusion, or that the party submitting the GRAS notice asked FDA to cease evaluating it. 81 Fed. Reg. at 55,0115. FDA does not approve or otherwise formally endorse a notifier's GRAS conclusion.[7]

STANDARD OF REVIEW

This Court must grant summary judgment if the moving party demonstrates that there is no genuine issue of material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986). In a case challenging a rule promulgated by a federal agency, for purposes of summary judgment, the deferential APA standard of review applies, *Fund for Animals v. Norton*, 365 F. Supp. 2d 394, 405-06 (S.D.N.Y. 2005), which focuses on whether the challenged agency action is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). APA review "is narrow, limited to examining the administrative record to determine whether the [issuance of the challenged rule] was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Riverkeeper, Inc. v. EPA*, 358 F.3d 174, 184 (2d Cir. 2004) (internal quotation marks omitted); *see also Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402,

[6] 21 C.F.R. § 170.265(b)(1). FDA may extend this time by 90 days on an as-needed basis. *Id.*

[7] The GRAS rule also provides that FDA will proactively make certain information readily accessible to the public, including a list of filed GRAS notices and the name and address of notifier, the name of the substance and its intended use, and the statutory basis for the GRAS conclusion. 21 C.F.R. § 170.275(b). FDA will also make public the text of any letter that FDA issues as described above, including "cease to evaluate" letters. *Id.* Other information in a GRAS notice is subject to public disclosure under the Freedom of Information Act, subject to redaction of confidential or trade secret information. *See* 21 C.F.R. § 170.225(c); 21 C.F.R. § 170.275(c); 81 Fed. Reg. at 55,001.

416 (1971). The reviewing court may not "substitute its judgment for that of the agency," *Overton Park*, 401 U.S. at 416, and must uphold the agency's action so long as it is "rational, based on consideration of the relevant factors and within the scope of the authority delegated to the agency by the statute," *Motor Vehicle Mfrs. Ass'n of the United States, Inc., v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42-43 (1983). The court reviews the administrative record and does not undertake its own fact finding. *See, e.g., Camp v. Pitts*, 411 U.S. 138, 142 (1973).[8]

ARGUMENT

I. THE VOLUNTARY NATURE OF GRAS SUBMISSIONS IS CONSISTENT WITH THE FDCA, THE APA, AND THE CONSTITUTION

A. Applying *Chevron* Deference, the GRAS Rule Must Be Upheld

The Court must review the GRAS rule under the two-step framework of *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984). Under that test, a Court must first determine "whether Congress has directly spoken to the precise question at issue. 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 Congress has not directly addressed the issue or has done so ambiguously, the Court must next determine whether the agency's construction is based on a permissible interpretation of the statute. *See id.* at 843, 843-44 n.11. As the Second Circuit has explained, this analysis is "highly deferential." *Ciba-Geigy Corp. v. Sidamon-Eristoff*, 3 F.3d 40, 49 (2d Cir. 1993). A court need not conclude that the agency's reading was the only one it could have adopted, or even the best of the available readings. *See*

[8] Plaintiffs have submitted several declarations with their motion for summary judgment, but they do not cite or rely upon them in their brief. If the declarations are intended to support Plaintiffs' standing, the government does not contest standing at this time. If instead the declarations are intended to supplement the administrative record, Plaintiffs waived any right to do so when they chose not to file such a motion by the date specified in this Court's scheduling orders. *See* ECF Nos. 52, 58, 64. In any event, Plaintiffs have shown no cause to supplement the record, and this Court may not otherwise consider such-extra record material. *See National Audubon Soc. v. Hoffman*, 132 F.3d 7, 14-15 (2d Cir. 1997). The Court should therefore not consider Plaintiffs' declarations.

Chevron, 467 U.S. at 843*; accord Barnhart v. Walton*, 535 U.S. 212, 218 (2002). This two-step analysis requires upholding the GRAS rule.

As a threshold matter, Congress has expressly granted FDA rulemaking authority to carry out the provisions of the FDCA. *See* 21 U.S.C. § 371 (granting to the Secretary of HHS "authority to promulgate regulations for the efficient enforcement of [the FDCA]"); *id.* § 393 (setting out FDA's mission and further delegating responsibility over FDCA). This express authorization to issue regulations implementing the FDCA is a delegation of *Chevron* gap-filling authority to FDA. *See Woods v. START Treatment & Recovery Centers, Inc.*, 864 F.3d 158, 168–69 (2d Cir. 2017).

i. *Chevron* Step 1

An agency's interpretation of a statute is invalidated under the first step of *Chevron* only if "Congress has *directly* spoken to the *precise question* at issue," *Chevron*, 467 U.S. at 842 (emphases added), and the agency has disregarded this clear and specific textual command. That is plainly not the case here. The 1958 Amendment expressly requires FDA's premarket approval of "food additives," and sets up an elaborate regime for requiring such approval. *See* 21 U.S.C. § 348. But the statute then excludes GRAS substances from the definition of "food additive." In other words, the FDCA is silent on whether the manufacturer must notify FDA of GRAS conclusions. Invalidation under step one of *Chevron* requires a specific and unambiguous expression of congressional intent; nowhere in the FDCA does Congress express an intention about GRAS submissions to FDA or GRAS record-keeping at all.[9] This is enough to reach the second step. *See Woods*, 864 F.3d at 168 (noting "[t]he first step of the *Chevron* analysis is determining whether the statute is ambiguous *or silent* on the specific question at issue," and holding that

[9] Indeed, as FDA noted in the preamble to the final rule, it is unclear whether FDA has authority to require GRAS notification and recordkeeping when the statute does not impose such a requirement. *See* 81 Fed. Reg. at 54,981-2.

because "Congress has chosen to remain silent on" a causation standard, it had "instead delegated a statutory gap-filling function" to the enforcement agency) (emphasis added).

Plaintiffs' arguments to the contrary are unpersuasive. The FDCA's "core purpose of 'ensuring' food safety," Pls. Mem. 17 (citing 21 U.S.C. § 393(b)(2)), is a highly general and flexible mandate. It cannot be the basis under *Chevron* step one for holding that the statute unambiguously imposes particular procedural requirements for achieving this goal. *See NRDC v. FDA*, 760 F.3d 151, 178 (2d Cir. 2014) ("[T]his broad statutory mandate . . . does not compel the agency to use any particular method to attain those goals."). It is especially implausible that this general purpose, in the absence of any more specific statutory text, requires anything like the particular procedure that Plaintiffs demand. The FDA adopted its current regime in part to allow the agency "to evaluate more, and higher priority, substances." 81 Fed. Reg. 54,961. A mandatory GRAS submission procedure, under which the FDA would need to evaluate a much greater volume of industry submissions, would hinder the agency from efficiently evaluating the highest priority food substances, in order to ensure food safety as effectively as possible. Congress has vested FDA, which is best positioned to weigh the competing methods for effectuating the core statutory purpose, with discretion to make this policy judgment. *See, e.g.*, *Commodity Futures Trading Comm'n v. Schor*, 478 U.S. 833, 845 (1986) ("An agency's expertise is superior to that of a court when a dispute centers on whether a particular regulation is 'reasonably necessary to effectuate any of the provisions or to accomplish any of the purposes' of the Act the agency is charged with enforcing; the agency's position, in such circumstances, is therefore due substantial deference.").

Plaintiffs also attempt to root a mandatory GRAS submission requirement in the FDCA's provision that, when reviewing food additives for premarket clearance, the FDA must 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). But this provision cannot be sensibly read, as Plaintiffs claim, to require FDA to develop a list of every GRAS substance that might conceivably interact with a food additive. The FDA already maintains a detailed list of GRAS substances, but it has consistently held for over sixty years—since shortly after the passage of the 1958 Amendment—that maintaining an *exhaustive* list would be impracticable. 21 C.F.R. § 182.1(a); 81 Fed. Reg. at 54,963. Congress has never imposed such an onerous requirement, or any specific procedure for considering the cumulative effects of additives. To determine how food additives interact with any chemically or pharmacologically related substances in the human diet is an extremely broad and multifaceted task. Congress delegated to the FDA the authority to determine how best to implement this provision because of the agency's unique expertise.

ii. *Chevron* Step 2

FDA's reasonable interpretation of statutory silence—that notice or FDA preapproval is not required—should be upheld under *Chevron*'s second step. Given the express delegation of rulemaking authority to enforce the FDCA and statutory language that addresses GRAS substances in only very general terms, Congress left a gap for FDA to exercise its enforcement discretion based on its expertise. The 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. The challenged regulation is informed by past experience and continues longstanding agency practice that has been effectively ratified by Congress. Under the highly deferential *Chevron* analysis, the Court should defer to this permissible interpretation of the statute.

Congress laid out an elaborate regime for FDA's premarket approval of "food additives" in section 348, but expressly carved out GRAS substances from this regime in subsection 321(s).

Had Congress wished to *require* FDA to conduct similar premarket review of GRAS substances, or even to require a subset of those procedures, it would have said so. "Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Russello v. United States*, 464 U.S. 16, 23 (1983) (quotation marks omitted). Congress's choice to carve out GRAS substances from premarket approval—and not to impose the mandatory submissions Plaintiffs imagine—shows that, at a minimum, FDA's interpretation that declines to impose mandatory premarket submissions for GRAS substances is reasonable.

As the agency noted in promulgating the rule, the 1958 Amendment is wholly silent "with respect to industry submissions to [FDA] on the use of GRAS substances." 81 Fed. Reg. at 54,971. Given this silence, it was reasonable for FDA to decline to adopt a mandatory preapproval regime, and instead rely upon industry compliance with the law in the first instance, backed by the threat of enforcement. *See Nat'l Cable & Telecommunications Ass'n, Inc. v. Gulf Power Co.*, 534 U.S. 327, 339 (2002) ("[A]s a general rule, agencies have authority to fill gaps where the statutes are silent . . . ."). The agency reasonably judged that a simpler, voluntary submission process would both improve upon the existing voluntary affirmation petition process by incentivizing manufacturers to submit information to FDA (thus increasing FDA awareness of the food supply and cumulative dietary exposure) and better use limited agency resources. 81 Fed. Reg. at 54,964, 54,979. Indeed, FDA cited data showing that the number of GRAS notices filed per year under the interim policy was more than four times higher than the number under the prior regime. *See id.* The agency considered and rejected the possibility of making recordkeeping mandatory—a matter on which the statute is also silent. *See id.* at 55,044.

Finally, the FDA's interpretation of the statute should be upheld because it has been implicitly ratified by Congress. *See Barnhart*, 535 U.S. at 220. In the more than sixty years since the 1958 Amendment was enacted, FDA has never interpreted the FDCA to require GRAS submissions or recordkeeping. Congress has confirmed that interpretation by amending the statute several times without requiring a mandatory GRAS regime: it has amended the FDCA's food additive provisions several times without amending the language of the GRAS provision to require such submissions. *See, e.g.*, 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)); Pub. L. 89-477, 80 Stat. 231 (June 29, 1966) (amending § 342(d)). This history alone demonstrates that Congress at a minimum concurred in the reasonableness of the FDA's interpretation. *Barnart*, 535 U.S. at 220 (holding that Congress's amendment of specific statutory provision without overriding agency interpretation constituted persuasive evidence of Congressional intent); *Schor*, 478 U.S. at 846 ("It is well established that when Congress revisits a statute giving rise to a longstanding administrative interpretation without pertinent change, the 'congressional failure to revise or repeal the agency's interpretation is persuasive evidence that the interpretation is the one intended by Congress.'" (citation omitted)); *Bellevue Hosp. Ctr. v. Leavitt*, 443 F.3d 163, 175-176 (2d Cir. 2006).

Plaintiffs' argument that the voluntary nature of GRAS submissions prevents FDA from "intelligently and rationally performing its regulatory duties," Pls.' Mem. at 19, has no foundation in the FDCA or administrative record. While FDA undoubtedly has authority to determine whether a substance is a "food additive" or GRAS, *see Southeastern Minerals, Inc. v. Harris*, 622 F.2d 758, 767 (5th Cir. 1980), nothing in the statute prevents FDA from exercising this authority on a case-by-case basis, wenforcement discretion, rather than through a mandatory premarket notification

and approval process. The GRAS Rule operates the way many important government requirements do: the government sets mandatory standards for private conduct, and parties are expected to meet those standards, risking serious sanctions if they fail to do so. The consequences of noncompliance with the GRAS requirements are severe, running from seizure of adulterated food or, injunction, to civil or even criminal penalties. *See generally* 21 U.S.C. §§ 331-337a. This enforcement regime no more gives manufacturers a license to flout GRAS requirements than the Department of Justice gives a "license" to commit insider trading by failing to pre-screen stock trades.

The FDA's authority to regulate unlawful marketing of unapproved food additives is not limited to those who submit voluntary GRAS notices. For example, FDA issued warning letters to manufacturers that used caffeine in alcoholic beverages without submitting GRAS notices. *See* AR 8649-56, 8662-66. FDA had concerns that caffeine was not GRAS for its intended use based on review of "publicly available [scientific] literature," and required that the manufacturers provide evidence supporting their GRAS conclusions under threat of enforcement action. *See, e.g.*, AR 8654-55. As another example, FDA last year advised a manufacturer of silver-lined food wrapping with purported antimicrobial properties that, because it was not aware of any GRAS basis for silver ions in food, it would be treated as a food additive. *See* March 23, 2018 Letter, available at https://www.fda.gov/media/113332/download.[10] FDA can and does take appropriate regulatory action to enforce the food additive premarket approval requirements in the FDCA.[11]

[10] This action postdates the rulemaking period and thus does not appear in the administrative record, but because the letter is publicly available and provides further context, the Court may take judicial notice of the action. *See, e.g.*, *Bowling v. Johnson & Johnson*, No. 17 Civ. 3982 (AJN), 2018 WL 1587598, at *4 (S.D.N.Y. Mar. 28, 2018) (taking judicial notice of FDA warning letters).

[11] *See, e.g.*, *United States v. Quantities of Finished and In-Process Foods*, No. 13-3675, ECF Dkt. 140 (N.D. Ga. Apr. 3, 2017); *United States v. 605 Cases, More or Less, of an Article of Food, Each Case Containing 12/135 Capsule Bottles*, No. 2:08–cv–11395–NGE–DAS, ECF Dkt. 24 (E.D.Mich. May 11, 2009); 81 Fed. Reg. at 54,965 (discussing warning letters related to caffeinated alcohol products).

Similarly, FDA is fully capable of enforcing the statute without mandatory recordkeeping.[12] Manufacturers are responsible for complying with the law, and are on notice that they need to be able to support their GRAS conclusions with evidence. 81 Fed. Reg. at 55,028.[13] If FDA has concerns about a product, FDA may request documentation of GRAS status, or otherwise research a product's status. If the manufacturer cannot meet its burden, the product will be subject to enforcement as an unapproved food additive. It is no answer to say that mandatory recordkeeping is necessary for FDA to detect *every* violation of the FDCA: like any law enforcement agency, FDA is not required to take action against *every* violation of a statute, a task that would be infeasible in any event. *See* 21 U.S.C. § 336; *NRDC, Inc. v. FDA*, 760 F.3d 151, 170-171 (2d Cir. 2014) (noting that agency decisions declining to proceed with enforcement actions are, for purposes of the APA, "committed to agency discretion") (citing *Heckler v. Chaney*, 470 U.S. 821, 832-33 (1985)).

Even if Plaintiffs could establish that mandatory GRAS notification or recordkeeping would incrementally improve FDA's ability to enforce the FDCA, that would not justify setting aside the GRAS rule as an unreasonable exercise of discretion. "[T]he scope of review under the arbitrary and capricious standard is narrow, and courts should not substitute their judgment for that of the agency." *Karpova v. Snow*, 497 F.3d 262, 267 (2d Cir. 2007) (internal quotation marks omitted). Courts are especially deferential to agency decisions about enforcement. *See NRDC*, 760

[12] Plaintiffs do not specify what "recordkeeping" they believe FDA must require, but they suggest that FDA should require "manufacturers to preserve 'the data and information that are the basis for the conclusion of GRAS status.'" Pl. Mem at 19 (quoting 81 Fed. Reg. 54,992, 55,028).

[13] FDA has issued guidance that manufacturers who do not submit GRAS notices should "[r]etain the data and information that support your independent GRAS conclusion and organize these data and information according to the organization [] of a GRAS notice" in order to "facilitate our evaluation of that independent GRAS conclusion if circumstances warrant." FDA, "Regulatory Framework for Substances Intended for Use in Human Food or Animal Food on the Basis of the Generally Recognized as Safe (GRAS) Provision of the Federal Food, Drug, and Cosmetic Act: Guidance for Industry," at 8 (Nov. 2017), https://www.fda.gov/media/109117/download.

F.3d at 170-171; *Emily's List v. FEC*, 581 F.3d 1, 22 n.20 (D.C. Cir. 2009) (Kavanaugh, J.) (upholding agency's use of bright-line regulatory rule even at the cost of perfect enforcement).

Plaintiffs' argument that the GAO Report shows that the GRAS Rule ignores important aspects of food safety is similarly meritless. The FDA addressed the GAO Report at length when enacting the GRAS Rule. AR 2081-93; *see also* 81 Fed. Reg. at 54,965. FDA acknowledged "legitimate questions" about whether a mandatory GRAS notice system would improve the agency's ability to enforce the statute, but concluded that the voluntary system created by the GRAS rule was an improvement on the existing voluntary affirmation process because—as explained above—it more effectively used agency resources and made voluntary submissions less burdensome, which, in turn, resulted in an uptick in such submissions. AR 2044, 2085; 81 Fed. Reg. at 54,964, 54,979. It was not arbitrary and capricious for FDA to base its decision on its own experience with the interim policy and adhere to its own longstanding practice of not requiring GRAS submissions.

Because the GRAS Rule represents a permissible interpretation of the 1958 Amendment by the agency explicitly delegated the authority to implement the statute, the Court should defer to the FDA's experience and expertise in this area and reject Plaintiffs' challenge.

B. Plaintiffs' Subdelegation Argument Is Also Meritless

Plaintiffs' claim that the voluntary nature of GRAS notification "shifts" to manufacturers FDA's "core" duty to "ensur[e] that our nation's food is safe and free from harmful substances," Pls. Mem. at 8-9, is equally meritless.

As an initial matter, Plaintiffs do not identify the putative constitutional basis of their subdelegation claims. Importantly, Plaintiffs do not allege that the GRAS rule delegates "legislative" power to private entities in violation of the Vesting Clause of Article I. Rather, Plaintiffs' argument appears to be that Congress could have authorized FDA to subdelegate

"GRAS determinations" to manufacturers, but—because it did not do so—the alleged subdelegation is *ultra vires*. But Plaintiffs point to no authority holding that this is a constitutional, as opposed to statutory, violation. Nor do they even suggest what constitutional provision such subdelegation violates.

To the contrary, the Second Circuit has treated claims of delegation of agency authority to others as a question of Congress's intent. *Cooling Water Intake Structure Coalition v. EPA*, 905 F.3d 49, 79-80 (2d Cir. 2018) (asking whether alleged subdelegation was permitted under Clean Water Act and not mentioning the Constitution); *Fund for Animals v. Kempthorne*, 538 F.3d 124, 132 (2d Cir. 2008) (asking whether alleged subdelegation "contravene[ed] the [Migratory Bird Treaty Act]" and not mentioning the Constitution).[14] Subdelegation of agency authority to outside parties is presumptively unlawful absent express Congressional authorization. *See U.S. Telecom Ass'n v. FCC*, 359 F.3d 554, 565 (D.C. Cir. 2004). But a "subdelegation" occurs only when the agency has handed over its "statutory responsibility" to an outside party or allows that party to make the "entire determination of whether a specific statutory requirement has been satisfied." *Fund for Animals*, 538 F.3d at 133 (internal citations and alterations omitted)).

There has been no such subdelegation here. As explained above, the FDCA does not impose mandatory GRAS notification on manufacturers or require FDA to review industry GRAS conclusions in advance of marketing. *Fund for Animals* is therefore dispositive. There, a federal agency with statutory authority to determine whether the "taking" of migratory birds complied with international agreements and to regulate such taking issued an order permitting states to allow the taking of cormorants without a permit. The Second Circuit held the order did not constitute a

[14] *But see Ry. Labor Exec. Ass'n v. Nat. Mediation Bd.,* 29 F.3d 655, 671 (D.C. Cir. 1994) (noting that unauthorized subdelegation "quite likely" violates the Constitution, without specifying a constitutional provision).

"subdelegation" because "[t]here is . . . no statutory requirement that the [federal agency] provide *prior* authorization in the form of a permit for specific takings." *Id.* It did not matter that the agency's order might "limit[] [the agency's] ability to regulate in advance those takings," because the statute did not require the agency to regulate them in advance. *Id.* Here too, there is no statutory requirement that FDA determine GRAS status in advance or require GRAS notifications.[15]

And more fundamentally, FDA has not surrendered or abdicated its enforcement authority or outsourced to manufacturers the power to make legally binding judgments about whether a substance is a "food additive." A manufacturer's conclusion that a use of a substance is GRAS and thus not a "food additive" does not preclude FDA from concluding otherwise. If FDA determines that the use of the substance is not GRAS (but instead, a food additive that is subject to premarket approval), FDA can take enforcement action—just as FDA can enforce the FDCA against manufacturers who illegally market adulterated or misbranded drugs. This arrangement does not "subdelegate" FDA's authority to determine whether a substance is a "food additive." *See Cooling Water*, 905 F.3d at 79-80 (an agency did not subdelegate its authority when it did not empower outside party to bind it); *Fund for Animals*, 538 F.3d at 134 (federal agency retained ability to enforce statute).

Nor does the GRAS rule insulate FDA from accountability or shield agency decisions from judicial review. While the FDCA and APA establish certain specific means for the public to participate in the "food additive" approval process and challenge "food additive" approvals in court, *see* Pls.' Mem. at 12 (citing 21 U.S.C. §§ 348(b)(5), (f)(1), (g) and 5 U.S.C. § 706(2)),

[15] By contrast, in the only authority Plaintiffs cite in which a court found improper subdelegation, there was no dispute that the FCC had subdelegated its express and affirmative statutory obligation "to determine" which network elements must be available to competitive local exchange carriers. *U.S. Telecom Ass'n,* 359 F.3d at 565. The D.C. Circuit rejected the agency's argument that the statute impliedly authorized such delegation. *Id.* at 565-68.

neither the FDCA nor the APA create a right to force FDA to determine whether a substance is a "food additive" so as to create a final agency action that may be challenged in court.

In short, Congress gave FDA discretion to allow voluntary GRAS notifications, and FDA's exercise of that discretion does not "subdelegate" authority or violate the separation of powers.

II. THE GRAS CRITERIA ARE CONSISTENT WITH THE FDCA

Plaintiffs also argue that the GRAS rule's criteria for GRAS determinations are at odds with the FDCA, but this argument also fails under *Chevron*. Plaintiffs claim that the Rule's criteria for determining GRAS status are contrary to the FDCA. But Plaintiffs can prevail on these claims only by demonstrating that the FDCA expressly precludes the chosen criteria (*Chevron* step 1) or by showing that the criteria embody an unreasonable or impermissible interpretation of the FDCA (step 2). They can do neither.

The FDCA provides only a general definition of what is GRAS: a substance must be "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). When read in tandem with Congress's express grant of authority to FDA to promulgate rules for enforcement of the FDCA, *see* 21 U.S.C. §§ 371, 393, the statute's broad definition plainly reflects a delegation to FDA to determine more specifically how to interpret broad statutory terms: for example, what constitutes "general recogni[tion] among experts," or what it means to "adequately show[]" safety. *See Washington Hosp. Ctr. v. Bowen*, 795 F.2d 139, 148 n.10 (D.C. Cir. 1986) ("When Congress uses broad and imprecise language, courts may assume that the agency has been delegated broad interpretive authority."). In the face of this broad delegation of authority, none of Plaintiffs' specific arguments against the criteria in the GRAS Rule overcome *Chevron* deference.

First, Plaintiffs mistakenly claim that the GRAS criteria permit GRAS conclusions to be based on "data, information, or methods" that are "hidden" from the scientific community and the public. Pl. Mem. 22. This argument depends on the meaning of the statute's term "generally recognized" as safe, but the GRAS criteria plainly embody a reasonable interpretation of what constitutes general recognition. Among other things, the criteria require (1) "common knowledge throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food that there is reasonable certainty that the substance is not harmful under the conditions of its intended use," 21 C.F.R. § 170.30(a); (2) that the data underlying the GRAS conclusion be "generally available and accepted," *id.* § 170.30(b); and (3) that the "quantity and quality of that scientific evidence" be the same as for food additives, *id.* Therefore, "[r]egardless of whether the data and information are published or unpublished . . . a GRAS conclusion must be based on data and information that are generally available and accepted, and as such, *are publicly available*." 81 Fed. Reg. at 54,973 (emphasis added). Moreover, the requirement of "common knowledge" in the scientific community "precludes a GRAS conclusion if the data and information . . . are only available in files that are not publicly accessible, such as confidential industry files." *Id.* These criteria are not contrary to the FDCA or otherwise arbitrary.

Second, Plaintiffs' concerns about conflicts of interest do not render the GRAS criteria arbitrary and capricious.[16] The FDCA is silent on mechanisms for preventing such conflicts here, and Plaintiffs cannot show that the Rule fails at *Chevron*'s second step. While it is true that there

[16] Plaintiffs cite a study which they claim shows that "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." Pls.' Mem. at 23 (citing AR 8220). The study reports that of the 451 conclusions reviewed, 22.4% were made by a manufacturer employee, 13.3% were made by an employee of a consulting firm, 64.3% were made by expert panels selected by manufacturers or consultants, and none were made by "standing expert panel[s] selected by [] third part[ies]." While the report says that this last category is "least likely to involve a conflict of interest," it does not define"financial ties" and carefully avoids claiming that every panel had a conflict of interest. AR 8220.

may be persons in the "scientific community" with interests in certain products, the GRAS rule requires "common knowledge *throughout* the scientific community" to support a GRAS conclusion. And although FDA has long been aware of concerns about the possibility of conflicts of interest on GRAS panels, *see* 81 Fed. Reg. at 55,026 (describing recommendations in 2010 GAO report), the agency made clear in the final rule that it intended to address that issue through guidance. *Id.*; *see also* AR 8637 (Pew Charitable Trusts recommending FDA establish guidance on conflicts of interest). The agency issued draft guidance on that subject in November 2017.[17]

Furthermore, the GRAS rule requires GRAS notices to include 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). A manufacturer that submits a false statement may, in some circumstances, be criminally liable. *See* 18 U.S.C. § 1001. Moreover, the rule reduces the likelihood of conclusions based on conflicts of interest by requiring GRAS notices to set forth objective evidence of GRAS status. *See, e.g.*, 21 C.F.R. §§ 170.225, 170.230, 170.235, 170.240, 170.245, 170.250; 170.255 (required parts of GRAS notice); *id.* § 170.250(e) (for nonpublic information, requiring explanation of how there can be a conclusion of GRAS status if qualified experts do not have access to such data and information); *id.* § 170.225(c)(9) (requiring certification that "GRAS notice is a complete, representative, and balanced submission that includes unfavorable information"). While it is true that such notices are voluntary, they also reflect FDA's expectations for what a manufacturer must be able to substantiate in the case of an enforcement action; thus, a manufacturer that departs from these standards, even when not submitting a notice, does so at its own risk. *See* 81 Fed. Reg. at 54,980-81 (explaining that FDA

[17] FDA, "Best Practices for Convening a GRAS Panel: Guidance for Industry," https://www.fda.gov/media/109006/download.

may undertake enforcement action against manufacturers who do not submit GRAS notices when FDA concludes that a substance is not GRAS).

Third, Plaintiffs hypothesize that manufacturers who submit GRAS notices will withdraw those notices and conclude that substances are GRAS if FDA raises safety concerns about the substances. Yet this policy concern does not render the FDA's interpretation of the statute impermissible. Rather, FDA is able to address such issues through its exercise of enforcement authority. *See, e.g.*, 81 Fed. Reg. at 54,980-81; 57 Fed. Reg. 22984, 22989 (May 29, 1992) ("If the producer begins to market the ingredient based on the producer's independent determination that the substance is GRAS and FDA subsequently concludes the substance is not GRAS, the agency can and will take enforcement action to stop distribution of the ingredient and foods containing it on the ground that such foods are or contain an unlawful food additive."). Courts recognize that a manufacturer's GRAS determination is not conclusive in an enforcement proceeding. *See, e.g.*, *United States v. An Article of Food*, 752 F.2d 11, 14-15 (1st Cir. 1985); *United States v. An Article of Food*, 678 F.2d 735, 739-40 (7th Cir. 1982); *United States v. Articles of Food & Drug Consisting of Coli-Trol 80, F4C-60 Feed Grade, Entrol-S Medicated, Entrol-P*, 518 F.2d 743 (5th Cir. 1975).

Fourth, FDA adequately addressed concerns about "newly synthesized" or "novel" substances. Plaintiffs ask FDA to arbitrarily impose a "set amount of time before concluding that novel substances are GRAS." Pls. Mem. 24. As FDA explained in issuing the final rule, it reasonably declined to do this because the requirement of "common knowledge" of safety "throughout the scientific community" satisfies the concern that the safety of novel substances might not be well established. *See* 81 Fed. Reg. at 54,976.

Finally, Plaintiffs also argue that the GRAS Rule is contrary to the Delaney Clause, *see* 21 U.S.C. § 348(c)(3)(A), insofar as it "fails to include criteria clarifying that carcinogenic substances

can *never* be deemed safe for use in food." Pls. Mem. at 24. Plaintiffs assume that the Delaney Clause governs the determination of whether a substance is GRAS or a food additive. This assumption cannot be squared with the plain text of the clause, which prohibits FDA from approving "food additives" that can cause cancer (including substances with a *de minimis* carcinogenic effect). 21 U.S.C. § 348(c)(1)(A), (3)(A). A substance is, by definition, *not* a "food additive" if it is GRAS. *Id.* § 321(s). For that reason, the D.C. Circuit has suggested (albeit in dicta) that applying the statutory GRAS provision may "logically precede" applying the Delaney Clause, and thus the Delaney Clause may not prohibit finding a substance with *de minimis* carcinogenicity to be GRAS. *See Public Citizen v. Young*, 831 F.2d 1108, 1119-20 (D.C. Cir. 1987).

Of course, whether a substance is carcinogenic is *relevant* to whether it is GRAS—and FDA's regulations make this clear. "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." 21 C.F.R. § 170.30(a). And that assessment of safety requires the scientific community to consider "the same quantity and quality of scientific evidence as is required to obtain approval of a food additive." *Id.* § 170.30(b). Thus, assuming the Delaney Clause is not a *legal* bar to GRAS status, carcinogenicity may *in fact* prevent the emergence of "general recognition" of safety. *See* 55 Fed. Reg. 5194, 5196 (Feb. 13, 1990) (explaining that, assuming the Delaney Clause leaves open a "theoretical possibility" that a carcinogenic substance can be GRAS, carcinogenicity will, in practice, likely prevent general recognition of safety).

Ultimately, it does not matter here whether the Delaney Clause restricts what substances may be GRAS. The Delaney Clause is a self-effectuating statute, and its legal force does not depend on its being repeated in regulations. If Plaintiffs are correct that Delaney Clause governs

GRAS conclusions, then it is of no moment that the GRAS rule "fails to include criteria" prohibiting carcinogens. The Delaney Clause *itself* would do that. Plaintiffs do not—and cannot plausibly—allege that anything in the GRAS rule contradicts the Delaney Clause, or affirmatively authorizes GRAS status for carcinogenic substances. On the other hand, if (as *Young* suggested) the Delaney Clause does not govern GRAS conclusions, then Plaintiffs have no basis for arguing that FDA acted unlawfully in "fail[ing] to include criteria" absolutely prohibiting carcinogens. Thus, whether or not the Delaney Clause applies, it is not a basis for invalidating the GRAS rule.

CONCLUSION

Applying the deferential APA standard of review, the GRAS rule should be sustained. Plaintiffs have not identified any aspect of the rule that is arbitrary and capricious or not authorized by law. To the contrary, the rule's voluntary notification and recordkeeping system accords with the FDCA, is consistent with historical practice, and is an appropriate exercise of the agency's discretion. And the criterial governing GRAS conclusions are likewise reasonable and in accordance with law. For these reasons, the Court should deny Plaintiffs' motion for summary judgment, grant Defendants' cross-motion for summary judgment, and enter judgment in favor of Defendants on all claims.

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Respectfully submitted,

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